ISSN: 0974-1291

# HIPPOCRATIC JOURNAL OF UNANI MEDICINE

Volume 9 • Number 2 April–June 2014

CENTRAL COUNCIL FOR RESEARCH IN UNANI MEDICINE

# HIPPOCRATIC JOURNAL OF UNANI MEDICINE

**Volume 9, Number 2, April – June 2014**

*Hippocratic J. Unani Med. 9(2): 1–166, 2014*

**CENTRAL COUNCIL FOR RESEARCH IN UNANI MEDICINE**
**Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)**
**Ministry of Health & Family Welfare, Government of India**

# Hippocratic Journal of Unani Medicine



*Editorial Office*

CENTRAL COUNCIL FOR RESEARCH IN UNANI MEDICINE
61-65 Institutional Area (Opposite 'D' Block), Janakpuri, New Delhi – 110 058, India
Tel.: +91-11-28521981, 28525982, 28525831/52/62/83/97, 28520501, 28522524, Fax : +91-11-28522965
Website : http://unanimedicine.com • Email : unanimedicine@gmail.com & ccrum@rediffmail.com

**Annual Subscription:** Rs. 300/- (India) US $ 100/- (Other Countries) **Single Issue:** Rs. 150/- (India) US$ 50/- (Other Countries)
Payments in respect of subscription may be sent by bank draft marked payable to Director General, CCRUM, New Delhi.

On behalf of Central Council for Research in Unani Medicine (CCRUM) published and printed by Prof. S. Shakir Jamil Director General, CCRUM at CCRUM headquarters, 61-65 Institutional Area (Opposite 'D' Block), Janakpuri, New Delhi – 110058 and printed at India Offset Press, A-1 Mayapuri Industrial Area Phase-1, New Delhi 110 064 (INDIA)

# Contents

# *Editorial*

Traditional medicine has a crucial role to play in combating new and re-emerging diseases and conditions. Examples range from the common aspirin and anti-malarial quinine, to the powerful anti-tumor agent taxol and anti-leukaemic vincristine. Currently, with recent advances in experimental methods of phytochemistry and pharmacology, there is resurgence of interest in the investigations of therapeutic effects of herbal drugs with more clinical, scientific and evidence – based approach in an effort to validate them and prove their medical efficacy and safety. Furthermore, in view of growing acceptability of herbal formulations and their commercialization, quality control standards are being enforced following Drugs & Cosmetics Act.

Unani system of medicine, although originated in Greece, is one of the recognized systems of medicine of the country. Although, the Unani medicine have been in use for centuries and are known for their therapeutic efficacies, there is a need to scientifically establish their efficacy and safety in order to achieve global acceptance. Organized research work in this system was, therefore, a need of the hour. In post independent era, Central Council for Research in Unani Medicine, through its clinical, drug research, literary research, survey & cultivation of medicinal plants programme is contributing significantly for last three decades. *Vitiligo, Sinusitis, Filariasis, Eczema, Malaria, Infective Hepatitis, Asthma,* are some of the conditions where Unani therapies have earned recognition after scientific validation.

The Council has been publishing the peer reviewed *Hippocratic Journal of Unani Medicine* (HJUM), mainly to bring out fundamental and applied aspects of Unani Medicine. The journal also publishes recent advances in other related sciences and traditional medicines as well as different streams of medical sciences, which have bearing on validation and scientific interpretation of various concepts and strengths of Unani medicine.

In view of an overwhelming response, the journal earlier published twice a year, its periodicity has now been changed to quarterly w.e.f. January 2008 to accommodate more articles for quick dissemination of research data among scientific community. The journal has sufficient room for invited articles from luminaries of modern medicine and sciences as well as scholars of Unani medicine. The broad areas being covered include clinical research on single and compound Unani drugs, validation of regimental therapy, Clinical and experimental pharmacological studies, standardization of single and compound drugs, development of standard operating procedures, ethnobotanical studies, experimental studies on medicinal plants and development of agro-techniques thereof, and literary research on classics of Unani medicine. The journal is also open for studies on safety evaluation of Unani and other herbo-mineral drugs, nutraceuticals, cosmotherapeutics, aromatics, oral health, life style disorders, sports medicine etc. and such other newer areas which are the outcome of modern day living.

The current issue of this journal provides 14 original and review papers in the areas of *clinical research, drug standardization, pharmacology, ethnobotanical surveys* and allied disciplines contributed by eminent scholars in their respective fields. It is hoped that data presented will contribute significantly in R&D sector of traditional drugs and prove to be an excellent exposition of current research efforts of scientists in this direction. Council acknowledges the authors for their contributions included in this issue and hope for their continued support in this endeavor. We wish to ensure the readers to bring out the future issues of the journal on time.

We at the CCRUM have been constantly striving to reach to higher standards and make HJUM the leading journal of Unani Medicine and related sciences. In this context, we thank our learned reviewers for their invaluable inputs in improving the manuscripts. We sincerely hope and trust that the mission can be accomplished with active partnership of quality-conscious individuals and institutions. Through these lines we seek your cooperation and support in materializing our dreams about the HJUM. In this regard, we request you for your as well as your colleagues' contributions for publication in and subscription to the journal. Further, we will appreciate if the journal is introduced far and wide. We would also welcome esteemed suggestions for achieving the highest standards of quality for the journal.

**(Prof. S. Shakir Jamil)**
Editor-in-Chief

# Clinical Evaluation of Coded Unani Drugs in Lymphatic Filariasis

**[1]*Mahboob-us-Salam, [1]Bilal Ahmad, [2]M.I. Alam, [2]S.M.Ahsan, [2]S.S. Ali Khan and [2]N. Sehar**

[1]Literary Research Institute of Unani Medicine (CCRUM), Central Library, First Floor, Jamia Hamdard, New Delhi-110062

[2]Regional Research Institute of Unani Medicine (CCRUM), Guru Govind Singh Hospital, Guzri, Patna City, Patna-800008

## Abstract

In the present study, clinical efficacy of two coded Unani drug combinations, UNIM-268 and UNIM-269 was evaluated with and without Munzij and Mushil therapy (MMT) on the patients of lymphatic filariasis (*Da'ul Feel)* at Regional Research Institute of Unani Medicine, Patna. Out of all the patients of *Da'ul Feel* registered during 2009-2011, seventy one cases completed the trial. The comparison between clinical and pathological findings of all the four groups before and after the treatment suggested that both the combinations are effective in the treatment of filariasis. However, the effect of UNIM-268 and UNIM-269 on lymphoedema was comparatively pronounced when used after Munzij and Mushil therapy.

**Keywords:** Lymphatic filariasis, *Da'ul Feel*, *Wuchereria bancrofti, Brugia timori, Brugia malayi, Munzij-Mushil Therapy*

## Introduction

Lymphatic filariasis is caused by infection with three nematode worms, *Wuchereria bancrofti*, *Brugia malayi*, *Brugia timori* which are transmitted to man by mosquitoes (Park, 2009). Out of the three nematode worms, *W. bancrofti* has wide distribution, affects about 115 million people and is found all over the tropics and subtropics, including Asia and the Pacific Islands, Africa, areas of South America and the Caribbean basins (Fauci *et al.,* 2008). It is a major public health problem in India and its various states such as Uttar Pradesh, Bihar, Orissa, Jharkhand, Andhra Pradesh, Tamil Nadu, Kerala and Gujrat are heavily infected (Park, 2009). In endemic areas, the disease is a major cause of debilitating and disfiguring manifestations such as lymphoedema, elephantiasis, hydrocele etc. (WHO, 1992).

According to Zakariya Razi and Ibn al-Quff Masihi the disease is caused by the Black Bile (*Sawda'*) (Razi, 1962; Masihi, 1356H.), while, Nuh Qamari has mentioned the abnormal flow of thick matter towards the legs as the causative factor (Qamari, 2008). Some physicians say that the disease, results due to the abnormality of Phlegm (*Balgham*) and Black Bile (Antaki, 2009), while few add pure sanguine to the list (Khan, 1885).

Diethyl carbamazine (DEC) is the only drug available for chemotherapeutic control of filariasis (Park, 2009). However, due to its variable efficacy and serious allergic reactions there is the need of finding out more efficacious and safer drugs to treat the filariasis. As the disease was known to Unani

[1]* Author for correspondence

physicians since ancient times, they have mentioned a large number of effective single and compound formulations, but no clinical data is available to support their claims. Keeping in view the above mentioned facts, the present study was conducted in the O.P.D. and I.P.D. section of Regional Research Institute of Unani Medicine, Patna to evaluate the clinical efficacy of two coded Unani drug combinations, UNIM-268 and UNIM-269 in the cases of lymphatic filariasis (*Da'ul Feel*) with and without *Munzij-Mushil Therapy*.

## Materials and Methods

The clinical trial was conducted in the O.P.D. and I.P.D. section of Regional Research Institute of Unani Medicine, Patna. Patients of lymphatic filariasis (*Da'ul Feel*) of either sex aged between 11-60 years having lower limb lymphoedema were selected for the study after thorough clinical examination. After obtaining the informed consent, the patients were subjected to laboratory investigations. The laboratory investigations performed at different stages of trial included haemoglobin (Hb), red blood corpuscles (RBC) count, total leukocyte count (TLC), differential leukocyte count (DLC), erythrocyte sedimentation rate (ESR), urine analysis, stool examination, blood smear for detection of microfilaiae (mfs) and absolute eosinophil count (AEC). Safety of trial drugs was monitored through performing liver function tests and kidney function tests periodically. Lymphoedema was measured with the help of measuring tape. Out of all the patients registered for the study during 2009-2011, total 71 cases completed the study. The results obtained at base line and after treatment were compared to evaluate the efficacy of trial drugs. All the registered subjects were randomly divided into following four groups e.g. Group A: 5 patients, Group B: 31 patients, Group C: 23 patients and Group D: 12 patients respectively.

Group A: UNIM-268 two tablets of 500 mg twice daily
UNIM-270 five grams powder
UNIM-272 twenty grams oil
UNIM-270 and UNIM-272 were mixed together and applied locally on the affected part
UNIM-271, twenty grams coarse powder of crude drugs, used as Nutool (Irrigation). Nutool is a mode of treatment in which luke warm decoction of crude drugs is poured on the affected part.

Group B: UNIM-269 two tablets of 500 mg twice daily
UNIM-270 five grams powder
UNIM-272 twenty grams oil

UNIM-270 and UNIM-272 were mixed together and applied locally on the affected part

UNIM-271 twenty grams coarse powder of crude drugs used as Nutool (Irrigation).

Group C: UNIM-MUNB (*Munzij*)

Decoction of UNIM-MUNB (crude drugs) in the dose of 125 ml was given orally on empty stomach early in the morning per day till the *Nuzj* appeared in the urine of patients

UNIM-MUSB (*Mushil*)

Decoction of UNIM-MUSB (crude drugs) in the dose of 125 ml was given orally on empty stomach early in the morning on alternate days for 5 days

UNIM-TAB (*Tabreed*)

Infusion of UNIM-TAB (crude drugs) in the dose of 50 ml was given orally on empty stomach early in the morning on alternate day to UNIM-MUSB administration for 5 days

After UNIM-MUNB, UNIM-MUSB and UNIM-TAB the patients of this group were given the same treatment as mentioned in group A.

Group D: UNIM-MUNB (*Munzij*)

Decoction of UNIM-MUNB (crude drugs) in the dose of 125 ml was given orally on empty stomach early in the morning per day till the *Nuzj* appeared in the urine of patients

UNIM-MUSB (*Mushil*)

Decoction of UNIM-MUSB (crude drugs) in the dose of 125 ml was given orally on empty stomach early in the morning on alternate days for 5 days

UNIM-TAB (*Tabreed*)

Infusion of UNIM-TAB (crude drugs) in the dose of 50 ml was given orally on empty stomach early in the morning on alternate day to UNIM-MUSB administration for 5 days.

After UNIM-MUNB, UNIM-MUSB and UNIM-TAB the patients of this group were given the same treatment as mentioned in group B.

Elastocrape bandage was used in all four groups. The duration of treatment was 120 days in group A and B, while in group C and D this duration was MMT+120 days. The clinical follow-up was done at regular interval of 30 days. The laboratory investigations were performed at baseline, after MM therapy (group C and D) and at the interval of 30 days in all the groups.

## Statistical analysis

All the data were expressed as mean ± S.E.M. and analyzed by One-way analysis of variance (ANOVA) followed by Dunnett's 't' test. Probability level of less than 5% was considered as statistically significant.

Table 1 : Age-wise distribution of the patients

| Age Group (Years) | Number of cases | Percentage (%) |
|---|---|---|
| 11-20 | 11 | 15.49 |
| 20-30 | 12 | 16.9 |
| 30-40 | 24 | 33.8 |
| 40-50 | 09 | 12.67 |
| 50-60 | 15 | 21.12 |
| Total | 71 | 100 |

Table 2 : Sex-wise distribution of the patients

| Sex | Number of cases | Percentage (%) |
|---|---|---|
| Male | 30 | 42.25 |
| Female | 41 | 57.74 |
| Total | 71 | 100 |

Table 3 : Socio-economic status of the patients

| Socio-economic status | Number of cases | Percentage |
|---|---|---|
| Poor | 48 | 67.6 |
| Average | 16 | 22.53 |
| Good | 07 | 09.85 |
| Total | 71 | 100 |

Table 4 : Chronicity status of disease

| Chronicity in years | Groups | | | |
|---|---|---|---|---|
| | A | B | C | D |
| Up to 1 year | 01 | 12 | 08 | 02 |
| 1 Year-5 Years | 04 | 17 | 14 | 09 |
| 5 Years-10 Years | Nil | 02 | 01 | 01 |
| Above 10 Years | Nil | Nil | Nil | Nil |

Table 5 : Clinical Parameters Before and After Treatment

| S. No. | Group | No. of Patients | Lymphadenitis | | Lymphangitis | | Fever | |
|---|---|---|---|---|---|---|---|---|
| | | | Base Line | After Treatment | Base Line | After Treatment | Base Line | After Treatment |
| 1 | A | 05 | 05 | 00 | 05 | 01 | 05 | 00 |
| 2 | B | 31 | 28 | 02 | 28 | 03 | 06 | 02 |
| 3 | C | 23 | 23 | 00 | 23 | 00 | 20 | 00 |
| 4 | D | 12 | 11 | 00 | 12 | 02 | 11 | 00 |

Table 6 : Filarial Oedema in Millimeters, Before and After Treatment

| Day of Measurement | Mean + S.E.M. (in mm.) | | | |
|---|---|---|---|---|
| | Group A | Group B | Group C | Group D |
| Base Line | 878.6 + 3.34 | 1029.5 + 8.60 | 953.56 + 1.17 | 1173.25 + 1.82 |
| After Treatment | 829 + 2.23* | 971.63 + 3.80** | 863 + 2.66** | 1023 + 12.24** |
| % of reduction | 5.58% | 5.63% | 9.44% | 12.78% |

One-way analysis of variance (ANOVA) followed by Dunnett's 't' test.
*P<0.05, **P<0.01 as compared to baseline.

Table 7 : Total Eosinophil percentage, Before and After Treatment

| Day of Measurement | Mean + S.E.M. | | | |
|---|---|---|---|---|
| | Group A | Group B | Group C | Group D |
| Base Line | 6.2 + 0.37 | 6 + 0.15 | 4.65 + 0.10 | 5.33 + 0.14 |
| After Treatment | 4.4 + 0.24** | 4 + 0.15** | 3.34 + 0.10** | 4.33 + 0.14** |
| % of reduction | 29.03% | 33.33% | 28.17% | 18.76% |

One-way analysis of variance (ANOVA) followed by Dunnett's 't' test.
**P<0.01 as compared to baseline.

Table 8: Absolute Eosinophil count (AEC), Before and After Treatment

| Day of Measurement | Mean ± S.E.M. | | | |
|---|---|---|---|---|
| | Group A | Group B | Group C | Group D |
| Base Line | 485.8 ± 2.01 | 425.4 ± 0.83 | 381.78 ± 1.22 | 358.58 ± 1.70 |
| After Treatment | 276.8 ± 2.15** | 246.8 ± 0.71** | 256.95 ± 1.23** | 256.5 ± 2.06** |
| % of reduction | 43.09% | 42.11% | 32.80% | 28.49% |

One-way analysis of variance (ANOVA) followed by Dunnett's 't' test.
**P<0.01 as compared to baseline.

## Results and Discussion

The maximum number of patients belonged to the age group of 30-40 years (Table-1). It shows that persons belonging to this age group (young working adults) are mostly affected, which may have serious economic and social implications as indicated by World Health Organization in its report (WHO, 1992).

Out of total 71 cases, 48 (67.6%) belonged to poor class of society (Table-3). This may be due to poor hygienic conditions in localities inhabited by them.

Clinical efficacy of two coded drug combinations was assessed on the basis of clinical observations and laboratory findings at baseline and after treatment which are shown in tables 05 to 08. The clinical parameters including fever, lymphadenitis and lymphangitis which were observed at baseline in most of the cases subsided after treatment with the trial drugs in majority of them but the response of trial drug used in group C was comparatively better (Table-5).

Percentage reduction in lymphoedema was observed to be 5.58%, 5.63%, 9.44% and 12.78% in group A, B, C and D respectively which is also found statistically significant ($P<0.05$) in Group A and highly significant ($P<0.01$) in Group B, C and D respectively as compared to baseline (Table-6). These results indicate that UNIM-268 and UNIM-269 are more effective in reducing the filarial oedema when used after MM therapy. This finding authenticates the observations made by Razi when he says that a decrease in the volume of affected leg can be achieved through purgation in early stage of the disease (Razi, 1962).

The decrease in eosinophil percent was observed to be 29.03%, 33.33%, 28.17% and 18.76% in group A, B, C and D respectively and also found highly significant ($P<0.01$) in Group A, B, C and D respectively as compared to baseline (Table-7). Percentage reduction in absolute eosinophil count was found to be 43.09%, 42.11%, 32.80% and 28.49% in group A, B, C and D respectively and also found highly significant ($P<0.01$) in Group A, B, C and D respectively as compared to baseline (Table-8).

During the course of the trial no adverse effects were reported. Biochemical parameters to evaluate the safety of trial drugs were found to be within normal range.

## Conclusion

On the basis of our observations, it can be concluded that both the trial drugs viz., UNIM-268, UNIM-269 are effective in the cases of lymphatic filariasis

(*Da'ul Feel)*. The lymphoedema, which is the most prominent feature of the disease and is responsible for social suffering, is markedly reduced only when the trial drugs are used after MM therapy. This reduction in filarial oedema becomes negligible when used without MM therapy as can be observed through the results obtained in group A and B. As there were no reports of any adverse effect and laboratory test for safety evaluation were within normal range, it can be suggested that the trial drugs are well tolerated and have no adverse effect and can be propagated as an alternate to diethyl carbamazine for the treatment of lymphatic filariasis.


## Acknowledgement

Authors are thankful to Central Council for Research in Unani Medicine, New Delhi, for the financial support provided for this study.


## References


Antaki, D., 2009. Tazkira uli'l Albaab, Vol. II. Central Council for Research in Unani Medicine, New Delhi, p. 183.

Fauci, A.S., Braunwald, E., Kasper, D.L., Hauser, S.L., Longo, D.L., Jameson, J.L., Loscolzo, J., 2008. Harrison's Principles of Internal Medicine, 17th Edn., Vol I. Mc Graw Hill Medical, New York, p. 1324.

Khan, M.A., 1885. Ikseer-i Azam, Vol. IV. Matba Nizami, Kanpur, p. 11.

Masihi, I.Q., 1356H. Kitab'ul Umda fi'l Jaraha, Daa'iratu'l Maarif al-Usmaniya, Vol. 1, Hyderabad, pp. 156-157.

Park, K., 2009. Park's Text Book of Preventive and Social Medicine, 20th Edn., M/S Banarsidas Bhanot Publishers, Jabalpur, pp. 232-238.

Qamari N., 2008. Ghina Muna, Central Council for Research in Unani Medicine, New Delhi, p. 285.

Razi, Z., 1962. Kitabu'l Hawi fi't Tibb, Daa'iratul Maarif al-Usmaniya, Vol. XI. Hyderabad, Volume XI, pp. 282-285.

WHO, 1992. Lymphatic Filariasis – The disease and its control. 5th Report of WHO Expert Committee on Filariasis. WHO Tech. Rep. Ser. No. 821, Geneva.

# Preliminary Physico-Chemical Evaluation of *Sunun Poste Mughilan*

**Mohammad Rashid, *Shariq Shamsi and Roohi Zaman**

Department of Ilmul Saidla
National Institute of Unani Medicine,
Kottigepalaya, Magadi Main Road,
Bangaluru-560091

## Abstract

Standardization is an important step towards the establishment of a consistent chemical profile and biological activity. It is a quality assurance program for production and manufacturing of herbal drugs. Herbal medicines are gaining more and more attention all over the world due to their long historical clinical practice and less side effects. The need of hour is to evolve a systemic approach and develop well accepted methodologies for the standardization of herbal formulations. *Sunun Poste Mughilan* is mentioned in Hamdard Pharmacopoeia of Eastern Medicine for dental ailments. The physico-chemical standardization of this formulation was carried out according to the parameters laid down by CCRUM, New Delhi. This evaluation included determination of organoleptic properties alcohol soluble matter, water soluble matter, successive extractive values, pH value, bulk density, tapped density, moisture content, loss of weight on drying, ash value, crude fiber content and volatile oil. The findings of this study may be helpful to evaluate the *Sunun Poste Mughilan* produced by different manufacturers.

**Keywords:** Dental ailments, *Sunun Poste Mughilan*, Standardization.

## Introduction

In Unani system of medicine, toothpowders are commonly known as Sunun. They contain finely powdered drugs. Medicinal plants have been used since ancient time to treat dental problems and discussed from time to time by many researchers. The use of Satyanasi (*Argemone mexicana*), Neem (*Azadirachta indica*) and Rehan (*Ocimum sanctum*) in dental health care has recently been reported (Sharma and Joshi, 2007). In Unani system of medicine, there are many single drugs which are used in the treatment of dental diseases. Such drugs include Anar (*Punica granatum*), Chobchini (*Smilax china*), Haldi (*Curcuma longa*), Aqarqarha (*Anacyclus pyrethrum*), Tambaku (*Nicotiana tabacum*), Suddab (*Ruta graveolens*) (Said, 1997). The compound drugs include Sununе Zard, Sununе Mulook, Sununе Mustahkam Dandaan and Sununе Mujalli. Traditional systems of medicine are considered effective. However, the data regarding their drug standardization is meagre. Central Council for Research in Unani Medicine, New Delhi has given guidelines for standardizing conventionally used Unani Formulation formulations.

Lack of proper quality standards in manufacturing and testing of Unani drugs are the main challenges. The application of GMP in the manufacturing of Unani medicines is an essential tool to assure quality. Standard Operating procedure

* Author for correspondence

(SOP) is an authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material (e.g. equipment operation, maintenance and cleaning; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific matter and batch production documentation (Anonymous, 2007). Most of the operations in the pharmaceutical companies are performed on the basis of specific written procedures. The introduction of SOPs in the community pharmacies will bring many benefits and provide an opportunity to demonstrate professionalism and responsibilities. (Anonymous, 2007).

An attempt has been made to standardize the Unani formulation Sunun Poste Mughilan. This formulation is used to strengthen the dental roots and a gum tonic as well as imparter of sparkle to the teeth (Kabiruddin, YNM and Said, 1997).

## Materials and Methods

### Preparation of Sunun

The method mentioned in Hamdard Pharmacopeia was followed for the preparation of Sunun Post Mughilan (Table 1). The ingredients except the bark of *Acacia arabica* were procured from the local crude drug supplier(s) in Bangalore. Bark of *Acacia arabica* was collected from the campus of NIUM, Bangalore. All the plant drugs were identified and authenticated by Dr. R. Sumathi, Research Officer, Foundation for Revitalisation of Local Health Tradition-Institute of Ayurveda and Integrative Medicine (FRLHT-IAM), Bangalore. The voucher specimens have been deposited in the museum of Institute of Ayurveda and Integrative Medicine, Bangalore.

The physical impurities present in the crude drugs were removed before drying the drugs. The dried drugs were grounded with an electric grinder, sieved through Mesh # 100 and the resultant powder (named as sufuf) was preserved in an airtight jar (Figure 1) (Said, 1997).

### Physico-Chemical Studies

The Physico-Chemical studies were carried out on Sunun Post Mughilan in the Dept of Ilmul Saidla, NIUM, Bangalore. The studies included the determination of organoleptic properties, (appearance, colour, odour and taste), alcohol soluble matter, water soluble matter, successive extractive values, pH values,

bulk density, tapped density, moisture content, loss of weight on drying at 105°C, ash values, crude fibers content and volatile oil.

Determination of Alcohol and Water Soluble Matter

*Cold Maceration method*

Five grams of Sunun (powder) were placed in a glass- stopper conical flask and macerated with 100 ml water for 6 hours with frequent shaking and then allowed to stand for next 18 hours. Filtrate was then collected rapidly through dry filter. 25 ml of the filtrate was transferred to a previously weighed and tarred flat-bottom petridish and evaporated to dryness on a water bath. The residual material was dried at $105^0$C for 6 hours and cooled in a desiccator for 30 minutes before weighing. The percentage of water soluble matter was calculated with reference to the amount of Sunun. The percentage of alcohol soluble content was determined as mentioned above by using alcohol in place of water (Anonymous, 2011).

*Successive Extractive Value*

The successive extraction of Sunun in three different solvents viz. petroleum ether (40-$60^0$C), chloroform and alcohol were carried out by Soxhlet apparatus for six hours on a water bath. The extracts were filtered using filter paper. After evaporation of the solvents on water bath, the extracts values were determined with reference to the weight of drug (% w/w). The procedure was repeated three times and the mean value for each extract was calculated (Anonymous, 1991).

*The pH value of 1% solution*

One gram of Sunun was mixed in accurately measured 100 ml of distilled water, filtered and pH measured with a pH digital meter. This procedure was repeated three times. The mean value and standard error were calculated (Anonymous, 1991).

*The pH value of 10% solution*

Ten grams of Sunun was mixed in accurately measured 100 ml of distilled water, filtered and pH measured with a pH digital meter. This procedure was repeated three times. The mean value and standard error were calculated (Anonymous, 1991).

*Bulk density*

Accurately weighed 20grams of Sunun was poured through a funnel into a tarred graduated cylinder. The cylinder was then lightly tapped twice to collect all the powder sticking on the wall of the cylinder. The initial volume was noted and the sample was then tapped until no further reduction in volume was observed. The volume was then read directly from the cylinder and used to calculate the bulk density; results are expressed in (g/ml). The bulk and tapped densities were calculated by the formula (Chaturvedi *et al.*, 2012; Lachman *et al.*, 1987; Kumar *et al.*, 2011).

$$\text{Bulk Density (BD)} = \frac{\text{Mass}}{\text{Volume}}$$

$$\text{Tapped Density} = \frac{\text{Mass}}{\text{Tapped Volume}}$$

Hausner's Ratio

Hausner's ratio is related to interparticle friction and as such can be used to predict the powder flow properties. The Hausner's ratio can be expressed as follows:

$$\text{Hausner's ratio} = \frac{Df}{Do}$$

Where Df = Tapped density and Do = Bulk density.

Hausner's ratio for Sunun was calculated by using above given formula (Kumar *et al.*, 2011; Lachman *et al.*, 1987; Chaturvedi *et al.*, 2012; Abdulsamad *et al.*, 2009).

Compressibility Index

It is a method to evaluate the flowability of the powder and the rate at which it packed down. It is also known as Carr's index. Compressibility Index of Sunun was calculated by using following formula (Abdulsamad *et al.*, 2009; Chaturvedi *et al.*, 2012).

$$\text{Carr's index (\%)} = \frac{[(\text{Tapped Density} - \text{Bulk Density}) \times 100]}{\text{Tapped Density}}$$

Moisture Content

The moisture content of the Sunun was determined by Toluene Distillation method. 10grams of Sunun was taken in a flask and 75 ml of distilled toluene

was added to it. Distillation was carried out for 5 hours. The volume of water collected in receiver tube (graduated in ml) was noted and the percentage of moisture calculated with reference to the weight of the air-dried drug taken (Jenkins *et al.*, 2008; Afaq *et al.*, 1994; Anonymous, 1991; Anonymous, 2011).

### Loss of Weight on Drying at 105°C

Two grams of Sunun was taken, spread uniformly and thinly in a shallow petridish. It was heated at a regulated temperature of 105°C, cooled in a desiccator and weighed. The process was repeated many times till two consecutive weights were constant. The percent loss in weight was calculated with respect to initial weight (Anonymous, 2011; Afaq *et al.*, 1994; Anonymous, 1991; Upendra *et al.*, 2010).

### Ash Values

#### *Total Ash*

Two grams of air dried Sunun was incinerated in a silica dish at a temperature not exceeding 450°C until free from carbon, cooled and weighed and the percentage was calculated with reference to air dried Sunun (Anonymous, 2011; Afaq *et al.*, 1994).

#### *Acid Insoluble Ash*

Total ash obtained in the previous experiment was boiled with 25ml of dilute hydrochloric acid for 5 minutes. The insoluble matter was collected on an ash less filter paper, washed with hot water and ignited at a temperature not exceeding 450°C and weighed after cooling. The percentage of acid insoluble ash was calculated with reference to the air dried Sunun (Anonymous, 2011; Afaq *et al.*, 1994).

#### *Water Soluble Ash*

Total ash obtained was boiled with 25 ml of distilled water for 5 minutes. The insoluble matter was collected on an ash less filter paper, washed with hot water and ignited. The weight of insoluble ash was subtracted from the weight of the total ash, giving the weight of the water soluble ash. The percentage of water soluble ash was calculated with reference to air dried Sunun (Anonymous, 2011; Afaq *et al.*, 1994).

## Determination of Crude Fibers

Fifteen grams of Sunun was exhausted first in 50 ml of diethyl ether by boiling for 30 minutes on water bath to remove fats and waxes. 200 ml of boiling sulphuric acid were added to the ether-exhausted Sunun in a 500 ml flask and flask was connected with a reflux condenser. The mixture was heated to boil for 30 minutes. Then it was filtered through filter paper and the residue washed on the filter with boiling water till filtrate lost acidic character. The residue was rinsed back into the flask with 200 ml boiling sodium hydroxide solution and allowed to boil for 30 minutes. After boiling, the mixture was filtered through a tared filter and the residue was washed with boiling water till it was neutral. The filtrate was dried at $110^0$ C until the constant weight(X). The dried residue was incinerated and the ash was weighed(Y).

Hence, the crude fiber content (X-Y) was obtained (Jenkins *et al*, 2008; Anonymous, 1991).

## Determination of Volatile Content

Fifty grams of Sunun was mixed with 30 ml of glycerol and 300 ml of water in the distillation flask. Few pieces of earthenware were added in the distillation flask. The Clavenger's apparatus was attached to the flask. The flask was heated with frequent agitation. The flask was rotated occasionally to wash down any material adhering to the upper part of the walls. After distilling for about five hours, heating was stopped and least five minutes later, volume of oil in graduated portion of the tube was read.

After this, distillation continued for a period of one hour and the volume of oil was noted. Distillation continues until successive readings of the volume of oil were same. The measured yield of volatile oil was taken to be the content of volatile oil in the Sunun (Anonymous, 1991; Afaq *et al.*, 1994).

Table 1 : Ingredients of Sunun Poste Mughilan

| S. No. | Unani Name | Scientific Name | Part Used | Quantity |
|---|---|---|---|---|
| 1 | Post Kikar | *Acacia arabica* | Bark | 400 g |
| 2 | Burnt Supari | *Areca catechu* | Nut | 100 g |
| 3 | Sange Jarahat | Silicate of magnesia | Stone | 100 g |
| 4 | Kath Safaid | *Acacia catechu* | Extract | 100 g |
| 5 | Zanjabeel | *Zingiber officinalis* | Dried Rhizome | 10 g |
| 6 | Filfil Siyah | *Piper nigrum* | Seed | 10 g |

Table 2 : The physicochemical data of Sunun Poste Mughilan

| Sl. No. | Parameters | | Mean ± SEM |
|---|---|---|---|
| 1. | Appearance | | Powder |
| 2. | Colour | | Brown |
| 3. | Smell | | Dull Smell |
| 4. | Taste | | Astringent |
| 5. | Alcohol soluble matter (%) | | 17.10 ± 0.12 |
| 6. | Water soluble matter (%) | | 12.48 ± 0.24 |
| 7. | Successive Extractive Values | Petroleum ether (%) | 3.74 ± 0.02 |
| | | Chloroform (%) | 1.52 ± 0.12 |
| | | Ethyl alcohol (%) | 16.64 ± 0.33 |
| | | Aqueous (%) | 13.41 ± 1.16 |
| 8 | pH (1% solution) | | 6.33 ± 0.12 |
| 9. | pH (10% solution) | | 5.64 ± 0.17 |
| 10. | Bulk Density (gm/ml) | | 0.48 ± 0.03 |
| 11. | Tapped Density (gm/ml) | | 0.82 ± 0.01 |
| 12. | Hausner's Ratio (HR) | | 1.75 ± 0.10 |
| 13. | Compressibility Index (%) | | 42.45 ± 3.41 |
| 14. | Moisture content (%) | | 7.33 ± 0.33 |
| 15. | Loss of weight on drying (%) | | 8.59 ± 0.03 |
| 16. | Total ash (%) | | 20.07 ± 0.01 |
| 17. | Acid insoluble ash (%) | | 18.87 ± 0.10 |
| 18. | Water soluble ash (%) | | 2.9 ± 0.35 |
| 19. | Crude fibers Content (%) | | 8.41± 0.16 |
| 20. | Volatile content (%) | | 0.57 ± 0.03 |

Fig. 1 : Laboratory Sample of Sunun Poste Mughilan

**Results and Discussion**

The physicochemical data of Sunun Poste Mughilan is presented in Table 2. The organoleptic studies indicated that the Sunun had powdery appearance and brown in colour. The smell was dull and taste astringent. The amount of drug soluble in a given solvent is an index of its purity (Jenkins *et al.*, 2008). The mean percentage of alcohol and water soluble content were found to be 17.10 ± 0.12 and 12.48 ± 0.24 respectively. Extractive value in different solvents is also an important parameter to check the quality of the drug and any variation in the chemical constituents leads to the change in the extractive values. It helps in determination of the adulteration and also an index of the purity of the drug. The mean percentage of Extractive values were determined in petroleum ether (40-60°C), chloroform, ethyl alcohol and water using Soxhlet's Apparatus and found to be 3.74, 1.52, 16.64 and 13.41 respectively (Jahan *et al.*, 2008). pH of 1% and 10% was 6.33 and 5.64 respectively. Bulk density is one of the measures of packing properties, compressibility and flow properties. It is used to determine the bulk densities of powdered drugs under loose and packed conditions respectively. The tapped density is an increased bulk density attained after mechanically tapping a graduated measuring cylinder or vessel containing the powder sample. The mean value of bulk density and tapped density of Sunun Poste Mughilan were found to 0.48 and 0.82 ml respectively. Compressibility Index and the Hausner's

ratio are the simple, fast and popular methods of predicting powder flow characteristics. The compressibility index has been proposed as an indirect measure of bulk density, size and shape, surface area, moisture content and cohesiveness of materials (Anonymous, 2006). The mean value of Hausner's Ratio and Compressibility Index were found to be 1.75 and 42.45 respectively. The moisture content and Loss of weight on drying are good parameters for detecting the quality of the drugs. Low or high moisture levels affect the quality of the drug and hence, its efficacy (Jahan *et al.*, 2008). The excessive moisture content becomes an ideal medium for the growth of the different types of bacteria as well as fungi which subsequently spoil the drug. The mean percentage of the moisture content and loss of weight on drying were found to be 7.33 and 8.59% respectively. Ash values of the drug are an important parameter for the detection of impurities and adulteration. It usually represents the inorganic salts naturally occurring in the drug and adhering to it but it may also include inorganic matter added for the purpose of adulteration. An ash determination furnishes a basis of judging the identity and cleanliness of the drug and gives information related to its adulteration with inorganic matter (Jenkins *et al.*, 2008). A high ash value is indicative of contamination, substitution, adulteration or carelessness in preparing the formulation for marketing. The mean percentage values of the total ash, acid insoluble ash and water soluble ash were found to be 20.07, 18.87 and 2.9 respectively. The determination of crude fibres is of considerable importance for examining the certain drugs and particularly of spices which are adulterated with the waste or refused material of the same drugs and spices. The mean percentage value of crude fibers value was found to be 8.67%. The light and atmospheric oxygen appears to have an adverse effect on most volatile oils which decompose on boiling with water. The excess heat may cause charing of the material resulting in the decomposition of the constituents of the oil. The wrong method of distillation and storage may damage the quality of the oil which can be judged to some extent by their appearance, odour and colour. (Afaq *et al.*, 1994). The mean percentage value of volatile oil content value was found to be 0.057%.

## Conclusion

The preliminary physicochemical constants for *Sunun Poste Mughilan* have been determined. They may be taken as standard reference for manufacturing this important Unani formulation. However, the detailed chemical and biological evaluation can help establish the exact parameters for standardised *Sunun Poste Mughilan*.

## Acknowledgement

The authors are grateful to Prof. Mansoor Ahmad Siddiqui, Director, National Institute of Unani Medicine, Bangalore, for providing necessary facilities for the present investigation.

## References

Anonymous, 2007. WHO guidelines on Good Manufacturing Practices (GMP) for Herbal Medicines. World Health Organisation, Geneva.

Anonymous, 2007. Standard Operating Procedures (SOPs) in Community Pharmacies. Sultanate of Oman, Ministry of Health. *Pharmaceutical Newsletter* 15(4): 1-3.

Anonymous, 2011. Quality Control Methods for Medicinal Plants Materials. WHO Geneva, Switzerland.

Anonymous, 1991, Physicochemical Standards of Unani Formulations, CCRUM, Ministry of Health & Family Welfare, Govt. of India, New Delhi, Part III, pp. 312, 314, 317, 329-330.

Abdulsamad A, Isah A.B., Gwarzo, M.S., Abbah, H.M., 2009. Evaluation of the Disintegrant Properties of Microcrystalline Starch Obtained from Cassava in Metronidazole Tablet Formulations. *Nigerian Journal of Pharmaceutical Sciences* 2(2): pp. 26–35.

Afaq SH, Tajuddin , Siddiqui MMH, 1994, Standardization of Herbal Drugs, AMU Press, Aligarh, pp.33, 34, 41-44, 52, 100.

Anonymous, 2006. The Japanese Pharmacopoeia. Ministry of Health, Labour and Welfare, Tokyo, Japan, pp.44, 68, 144, 1730.

Chaturvedi S, Agarwal, V.K., Verma, A., Verma, N., Singh, S., 2012, Comparative Evaluation of Natural and Semi-Synthetic Superdisintegrants in the formulation of Oro-dispersible Tablets of Norfloxacin. *International Journal of Pharmacy and Pharmaceutical Sciences* 4(3): 576-583.

Jenkins GL, Knevel AM, Diagangi FE, 2008. Quantitative Pharmaceutical Chemistry. CBS Publishers & Distributors Pvt. Ltd, New Delhi, 6th ed., pp.225-227, 235-242.

Jahan N, Afaque S, Khan N, Ahmad G, Ansari A, 2008. Physico-chemical studies of the Gum acacia. *Natural Product Radiance* 7(4): 335-337.

Kumar T, Chandrashekar KS, Tripathi DK, Nagori K, Pure S, Agrawal S, *et al.*, 2011. Standardization of Gokshuradi Churna: An Ayurvedic Polyherbal Formulation. *J. Chem. Pharm. Res* 3(3): 742-749.

Kabiruddin, M., YNM. Al-Qarabadin. Kashmir Book Depot, Faisalabad, p.595.

Lachman, L., Liberman, H.A., Kanig, J.L., 1987. The Theory and Practice of Industrial Pharmacy, 3rd Edition, Varghese Publishing House, Mumbai, pp.183, 316.

Sharma V., Joshi B.D., 2010. Traditional Medicines for Dental Health Care Amongst the Local People of Almora Dist. of Central Himalaya in India. *Asian Journal of Traditional Medicine* 5(3): 117-121.

Said H.M., 1997. Hamdard Pharmacopeia of Eastern Medicine, 2nd Edition. Sri Satguru Publication, A division of Indian Book Centre, Delhi, India, pp.166-67.

Upendra, K., Patil, B.S., Korwar, P.G., 2010. Evaluation of tapioca sago starch as a binder in tablet formulation. *Journal of Pharmacognosy and Herbal Formulations*1(1): 1-8.

# Physico-chemical Study of a Unani Antipruritic Formulation: Safoof Kharish

**Shahid Shah Chaudhary, Mohd Tariq, *Shariq Shamsi and Roohi Zaman**

Department of Ilmul Saidla
National Institute of Unani Medicine
Kottigepalya, Magadi Main Road,
Bangaluru-560091

## Abstract

*afoof Kharish* is a compound formulation of Unani Medicine which acts as *Daf-e-Ufoonat* (antiseptic) and *Jali* (detergent), applied topically to treat *Kharish* and *Hikka* (pruritus). It contains one herbal drug i.e. Kamila (*Mallotus philippinensis*) and three mineral drugs i.e. Gandhak (*Sulphur*), Safaida Kashghari (*Zinc oxide*) and Murdar Sang (*Letharge*). Until now no physico-chemical standards are available to assess the quality of the formulation. Therefore standardization of the finished product was done by evaluating the relevant organoleptic and physicochemical parameters like pH, ash values, extractive values, bulk density, tapped density, compressibility index, hausner's ratio, angle of repose, TLC etc. The physicochemical characteristics obtained from this study will be helpful for quality evaluation and to set the Pharmacopoeial standards for *Safoof Kharish*.

**Keywords:** *Kamila*, Physicochemical properties, *Safoof Kharish*, Unani Medicine

## Introduction

To rescue man from the clutches of disease several system of medicine practised in the world, every system with its own basis, philosophy and therapeutics, but with one common object i.e. alleviation of disease (Said, 1997). During the last decade, use of traditional medicine has expanded globally and has gained popularity. Unani System of Medicine is one among them which was originated in Greece. The great Greek Philosopher & Physician Hippocrates (460 - 377 B.C.) is the founder of Unani Medicine, later Galen, Rhazes and Avicenna enriched the System (Anonymous, 2007). World Health Organisation (WHO) pays attention to herbal medicinal products by bringing out monographs, guidelines on Quality control and on research methodologies in traditional medicine. India has made rules for Good Manufacturing Practices (GMP) on traditional Ayurveda, Unani and Siddha (ASU) products. Standard operating procedures and standards of raw and finished products are mentioned in pharmacopoeias and formularies of ASU (Venkat *et al.*, 2010). Standard of any drug relate to the uniformity in quality. A standard may be reflected by descriptive or numerical values obtained through assessment of quality by a given protocol (Venkat *et al.,* 2010). Standardization of herbal formulations is an essential factor in order to assess the quality, purity, safety and efficacy of drugs based on the concentration of their active principles. Evaluation of physicochemical properties of the formulation is

* Author for correspondence

essential for the assessment of the quality, that is, ash values determination, such as total ash, water-soluble ash and acid-insoluble ash. The extractive values of the formulation are also performed to ensure the presence of plant actives and their solubility profile.

*Safoof* are the fine powder forms of medicinal preparations made of plant, animal and mineral origin drugs. These are used internally as well as externally (Chaudhary *et al.,* 2013). *Safoof Kharish* is an externally used fine powder, which acts as *Daf-e-Ufoonat* (antiseptic) and *Jali* (detergent) (Anonymous, 2011) widely used to treat *Kharish* and *Hikka* (pruritus). It is advised to apply locally on the skin after mixing sufficient quantity of powder with jasmine oil. It is a Pharmacopoeal preparation, composed of one herbal drug i.e. Kamila (*Mallotus philippinensis*) and three mineral drugs i.e. Gandhak (*Sulphur*), Safaida Kashghari (*Zinc oxide*) and Murdar Sang (*Letharge*). *Kamila* is used to treat acne, scabies, pruritus and helminthiasis (Anonymous, 2007). *Gandhak* is applied externally in the form of paste for ringworm, scabies and other parasitic diseases (Nadkarni, 2009). *Murdar Sang* is a powerful local astringent, cooling and an insecticide; it is used externally as ointment for baldness, itching, ulcers, acne, eczematous eruptions and other skin diseases (Nadkarni, 2009). As *Safaida* have soothing action on skin therefore is used externally to treat burns and various eye diseases (Kabiruddin, 2007).

Because of the rapid progress of the herbal drug industry in India for the last quarter century, an increasing need is felt to standardize the Unani products. It is necessary to develop the scientific protocols such as SOP and pharmacopoeial standards of Unani formulations. Therefore, in the present study, physicochemical evaluation of the Unani formulation *Safoof Kharish* has been carried out because these evaluations are surprisingly uncharted till date and determination of these parameters are very essential to assure the quality, safety, and efficacy of this formulation.

## Materials and Methods

### Materials

Kamila (*Mallotus philippinensis*), Gandhak (*Sulphur*), Safaida Kashghari (*Zinc oxide*) and Murdar Sang (*Letharge*) were purchased from the local market of Bangalore. All the reagents and solvents used were of analytical grade.

### Preparation of formulation

The formulation was prepared as prescribed in National Formulary of Unani

Medicine (NFUM) part-VI. Twenty grams of each ingredient namely, kamila (*Mallotus philippinensis*), gandhak (*Sulphur*), safaida kashghari (*Zinc oxide*) and murdar sang (*Letharge*) were weighed accurately and made into fine powder separately by passing through sieve no. 120 (Table 1). The powders were mixed in a mortar, again passed through 120 no. sieve and packed in plastic containers (Fig.1).

### Determination of pH in 1% solution and 10% solution

An accurately weighed one gram and ten gram powder was dissolved separately in 100 ml distilled water, filtered and pH was measured using a digital pH meter (Anonymous, 1986).

### Determination of loss on drying

The percentage loss on drying (%LOD) was determined for *Safoof Kharish* gravimetrically in which 5 g of accurately weighed air-dried material was placed in a previously dried and tared petriplate. The sample was dried in an oven at 100°C–105°C until two consecutive weighing did not differ by more than 5 mg (Afaq *et al.,* 1994).

### Bulk density

Bulk Density is the ratio between the given mass of a powder and its bulk volume. 20gm of the powder is dried and filled in a 50 ml measuring cylinder. Carefully level the powder without compacting, and read the unsettled apparent volume to the nearest graduated unit. This is repeated to get average values. The Bulk Density was calculated in g per ml by using the formula (Halith *et al.,* 2009).

$$\text{Bulk Density} = \frac{\text{Mass}}{\text{Bulk Volume}}$$

### Tapped density

The tapped density is an increased bulk density attained after mechanically tapping a container containing the powder sample. 20gm of the powder is dried and filled in a 50 ml measuring cylinder. Powder sample was tapped for 500 and 750 taps and the corresponding volumes were noted. The powder was subjected to tapping until the difference between succeeding measurements is less than two ml. The Tapped Density was calculated in g per ml by using the formula (Lachman *et al.,* 1991).

$$\text{Tapped Density} = \frac{\text{Mass}}{\text{Tapped Volume}}$$

Carr's index (or) % compressibility

It indicates powder flow properties. It is expressed in percentage and is calculated by the following formula (Moiz *et al.,* 2011).

Carr's Index (%) = [(Tapped density – Bulk Density) / Tapped Density] × 100

Hausner ratio

Hausner ratio is an indirect index of ease of powder flow. It is calculated by the following formula (Moiz *et al.,* 2011).

Hausner's Ratio = Tapped density / Bulk Density

Angle of repose

The fixed funnel method was employed to measure the angle of repose. A glass funnel was secured with its tip at a given height (h), above the graph paper that is placed on a flat horizontal surface. The powder was carefully pored through the funnel until the apex of the conical pile just touches the tip of the funnel. The radius (r) of the base of the conical pile was measured. The angle of repose (θ) was calculated using the following formula. Values for angle of repose ≤ 30 usually indicate free flowing material and angle ≥ 40 suggested a poor flowing material (Subrahmanyam, 2009).

$$\theta = \tan^{-1} (h/r)$$

Determination of ash values

*Total ash*

Two grams of the powdered material was accurately weighed and placed in a previously ignited and tared silica crucible. The material was ignited to a temperature of 500–600°C until free from carbon, cooled and weighed and the percentage was calculated in mg/g of powder drug (Anonymous, 2007).

*Acid-insoluble ash*

Total ash was boiled gently with 25ml of dilute hydrochloric acid for five minutes. The insoluble matter was collected on an ash less filter paper washed with hot water and ignited at a temperature not exceeding 450°C and weighed after cooling. The percentage of acid insoluble ash was calculated in mg/g of powder drug (Anonymous, 2007).

*Water soluble Ash*

Total ash was boiled with 25 ml of distilled water for five minutes. The insoluble matter was collected on an ash less filter paper, washed with hot water and ignited. The weight of insoluble ash was subtracted from the weight of the total ash, giving the weight of the water soluble ash. The percentage of water soluble ash was calculated in mg/g of powder drug (Anonymous, 2007).

Determination of Extractive values

The extractive values were recorded in water, alcohol, petroleum ether and chloroform separately by percolation in soxhlet apparatus with a view to study the distribution of various constituents of *Safoof Kharish*. Accurately weighed five gram of coarsely powdered air-dried material was taken and subjected to separate extraction with each solvent. The extracts were filtered using filter paper (Whatman No.1) and after evaporation of the solvents on water bath, the extractive values were determined with reference to the weight of drug. The procedure was repeated three times and the mean value for each extract was calculated (Jenkins *et al.,* 2008).

Thin layer chromatography

Preparation of extracts for TLC: Two gram of *safoof* was soaked in petroleum ether and chloroform separately for 18 hours, refluxed for ten minutes on water bath and filtered. The filtrates were concentrated on water bath and made up to 5ml in a standard flask separately.

Method of developing for TLC: Pet. ether and Chloroform extracts were applied on precoated silica gel 60 F254 TLC plate (Merck Germany) as absorbent and developed the plate using solvent systems, benzene and chloroform in ratio 2:2 v/v in which 3 drops of acetic acid was added. After developing, the plates were dried and exposed to iodine vapours to visualize the spots (Anonymous, 1992).

**Table 1 :** Ingredients of *Safoof Kharish*

| Unani Name | Botanical/English Name | Quantity |
|---|---|---|
| Kamila | *Mallotus philippinensis* | 20 gm |
| Gandhak | *Sulphur* | 20 gm |
| Safaida Kashghari | *Zinc oxide* | 20 gm |
| Murdar Sang | *Letharge* | 20 gm |

Table 2 : Organoleptic characteristics of *Safoof Kharish*

| | |
|---|---|
| Colour | Light Pink |
| Odour | Sulphur like |
| Texture/State | Fine Powder |

Table 3 : Physicochemical tests of *Safoof Kharish*

| S. No. | Parameters | 1 | 2 | 3 | Mean±SD |
|---|---|---|---|---|---|
| 1. | pH(1%) | 6.56 | 6.59 | 6.67 | 6.6±0.056 |
| 2. | pH(10%) | 7.53 | 7.53 | 7.59 | 7.5±0.034 |
| 3. | Loss of weight on drying (%) | 0.803 | 0.911 | 0.945 | 0.886±0.0741 |
| 4. | Bulk density(gm/ml) | 0.8695 | 0.8695 | 0.8695 | 0.869±6.63 |
| 5. | Tapped density(gm/ml) | 1.4285 | 1.4285 | 1.4285 | 1.4285±1.32 |
| 6. | Carr's index(%) | 39.13 | 39.13 | 39.13 | 39.13±0.00 |
| 7. | Hausner's ratio | 1.6428 | 1.6428 | 1.6428 | 1.6428±0.00 |
| 8. | Total ash(%) | 70.63 | 71.91 | 70.52 | 71.02±0.772 |
| 9. | Acid insoluble ash(%) | 44.89 | 44.32 | 43.97 | 44.39±0.464 |
| 10. | Water soluble ash(%) | 1.26 | 1.20 | 1.31 | 1.25±0.055 |
| 11. | Angle of Repose | 51° | 50° | 50° | 50.33±0.577 |
| 12. | Extractive Values Aqueous | 1.36 | 1.52 | 1.30 | 1.393±0.113 |
| 13. | Ethanolic | 6.56 | 6.72 | 6.43 | 6.57±0.145 |
| 14. | Petroleum Ether | 2.28 | 1.90 | 1.89 | 2.02±0.222 |
| | Chloroform | 3.9 | 4.1 | 4.2 | 4.06±0.152 |

Table 4 : TLC of *Safoof Kharish*

| Extract | Solvent System | Treatment | No. of Spots | $R_f$ Values |
|---|---|---|---|---|
| Petroleum Ether | Benzene: Chloroform (2:2) + 3 drops of acetic acid | Exposed to Iodine vapours | 2 | 0.83, 0.45 |
| Chloroform | Benzene:Chloroform (2:2) + 3 drops of acetic acid | Exposed to Iodine vapours | 4 | 0.84, 0.43, 0.26, 0.12 |

Fig. 1: Finished Product *Safoof Kharish*

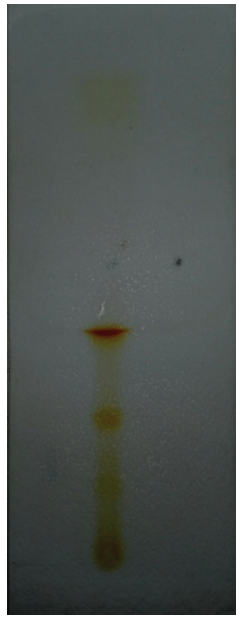


Fig .2 : TLC for Chloroform extract

Fig. 3 : TLC for Petroleum Ether extract

## Results and Discussion

Organoleptic characteristics of *safoof kharish* showed light pink colour, sulphur like odour and homogenous fine powder (Table 2). These characteristics might be useful for distinguishing it from its substitutes and adulterants. pH of 1% and 10% solution (w/v) of *safoof kharish* was found to be 6.6±0.056 and 7.5±0.034 respectively. Total ash value of *safoof kharish* was found to be 71.02±0.772%. High content of total ash value may be due to the presence of three mineral origin drugs in formulation, as *kamila* the only organic drug in formulation have total ash value of NMT 6% (Anonymous, 2007). Acid insoluble ash was found to be 44.39±0.464%, it showed that part of total ash which was insoluble in dilute hydrochloric acid. Water soluble ash was found to be 1.25±0.055% (Table 3). Ash values are useful in determining authenticity and purity of drug and in detection of low grade product, excess of earthy matter and exhausted drugs. Loss of weight on drying was found to be 0.886±0.0741%, it tells about the moisture content. The moisture content of the formulation should be minimized in order to prevent decomposition of the formulation either due to chemical change or microbial contamination (Kokate *et al.,* 2010). Extractive values of the formulation in different solvents like water, ethanol, petroleum ether and chloroform was found to be 1.393±0.113%, 6.57±0.145%, 2.02±0.222% and 4.06±0.152% respectively (Table 3). The extracts obtained by exhausting crude drugs are indicative of approximate measure of their chemical constituents (Kokate *et al.,* 2010).The extractive value of the formulation determines the quality as well as purity of the formulation. In the present study extractive values were found to be more in alcohol than other solvents. The bulk density of a powder is the ratio of the mass of an untapped powder sample and its volume including the contribution of the interparticulate void volume. Bulk density of the formulation was found to be 0.8695±6.63 gm/ml (Table 3). The bulk density can be use as a quality control measure, used to check the uniformity of bulk chemicals and in selecting the proper size of a container and packing material (Subrahmanyam, 2009). On the other hand tapped density is an increased bulk density attained after mechanically tapping a container containing the powder sample. Tapped density of the formulation was found to be 1.428±1.32 gm/ml (Table 3). Compressibility index and Hausner ratio are measures of the tendency of a powder to be compressed and also indicate the flow property. Values of Carr's index ≤ 10% indicate excellent flow and > 38% indicate very poor flow property (Table 3). Similarly values of Hausner's ratio 1.00-1.11 indicate excellent flow and > 1.60 indicate very poor flow property (Nuka *et al.,* 2012). Values of Carr's index and Hausner's ratio for *safoof kharish* were found to be 39.13±0.00% and

1.642±0.00 respectively and showed poor flow property of the formulation. Flow characteristics are also measured by angle of repose. Values for angle of repose ≤ 30º indicate a free flowing material and angles ≥ 40° suggest a poorly flowing material. In the present study increased angle of repose i.e. 50°.33'±0.577 was found which showed very poor flow property of the formulation (Table 3). It is due to the small particle size (passed through 120 mesh). The TLC of *Safoof Kharish* (petroleum ether and chloroform extract) was developed in Benzene and Chloroform in ratio 2:2 v/v solvent system in which three drops of acetic acid was added (Fig. 2&3). Plates exposed to iodine vapours showed two spots with $R_f$ values 0.83, 0.45 for petroleum ether extract and four spots with $R_f$ values 0.84, 0.43, 0.26, 0.12 for chloroform extract (Table 4). TLC is one of the important parameter used for detecting adulteration and judging the quality of drugs.

## Conclusion

Among the various Unani formulations *Safoof Kharish* is one which is widely use in common practice but still its official physicochemical standards are not present. Therefore an attempt has been made to establish the scientific basis of the formulation. The physicochemical characteristics obtained may be used for quality evaluation and the standardization of the compound formulation *Safoof Kharish*. These explorations will definitely help to set a standard for this traditional medicine. Further analytical and other studies may be conducted to make its complete monograph.


## Acknowledgement

The authors are highly thankful to Prof. M.A. Siddiqui, Director, National Institute of Unani Medicine (NIUM), Bangalore, for support and providing the best possible facilities.


## References


Afaq, S.H., Tajuddin, Siddiqui M.M.H., 1994. Standardization of Herbal Drugs. A.M.U. Press, Aligarh, p. 41.

Anonymous, 1986. Physicochemical standards of Unani formulations, Part I. CCRUM, Ministry of Health & Family Welfare, Govt. of India, New Delhi, p. A50.

Anonymous, 2007. The Unani Pharmacopoeia of India. Part-I, Vol 1. CCRUM, Ministry of Health & Family Welfare, Govt. of India, New Delhi, p. 17, 45, 109.

Anonymous, 2011. National Formulary of Unani Medicine, Part VI. CCRUM, Ministry of Health & Family Welfare, Govt. of India, New Delhi, p. 104.

Anonymous, 1992. Standardization of single drugs of Unani medicine, Part-II. CCRUM, Ministry of Health & Family Welfare, Govt. of India, New Delhi, p. 201.

Chaudhary, S.S., Tariq, M., Zaman, R., Imtiyaz, S., 2013. Solid dosage forms in Unani system of Medicine. *Journal of Pharmaceutical and Scientific Innovation* 2(3):17-22.

Halith, S.M., Abirami, A., Jayaprakash, S., Karthikeyini, C., Pillai, K.K., Firthouse, P.U.M., 2009. Effect of *Ocimum sanctum* and *Azadirachta indica* on the formulation of antidandruff herbal shampoo powder. *Scholar Research Library* 1 (2): 68-76.

Jenkins, G.L., Knevel, A.M., Digangi, F.E., 2008. Quantitative Pharmaceutical Chemistry, 6th ed. CBS Publishers, New Delhi, p.235.

Kabiruddin, M., 2007. Makhzanul Mufardat yani Kitab ul Advia. Idarah Kitab ul Shifa, New Delhi, p. 346.

Kokate, C.K., Purohit, A.P., Gokhale, S.B., 2010. Pharmacognosy. Nirali Prakashan, Pune, 45th ed., p.6.19-6.22.

Lachman, L., Liberman, H.A., Kanig, J.L., 1991. The Theory and Practice of Industrial Pharmacy. Varghese Publishing House, Mumbai, India, 2nd ed, p. 183.

Moiz, M., Srinivas, M.P., Sadanandam, M., 2011. Formulation and evaluation of bilayered tablets of montelukast and levocetrizine dihydrochloride Using natural and synthetic polymers. *International Journal of Drug Delivery* 3 (4): 597-618.

Nadkarni, K.M., 2009. Indian Materia Medica. Popular Prakashan Private Limited, Mumbai, Vol. 2nd, 3rd ed, p.86, 122.

Nuka, R., Potu, A.R., Nandan, N.R., 2012. Formulation development and in-vitro evaluation of ramipril micropellets. *World Journal of Pharmaceutical Research* 2(1): 76-87.

Said, M., 1997. Hamdard Pharmacopoeia of Eastern Medicine. Sri Satguru Publications, Delhi, p. 7.

Subrahmanyam, C.V.S., 2009. Text book of Physical Pharmaceutics. Vallabh Prakashan, 2nd ed., Delhi, pp. 216, 222-224

Venkat, P., Sudha, P., Lalitha., 2010. Quality control of Indian traditional medicines. Institute of Ayurveda and Integrative Medicine (I-AIM), Bangalore, pp. 8,15.

# Role of Unani Drugs in Normalizing Altered Liver Functions in Post Cholecystectomy and Choledocholithotomy Patients

**[1]*Anis Ismail, Iqbal Aziz, Rahida Hilal, Albina and Mehjabeen Fatima**

Department of Jarahat,
Ajmal Khan Tibbiya College,
Aligarh Muslim University,
Aligarh – 202001

## Abstract

The study of liver is a priority area because the liver plays a big role in normal physiology and is affected by a wide variety of diseases. The liver functions derange not only in liver disorders but in Cholecystitis and Choledocholithiasis as well.

In Unani medicine many mufrad and murakkab drugs have been proved to have hepatoprotective activity. A study was conducted on 100 patients in department of Jarahat, Ajmal Khan Tibbya College, AMU, Aligarh. All patients underwent cholecystectomy and/or choledocholithotomy. Patients were divided randomly into two groups of fifty each. In postoperative period, Group A (test group) was given the unani drugs and Group B (control group) was not given any drug. Patients (Group A) were given Sherbat-E-Deenar (10 ml) and Majoon Dabeed-ul-ward (6 gm), twice daily upto 3 months of post operative period.

Patients were assessed according to symptoms and changes in liver function test. After completion of study it was observed that the patients of group A, who were given unani drugs showed improvement in symptoms and liver function test more rapidly in comparison to the patients of group B who did not recieve any medication.

**Key words**: Cholelithiasis, Choledocholithiasis, Hepatoprotective.

## Introduction

Stone in extra-hepatic biliary system are most commonly found in gall bladder (cholelithiasis) and may be found in cystic duct and common bile duct (choledocholithiasis). Choledocholithiasis is mainly caused by migration of stones from gall bladder (secondary bile duct stones.). In around 10% cases of cholelithiasis, stones are found in the common bile duct. Choledocholithiasis may be found associated with cholelithiasis or may occur after many years of cholecystectomy (primary bile duct stones). Cholelithiasis is the most common surgical pathology in north India (Sarin *et al.,* 1986).The prevalence of gall stones in adult population is 6.12% (men-3.07% and women-9.6%) and it rises with age in both sexes to a peak in 6$^{th}$ decade. Prevalence is significantly higher in age adjusted parous women than in nullipara (Khusroo *et al.,* 1989).

In Classical books of Unani medicine, Unani philosophers had described various theories of cholelithasis, choledocholithiasis and jaundice like Rabban

[1]* Author for correspondence

Tabri (821 AD) and Majoosi (1010 AD), both described obstruction as a cause of jaundice (Majoosi, 2010; Tabri, 1997 and Tabri, 1981). Rhazes (936 AD) gave the types of jaundice as obstructive and non-obstructive. According to Avicenna (1037 AD) the obstruction in liver (suddah-e-kabid) is the cause of jaundice and this theory was also supported by Ibn-e-Hubal (1213AD) (Ibn-e-Hubul, 1363 H; Lubhaya, 1979).

Akbar Arzani in 1721 AD stated that thick viscid bile is the cause of gall stone while Nafees-Ibn-e-Auz in 1669 AD wrote that the stone in the liver is the cause of jaundice and surgery is the only remedy. Sheikh-ur-Raees, Ibn-e-Sina in 980-1037 AD also mentioned about gall stones in his treatise Cannon of Medicine. (And also Arzani, 1952; Ibn Nafees, 2007; Ibn Sina, YNM; Ibn Sina, 1895; Ibn Sina, 1906).

In Unani classics yarqan (jaundice) is mentioned as a condition in which level of bile in blood circulation is increased, which causes yellow discoloration of sclera and the skin and it is broadly divided into Suddi (obstructive) and ghair suddi (non obstructive) (Majoosi, 2010; Ramzi *et al.,* 1999). Unani physicians also divided yarqan on the basis of color as Yarqan-e-asfar (yellow discoloration of sclera, skin and all the fluids of body) and yarqan-e-aswad (black discoloration of stool, urine and even sweat). Many other classification of yarqan have also been described in old Unani literature (Ramzi *et al.,* 1999). According to Allama Najeeb Uddin Samarqandi, the color of the whole body turns yellow or black in case of yarqan and it is due to absorption of yellow or black khilt (humor) by skin and its underlying structures (Kabiruddin, 1940; Kabiruddin, 1946; Kabiruddin, 1916).

In Unani many Mufrad (single) and Murakkab drugs have been used in liver disorders. Some Unani Mufrad (single) drugs have been found to have hepatoprotective activity like Mako (*Solanum nigrum*), Gul-e-ghafis (*Agrimonia eupatoria*), Dar-e-hald (*Berberis aristata*), Gul-e-Tisu (*Butea frondosa*); Kasni (*Cichorium intybus*); Kutki (*Picrorrhiza kurroa*); Bhangra (*Eclipta alba*), Harad (*Terminalia chebula*); Rehan/Tulsi (*Ocimum sanctum*) and Anar (*Punica granatum*) (Asockson *et al.,* 2001; Chattopadhyay *et al.,* 1992; Chauhan *et al.,* 1992; Doreswamy and Sharma, 1995; Venu and Latha, 2002; Zafar and Ali, 1998). Similarly, many Murakkab preparations have also been shown to possess hepatoprotective activity such as jigrine, icterine (Doreswamy and Sharma, 1995).

Important factors, responsible for gall stone formation are metabolic, infective and bile stasis, Bactibilia, chemical imbalance pH imbalance, increased bilirubin excretion and the formation of sludge are the principal factors that lead

to choledocholithiasis. Obstruction of common bile duct leads to pain, jaundice, cholangitis, pancreatitis and sepsis.

Patients with choledocholithiasis may be completely asymptomatic in about 7% of cases and approximately 25-50% patients have symptoms and require treatment and clinical presentation depends on the degree and level of obstruction and on the presence and absence of biliary infection. Pain is the most frequent presenting symptom. Patient becomes jaundiced when common bile duct becomes obstructed and conjugated bilirubin enters into the blood stream. It can be episodic.

In modern concept surgery is the only modality to cure the patients. Different types of operative procedures are recommended such as choledocholithotomy and T-tube enclosure, choledochoduodenostomy etc for the stone removal and restoration of normal liver function (Russell *et al.,* 2000).

The liver function are deranged not only in the liver disorders but also in cholecystitis, cholelithiasis and choledocholithiasis as they cause the liver damage resulting into the deranged liver function (Ramzi *et al.,* 1999; Schwartz *et al.*, 1990).

We undertook this study to find out the effect of cholelithiasis and choledocholithiasis on liver function and also to find out the role of Unani drugs (Sharbat-e-deenar and Majoon Dabeed-ul-ward) (Razi, 2000; Rehman, 1991) in improving liver function after cholecystectomy and choledocholithotomy considering an additional factor that the liver function is deranged not only by the disease, but also by operative trauma and anesthetic drugs.

## Material and Method

This study was an experimental randomized controlled clinical trial conducted during 2003-2008 in the department of Jarahat, Ajmal khan Tibbiya College, AMU, Aligarh.

Written and well Informed consent was taken from the patients before participation into the study. Inclusion and Exclusion Criteria.

Patients who were diagnosed with cholelithiasis and choledocholithiasis by Ultrasound along with deranged liver function test were included in the study and the patients who were having deranged liver function due to causes other than cholelithiasis and/or choledocholithiasis like Hepatitis, Cirrhosis of liver, Cholengiocarcinoma, Carcinoma of head of Pancreas, were excluded from the study.

100 patients diagnosed with cholelithiasis and choledocholithiasis by ultrasound were included in the study. Patients were diagnosed on the basis of subjective (Pain in abdomen, nausea, vomiting etc) as well as objective parameters (Haemogram, liver function test, ultrasound etc). Those patients who had deranged liver function and having signs and symptoms of cholangitis were prepared for surgery by giving IV Fluids, IV antibiotics and injection Vitamin K.

All patients underwent cholecystectomy and/or choledocholithotomy. The selection of patients for choledochoduodenostomy or T-tube drainage was decided preoperatively. T-tube drainage was performed in the patients having adhesions, common bile duct upto 1cm in diameter, single common bile duct stone and in patients in whom mobilization of the duodenum was difficult. In rest of the patients choledochoduodenostomy was done.

The patients were divided randomly into two groups of fifty each, named as Group A and Group B. Group A (Test Group) has been given the test drugs and Group B (Control) has not been given any drug in the post operative period.

Treatment was started after seven days of surgery and liver function test was conducted at regular intervals (07days, 15days, 1month, 2months and 3months). Sharbat-e-deenar (10ml) and Majoon Dabeed-ul-ward (6gms) was given orally twice daily to the patients of test group. Majoon Dabeed-ul-ward is a pharmacopeal drug and its main constituent is Gulab (*Rosa damascus*). Sharbat-e-deenar is a viscid preparation , tukhm-e-kasoos (*Cuscuta reflexa*) is its main ingredient. Duration of treatment was six weeks. Constituents of both the drugs are given in Table 1. Follow up was also maintained even after termination of therapy in both groups. The collected data were analyzed by applying student't' test.

## Improvement or assessment criteria

Assessment was done and assessment was done at regular intervals ($7^{th}$ day, $15^{th}$ day, 1 month, 2 months, 3 months intervals) by observing the effect of drugs on clinical symptomatology of the patients postoperatively after medication with the sample drugs and observing the LFT in the form of Serum Bilirubin, SGOT, SGPT and SAP levels at various levels at various intervals in postoperative period.

## Results and Observations

Clinical evaluation was done on the basis of subjective and objective parameters. Out of 100 patients, 90 (90.0%) were females and 10 (10%) were male with the ratio of male: female is 9:1 (Table 2).

During the study among pre-operative complaints maximum no. of patients (99%) complained of pain in rt. upper abdomen, 14% complained of nausea, 52% vomiting, 66% yellowish discoloration of eyes, 48% yellowish discoloration of body, 30% itching all over the body, 30% fever, 34% flatulence, 40% dyspepsia, 66% heartburn and 66% loss of appetite (Table 3).

Table no. 4 shows effect of test drugs on symptomatology in postoperative period. In group A Complain of pain in abdomen improved in 41 patients (no. of patients reduced from 50 to 9 and the improvement was of 82%) and 36 patents improved in group B (no. of patients reduced from 49 to 13 and the improvement was of 73%). Among the patients, complaining nausea 12 got improved in group A (no. of patients reduced from 32 to 10 and the improvement was of 37.5%), whereas in group B just 4 patients improved (no. reduced from 20 to 16 and the improvement was of 20%). Among the patients complaining vomiting, 28 patients improved (the no. reduced to 04 from 32 and the improvement was of 87.5%) in group A, 17 patients improved in group B (no. reduced to 03 from 20 and the improvement was of 85%). In group A, yellowish discoloration of eyes improved in 31 patients (the no. reduced from 33 to 2 and the improvement was of 93.9%) and in group B, 29 patients improved (the no. reduced from 33 to 4 and the improvement was of 87.8%). In group A among the patients who were having yellowish discoloration of body, 24 improved (no. reduced from 25 to 1 and the improvement was of 96%) and in group B. 22 patients improved (no. of patients reduced from 23 to 1 and the improvement was of 95.6%). In group A, among the patients having itching all over body 14 improved (no. reduced from 15 to 1 and the improvement was of 93.3%) and in group B, 15 out of 15 patients were improved and the improvement was of 100%. Among the patients who were having fever, 19 patients improved (no. reduced to 1 from 20 and the improvement was of 95%) in group A and in group B, 8 patients improved (no. reduced from 10 to 2 and the improvement was of 80%). The flatulence improved in 18 patients (no. of patients reduced from 20 to 2 and the improvement was of 90%) in group A and 8 patients improved in group B (no. of patients reduced from 14 to 6 and the improvement was of 57%). Heartburn improved in 34 patients (no. of patients reduced from 36 to 2 and the improvement was of 94.4%) in group A and 23 patients improved in group B (no. of patients reduced from 30 to 7 and

the improvement was of 76.6%). The dyspepsia improved in 22 patients (no. of patients reduced from 23 to 1 and the improvement was of 95.6%) in group A and 13 patients improved in group B (no. of patients reduced from 17 to 4 and the improvement was of 76.4%). There is a marked improvement in loss of appetite, 28 patients out of 29 improved (no. reduced from 29 to 1 and the improvement was of 96.5%) in group A, and in group B 30 patients improved out of 37 (no. reduced from 37 to 7 and the improvement was of 81%).

Thus, it was found that the symptomatic improvement was more marked in group A as compared to group B in the postoperative period.

Table no. 5 shows comparative changes in serum bilirubin levels in both the groups of patients. In group A 14 patients and in group B 16 patients had high serum bilirubin preoperatively (more than 5 mg %). After operation and medication with test drugs the number of patient gradually reduced to 08, 06, 03, 01 in 7 days, 15 days, 1 month and 2 month respectively and on completion of the treatment (after 3 months) there was no patient with more than 5mg% serum bilirubin in group A, while in group B the no. of patient gradually reduced from 16 to 08, 05, 03, 01 after 7 days , 15 days, 1 month and 2 month respectively and on completion of the treatment (after 3 months) 01 patient had more than 5mg% serum bilirubin.

In the range of 3.1-5mg%, 10 patients presented in group A and 8 in group B preoperatively. After 7 days, 15 days, 1 month, 2 month the no. of patients reduced to 10, 06, 03, 01 (in group A) and in group B the no. of patients reduced to 06, 05, 04, 03 respectively and after completion of treatment (after 3 months) there was no patient left in range of 3.1 to 5 mg % of serum bilirubin.

There were 8 and 12 patients who had serum bilirubin between 1.1-3 mg % preoperatively in groups A and B respectively, number of patient in this range reduced to 02 in both the groups respectively.

In the range of 0-1mg%, there were 18 patients in group A and 16 in group B preoperatively and the number of patient increased to 48 in group A and 46 in group B after 3 month. It shows that the patients are shifting from higher serum bilirubin to normal serum bilirubin. For table no 5, the ‘t’ value after 15 days is 0.58, after one month is 0.55, after 2 months is 1.31 and after 3 months 1.22.

Table no. 6 shows the improvement in SGOT in groups A and B. There were 10 patients who had SGOT higher than 80 units preoperatively in group A and 12 patients in group B. After 3 months the number of patients reduced to 1 in both the groups.

In the range of 41-80 units, there were 14 and 12 patients in group A and B respectively. Then the number reduced to 04 after 2 month in group A and 14 on after 2 month in group B postoperatively. There was no patient in this range after 3 months in group A, while in group B, 10 patients remained.

There were 26 patients each in both the groups of patients who had SGOT in the normal range (0-4 units). The no. of patients progressively increased from 7$^{th}$ day to 3$^{rd}$ month in this range (from 26 to 50 in group A and from 26 to 39 in group B), this is due to shift of patients from higher to normal range and the same pattern was observed in group B also but the increase was not in that proportion as in group A. This shows that the sample drug normalizes the liver function earlier. . For table no 6, the 't' value after 15 days is 0.43, after one month is 0.64, after 2 months is 2.35 ($p<0.05$) and after 3 months 2.47 ($p<0.05$).

Table no.7 shows improvement in SGPT levels. Preoperatively there were 10 patients in group A and 8 patients in group B, who had more than 80 units SGPT levels and the number reduced to 0 after 2 month of treatment in group A while in group B there was 1 patient who had high (>80 units) SGPT levels even after 3 months.

In the range of 36-70 units there were 12 and 16 patients in group A and B respectively and the number reduced to 0 and 10 in group A and B after 3 months respectively. There were 28 patients in group A and 26 patients in group B with normal range of SGPT levels (0-35 units). This number increased to 50 and 39 in group A and B respectively, with time due to shift of patients from higher to normal range. . For table no 7, the 't' value after 15 days is 0.65, after one month is 1.23, after 2 months is 1.76 and after 3 months 3.19 ($p<0.01$).

Table no. 8 shows improvement of SAP levels in group A and B. In range of SAP >33 units, there were 11 patients in group A and 16 in group B in the preoperative period. After three months the number reduced to 2 in group A and 4 in group B. Preoperatively, there were 07 patients in group A and 13 in group B in the range of 23-33 units and the number reduced to 03 and 07 in group A and B respectively. There were 29 and 12 patients preoperatively in the range of 12-22 units in group A and B respectively. After 03 months the number declined to 17 in group A and increased to 27 in group B. In the normal range (0-11 units) there were 13 patients in group A and 09 in group B preoperatively. After 3 months the number of patient increased from13 to 28 in group A and from 09 to 12 in group B and this increase is due shifting of patients from higher range to normal range which is more marked in group A. . For table no 8, the 't' value after 15 days is 1.79, after one month is 2.1 ($p<0.05$), after 2 months is 2.37 ($p<0.05$) and after 3 months 2.38 ($p<0.05$).

Table 1 : Composition of Test Drugs

| Contents | Botanical name | Part used/Form |
|---|---|---|
| Sharbat-e-deenar | | |
| Bekh-e-Kasni | *Cichorium intybus* | Root |
| Tukhm-e Kasni | *Cichorium intybus* | Seed |
| Gul-e-surkh | *Rosa damascena* | Flower |
| Gul-e-neelofar | *Nymphaea alba* | Flower |
| Gaozaban | *Borago officinalis* | Leaves, Flower |
| Tukhm-e-Kasoos | *Cuscuta reflexa* | Seed |
| Rewand Cheeni | *Rheum emodi* | Root |
| Majoon Dabeed-ul-Ward | | |
| Sumbul-ut-teeb | *Veleriana officianalis* | Herb/Whole plant |
| Mastagi | *Pistacia lintiscus* | Resin/Gum |
| Zafran | *Crocus sativus* | Style and stigma |
| Tabasheer | *Bambusa arundinacea* | Rutubat |
| Darcheeni | *Cinnamomum zeylanicum* | Bark |
| Asaroon | *Asarum europaeum* | Root |
| Qust sheerin | *Saussurea lappa* | Root |
| Ghafis | *Agrimonia eupatoria* | Flower |
| Tukhm-e-Kasoos | *Cuscuta reflexa* | Seed |
| Luk-e-maghsool | *Coccus lacca* | Usara |
| Tukhm-e Kasni | *Cichorium intybus* | Seed |
| Tukhm-e Karafs | *Apium graveolens* | Seed |
| Zarawand taweel | *Aristolochia clematitis* | Root |
| Habb-e-balsan | *Commiphora opobalsamum* | Fruit/Oil/wood |
| Qaranfal | *Eugenia caryophyllata* | Dried flower bud |
| Dana-e-heel khurd | *Elettaria cardamomum* | Fruit |

Table 2 : Distribution of patients according to sex

| Sex | Number | Percentage (%) |
|---|---|---|
| Male | 10 | 10 |
| Female | 90 | 90 |

Table 3 : Symptomatology in patients preoperatively

| Symptoms | No. of Patients | %age | Male | %age | Female | %age |
|---|---|---|---|---|---|---|
| Pain in rt. Upper abdomen | 99 | 99.0 | 10 | 10.1 | 89 | 89.0 |
| Nausea | 14 | 14 | 03 | 21.4 | 11 | 78.6 |
| Vomiting | 52 | 52 | 02 | 3.8 | 50 | 96.2 |
| Yellowish discoloration of eyes | 66 | 66 | 07 | 10.6 | 59 | 89.9 |
| Yellowish discoloration of body | 48 | 48 | 07 | 14.5 | 41 | 85.5 |
| Itching all over body | 30 | 30 | 07 | 23.3 | 23 | 76.6 |
| Fever | 30 | 30 | 04 | 13.3 | 26 | 86.7 |
| Flatulence | 34 | 34 | 03 | 8.8 | 31 | 91.2 |
| Dyspepsia | 40 | 40 | 10 | 25.0 | 30 | 75.0 |
| Heartburn | 66 | 66 | 09 | 13.6 | 57 | 86.4 |
| Loss of appetite | 66 | 66 | 13 | 19.7 | 53 | 80.3 |

Table 4 : Effect of the drug on symptomatology of patients

| Symptomatology | Patients on drug | | | Patients without drug | | |
|---|---|---|---|---|---|---|
| | Before treatment | After treatment | Improvement in percentage | Before treatment | After treatment | Improvement in percentage |
| Pain in rt. Upper abdomen | 50 | 09 | 82% | 49 | 13 | 73.4% |
| Nausea | 32 | 10 | 37.5% | 20 | 16 | 20% |
| Vomiting | 32 | 04 | 87.5% | 20 | 03 | 85% |
| Yellowish discoloration of eyes | 33 | 02 | 93.9% | 33 | 04 | 87.8% |
| Yellowish discoloration of body | 25 | 01 | 96% | 23 | 01 | 95.6% |
| Itching all over body | 15 | 01 | 93.3% | 15 | 00 | 100% |
| Fever | 20 | 01 | 95% | 10 | 02 | 80% |
| Flatulence | 20 | 02 | 90% | 14 | 06 | 57% |
| Dyspepsia | 23 | 01 | 95.6% | 17 | 04 | 76.4% |
| Heartburn | 36 | 02 | 94.4% | 30 | 07 | 76.6% |
| Loss of appetite | 29 | 01 | 96.5% | 37 | 07 | 81% |

Table 5 : Relation of total serum bilirubin with duration

| Range of total serum bilirubin | No. of Patients preoperatively | No. of Patients postoperatively on drug | | | | | No. of Patients preoperatively | No. of Patients postoperatively without drug | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | O7 days | 15 days | 01 month | 02 months | 03 months | | O7 days | 15 days | 01 month | 02 months | 03 months |
| 0-1 | 18 | 20 | 26 | 36 | 42 | 48 | 16 | 24 | 26 | 33 | 41 | 46 |
| 1.1-3 | 08 | 12 | 12 | 08 | 06 | 02 | 10 | 12 | 14 | 10 | 05 | 02 |
| 3.1-5 | 10 | 10 | 06 | 03 | 01 | 00 | 08 | 06 | 05 | 04 | 03 | 00 |
| >5 | 14 | 08 | 06 | 03 | 01 | 00 | 16 | 08 | 05 | 03 | 01 | 00 |
| Total | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |

Table 6 : Relation of SGOT with duration

| Range of SGOT | No. of Patients preoperatively | No. of Patients postoperatively on drug | | | | | No. of Patients preoperatively | No. of Patients postoperatively without drug | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | O7 days | 15 days | 01 month | 02 months | 03 months | | O7 days | 15 days | 01 month | 02 months | 03 months |
| 0-40 | 26 | 28 | 32 | 38 | 46 | 50 | 26 | 28 | 30 | 32 | 34 | 39 |
| 41-80 | 14 | 12 | 12 | 08 | 04 | 00 | 12 | 17 | 16 | 15 | 14 | 10 |
| >80 | 10 | 10 | 06 | 04 | 01 | 01 | 12 | 05 | 04 | 03 | 02 | 01 |
| Total | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |

Table 7 : Relation of SGPT with duration

| Range of SGPT | No. of Patients preoperatively | No. of Patients postoperatively on drug | | | | | No. of Patients preoperatively | No. of Patients postoperatively without drug | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | O7 days | 15 days | 01 month | 02 months | 03 months | | O7 days | 15 days | 01 month | 02 months | 03 months |
| 0-35 | 28 | 30 | 34 | 40 | 44 | 50 | 26 | 36 | 30 | 34 | 36 | 39 |
| 36-70 | 12 | 12 | 10 | 08 | 06 | 00 | 16 | 18 | 15 | 12 | 12 | 10 |
| >80 | 10 | 10 | 06 | 04 | 00 | 00 | 08 | 06 | 05 | 04 | 02 | 01 |
| Total | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |

Table 8 : Relation of serum alkaline phosphotase (SAP) with duration

| Range of SAP | No. of Patients preoperatively | No. of Patients postoperatively on drug | | | | | No. of Patients preoperatively | No. of Patients postoperatively without drug | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | O7 days | 15 days | 01 month | 02 months | 03 months | | O7 days | 15 days | 01 month | 02 months | 03 months |
| 0-11 | 13 | 15 | 18 | 23 | 26 | 28 | 09 | 09 | 10 | 11 | 12 | 12 |
| 12-22 | 29 | 21 | 22 | 19 | 18 | 17 | 12 | 18 | 21 | 23 | 25 | 27 |
| 23-33 | 07 | 05 | 04 | 04 | 03 | 03 | 13 | 12 | 11 | 09 | 08 | 07 |
| >33 | 11 | 09 | 06 | 04 | 03 | 02 | 16 | 11 | 08 | 07 | 05 | 04 |
| Total | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |

## Discussion

The hepato-protective drugs help in the recovery of liver after damage caused by infection or obstruction or metabolic disease. Although it has been proved, that liver recovers with time, once the cause has been overcome. Most of Unani hepato-protective drugs are Muqawwi-e-jigar, Muhallil-e-auram-e-jigar and they speed up the recovery of hepatocytes thus help in resolving the symptoms of jaundice. Choledocholithiasis is one of the important cause of the obstructive jaundice.

The objective of this study was to demonstrate that some of the unani hepato-protective drugs speed up the recovery after operation as shown in results of the present study. In the study we evaluated two compound Unani drugs which hasten up the recovery of the liver function, and their efficacy has been assessed by the improvement in the enzymatic levels.

In case of obstructive jaundice, once the obstruction is relieved the symptoms disappear. In our study though in both the groups (experimental as well as control) the symptoms disappeared in the same time period, but it has been found that unani drugs are effective at the cellular level also, which can be demonstrated by decrease in the enzymes and serum bilirubin levels. In group A, the chemical parameters became normal in one month period and group B took three months.

Inspite of tremendous advances made in allopathic medicine, no effective scientifically proven hepato-protective medicine is available. Only high carbohydrate diet and bed rest is advised for the recovery of liver. Unani drugs are known to play a vital role in the management of the liver disease.

In Tibb-e-Unani about 42 and in Ayurveda 71 drugs are employed to cure the liver disease. Nearly 150 phytoconstituents from 101 plants are claimed to have hepatoprotective properties. In India more than 87 medicinal plants are used in different combinations (Sharma *et al.,* 1995; Subramanium and Pushpangadan, 1999).

The study was conducted on Arq-e-Afsanteen ( A Unani hepatoprotective drug and is used in different liver ailments) in department of jarahat, A.K.T.college in 2006 and it demonstrates that the patients who were on Arq-e-Afsanteen took 3 months to bring the deranged liver function test upto the normal level in comparison to control group which took around 6 months (Aziz *et al.,* 2008).

Another study conducted on poly herbal compound drug, “Kabdeen”, showed beneficial effect on liver enzyme levels. In this study enzyme as well as

serum bilirubin touched the normal level earlier in the experimental group as compared to the control group (Aziz *et al.,* 2008).

Similar effects had been noted in our study that sharbat-e-deenar and majoon dabeed-ul-ward when given to post operative patients of choledocholithiasis, showed beneficial effects on liver enzymes. Serum bilirubin as well as enzymes became normal earlier in maximum number of patients in test group as compared to control group.

## Conclusion

It is the demand of today's scientific medical education, to demonstrate the effect of unani drug on cellular or enzymatic level as unani drug possess various properties, besides being Muqawwi-e-jigar and Muhallil-E-Auram-E-Jigar.

In this study we have tried to demonstrate that the drugs Sharbat-e-Deenar and Majoon Dabeed-ul-ward affect the cellular activity of the hepatocytes and the results are positive. In our study though in both the groups (experimental as well as control) the clinical symptoms improved in nearly the same time period but in group A, the chemical parameters (assessed by LFT) became normal in one month period and group B took three months which shows that Unani drugs are effective at cellular level which can be demonstrated by decrease in the enzymatic and serum bilirubin levels.

## References


Arzani, H.M.A., 1952. Mezan-ul-Tibb; 4th edition, Daftar-ul-Maseeh, Hyderabad, Deccan. pp. 159-61.

Asockson, C., Ganeson, V., Anuradha, L., Asock , K. N. P., Bala, K. P. and Geetha, V. G., 2001. Hepatoprotective activity of *Punica granatum. Indian Drugs* 38: 183-86.

Aziz, I., Khan, M.N., Hasan, F. and Anwar, A.K., 2008. Role of "Kabdeen" (Unani compound drug) on Liver function test in post choledocholithotomy patients. *Hamdard Medicus* 51(4): 182-88.

Aziz, I., Khan, M.N. and Shah, A.H., 2008. Role of Afsanteen in normalizing liver function after choledocholithotomy. *Hippo. J. Unani Medicine* 4(2):7-13.

Chattopadhyay, R.R., Sarkar, S.K., Ganguly, S., Medda, C. and Basu, T.K., 1992. Hepatoprotective activity of *Ocimum sanctum* leaf extract against

Paracetamol induced Hepatic damage in Rats. *Indian J. of Pharmacology* 24: 163-65.

Chauhan, C.K., Nanivadekar, S.A. and Billimoria, F.R., 1992. Effect of a herbal Hepatoprotective product on drug metabolism in patients of cirrhosis and hepatic enzyme function in experimental liver Disease. *Indian J. of Pharmacology* 24: 107-10.

Doreswamy, R. and Sharma, D., 1995. Plant drugs for liver disorders management. *Indian Drugs* 32: 139-44.

Ibn Nafees., 2007. (Translated by Allama Hakeem Mohd Kabiruddin), Sharahul Ashab, Vol II. Aijaz Publishing House, New Delhi, pp. 547-52.

Ibn Sina, YNM. Al Qanoon Fil Tib (Translated in urdu by Hussain G.S.), Vol I. Munshi Naval Kishore, Lucknow, pp. 141-42.

Ibn Sina., 1895. Kitab Al Qanoon Fit Tib, Vol. 2. (Translated by Molvi Hakeem Syed Ghulam Hussain), Matba Munshi Naval Kishore, Kanpur, p. 90.

Ibn Sina., 1906. Tarjuma Qanoon. Vol. 2. Shaikh Bu Ali Sina, Hakeem Syed Hussain, Matba Munshi Naval Kishore, Lucknow, pp. 53-54, 83, 98-99, 103, 133-34, 195.

Ibn-e-Hubal., 1363 H. Kitabul Mukhtarat fil tib. Vol. III rd. Daftar-ul-Maseeh, Hyderabad, Deccan, pp. 345-46, 355-56, 387.

Kabiruddin, A.H.M., "AL-Akseer".1940. Vol. IInd. Maktaba-al-shifa, Faisalabad, Pakistan, pp. 167, 870, 913-14.

Kabiruddin, H.M. 1946. Bayaz-e-Kabir, 11th ed. Vol. II, Hyderabad, Deccan, p. 111.

Kabiruddin, M., 1916. Tarjuma-e-Kabir, Vol. II. Aijaz publishing house, New Delhi, pp. 666-67, 693, 699-700.

Khusroo, M.S., Maahajan, R., Zargar, S.A., Javid, G. and Sapru, S., 1989. Prevalence of biliary tract disease in India: A Sonographic study in adult population in Kashmir. *Gastroenterology* 30: 201-205.

Lubhaya, H.R., 1979. Delhi ke Muntakhab Murakkabat. Goswami Kutub Khana, Delhi, p. 189.

Majoosi, A., 2010. Kamilus-Sana-E-Tib, 2010. Vol. I, Part I, Idara-e-Kitabus Shifa, New Delhi. pp. 376-77.

Ramzi, S.C., Kumar, V., Collins, T., 1999. Pathological Basis of Diseases. 6th ed. Harcourt Asia (PTE, Ltd.) and W.B.Saunders Company, pp. 848-50.

Razi, A.B.M.Z., 2000. Kitab-ul- Havi, Vol. 7th (Urdu translation), Ali Corporation India, Delhi, pp. 121-23.

Rehman, H.S.Z., 1991. Kitabul Murakkabat. Publication division, Aligarh Muslim University Aligarh, pp. 104-105.

Russell, R.C.G, Williams, N.S. and Bulstrode, C.J.K., 2000. Bailey and Love's; Short Practice of Surgery, 23rd ed., Arnold (member Hodder Headline group) and Oxford University press Inc., New york. pp. 965-66.

Sarin, S.K., Kapur, B.M.L. and Tondon, R.K., 1986. Cholesterol and pigment gall stones in North India: A prospective analysis *Dig Dis. Sci.* 31(10): 1041-5.

Schwartz, S.I., Ellis, H. and Husser, W.C., 1990. Maingot's Abdominal operations, Vol. IInd, 9th ed. Appleton and Lange; A publishing division of Prentice Hall, p. 1381.

Sharma, M., Tripathi, P., Singh. V.P. and Tripathi, Y.P., 1995. Hepatoprotective and toxicological evaluation of hepatomed, an ayurvedic drug. *Indian J. Exp. Bio.* 33(1): 34-7.

Subramanium, A., Pushpangadan, P., 1999. Development of Phytomedicines for Liver diseases. *Indian J. of Pharmacology* 31: 166-75.

Tabri, 1981. Firdaus-ul-Hikmat, (translated in Urdu by Hakeem Rasheed Ashraf Nadvi) Matba Hamdard Foundation Press, Karachi. pp. 635-37.

Tabri, A.H.A.M., 1997. Moalijatul Buqratiya, Vol. III. CCRUM, Ministry of Health & Family Welfare, New Delhi, p. 231.

Venu, K. M.R. and Latha, M.S., 2002. Hepatoprotective effect of the Methanolic extract of 29. *Curculigo orchioides* in Ccl4 treated Male Rats. *Indian J. Pharmacology* 34: 269-75.

Zafar, R. and Ali, S.M., 1998. Antihepatotoxic effect of root and root callus extract of *Cichorium intybus* Linn. *J. of Ethnopharmacology* 61(22): 227-31.

# Study of Anti-ulcer Activity of *Coriandrum sativum* Linn. in Aspirin Induced Gastric Ulcer in Albino Rats

**[1]Shagufta Nikhat,**
**[2]Ghufran Ahmad and**
**[3]Nasreen Jahan**

[1]Jamia Tibbiya Deoband,
Deoband-247554, U.P.

[2]Dept. of Ilmul Advia,
A.K. Tibbiya College,
Aligarh Muslim University,
Aligarh-202002

[3]Dept of Ilmul Advia,
National Institute of Unani Medicine,
Kottige Palya, Magadi Road,
Bangalore-500091

## Abstract

Fruits of *Coriandrum sativum* Linn have been described in Unani literature to possess anti-gastritis, anti-ulcer, sedative, hypnotic, anti-anxiety and anti-stress activity. It has been studied scientifically for anti-ulcer activity on some of the parameters but no study has been conducted so far, for its role in aspirin induced gastric ulcer. The present study was designed to investigate the anti ulcer activity of hydro alcoholic extract of coriander against aspirin induced gastric ulcer in Wistar rats of either sex, weighing 150-200 gm. The animals were divided into 8 groups of 8 animals each. Different groups represented plain control (vehicle), negative control (ulcer induced), standard control (pre and post-treated with ranitidine) and four test groups, two each for preventive (pre-treated with 160 mg/kg and 273 mg/kg of extract) and curative (post-treated with 160 mg/kg and 273 mg/kg of extract) studies. Animals were treated for five days before or after the ulcer induction and sacrificed thereafter. Their stomach was dissected out and observed for lesions. The scoring of lesions was done to calculate the ulcer index and ulcer score. Histopathological studies were also carried out.

A significant decrease in ulcer index and ulcer score and remarkable changes in histopathological slides in curative group suggested that coriander possesses significant anti ulcer activity.

**Keywords:** *Coriandrum sativum*, Anti-ulcer, Aspirin, Unani Medicine

## Introduction

Peptic ulcer disease (PUD) is one of the most common gastrointestinal disorders, which causes a high rate of morbidity (Andreoli *et al.,* 2001), while the most common causes of peptic ulcer include *H. pylori* infection and excessive use of Non-Steroidal Anti-Inflammatory Drugs (NSAID) such as aspirin, ibuprofen, indomethacin and diclofenac sodium etc. The incidence of ulcer disease increases with age, due to excessive use of NSAIDs and the reduction in tissue prostaglandins (Andreoli *et al.,* 1993). Being one of the most commonly prescribed drugs worldwide NSAIDs always remain a threat to the health of gastric mucosa. The therapy of peptic ulcer involves decreasing the secretion of acid with $H_2$-receptor antagonist or proton pump inhibitor, neutralizing the secreted acid with antacids and enhancing the mucosal protection mechanism by cytoprotective agents. The later one is being appreciated and taken up as equally important measure to that of anti-

[2]* Author for correspondence

secretory agents in the management of peptic ulcer (Horn, 2000). Although these drugs have brought about remarkable success in the field of ulcer therapy but their efficacy and safety are still debatable because there are incidences of relapses, adverse effects and danger of drug interactions during ulcer therapy (Dharmani and Palit, 2006; Goel and Sairam, 2002). A number of plant drugs in recent years have been shown to possess significant anti ulcer effect. Most of the herbal drugs used in the management of peptic ulcer have been reported to reduce the offensive factors, they have been proved to be safe and effective and showed better patient tolerance. Therefore the use of natural drugs alone or in combination with other drugs is being seriously considered to manage the PUD (Goel and Sairam, 2002).The first drug reported effective against ulcer was carbenoxolone, discovered as a result of research on a commonly used indigenous plant, *Glycyrrhiza glabra* (Singh and Majumdar, 1999).

*Coriandrum sativum* Linn (coriander) which is considered both a herb and a spice, as both its leaves and seeds are used as a seasoning condiment is an important drug of Unani medicine (Saeed and Tariq, 2007). Its seed is used as carminative, stomachic, refrigerant, sedative; anti secretory and anti gastritic etc (Chaudhry and Tariq, 2006). It is an important ingredient of a number of pharmacopoeal and non pharmacopoeal preparation used to treat gastric disorders including gastritis and ulcer. In some of the studies it has been shown to produce anti ulcer effect in experimental models where the ulcers were induced with alcohol and stress etc. However, it was not studied against NSAIDs which are among the most commonly used therapeutic agents but are liable to induce gastric ulcer. Therefore the present study was designed to study the anti ulcer effect of seeds of *Coriandrum sativum* in aspirin-induced gastric ulcer in albino rats.

## Materials and Methods

### Plant Material

Seeds of coriander were purchased from the local market of Bangalore, Karnataka. An authorized committee of National Institute of Unani Medicine (NIUM), Bangalore, comprising of pharmacognosists, Unani experts and medicinal chemists confirmed the identity and the quality of the drug sample.

The drug was dried in shade and powdered coarsely in an electric grinder. The powder was then extracted in hydroalcoholic solution (50%+50%) in the ratio of 1:5, (100 gm of powdered drug was taken into 500 ml of hydroalcoholic

solution) with the help of a Soxhlet apparatus for 8 hrs. The liquid extract was then filtered and concentrated on water bath. The concentrated extract was weighed and the yield percentage was calculated with reference to the weight of crude drug. The yield was found to be 19.48% w/w.

### Dosage of the test drug

The human therapeutic dose of coriander described in Unani literature, is 5-7 gm (Anonymous, 2007; Ghani, ynm). Its dose for albino rats was calculated by multiplying the higher dose of 7 gm by the conversion factor of 7 (Freirich *et al.,* 1966) and found to be 820 mg/kg body weight for rats. To study the dose dependent effect of the test drug, a second dose calculated by the method of Miller and Tainter (1944) and found to be 1400 mg/kg, was also used. The dose of extract corresponding to the dose of crude drug i.e. 160 mg/kg and 273 mg/kg respectively was used. The standard drug ranitidine (50 mg/kg) was purchased from Ranbaxy Laboratories Limited, Hyderabad (India) while the aspirin (200 mg/kg), used as ulcerogenic agent was of analytical grade, in the form of crystalline acetyl salicylic acid, supplied by Sigma Aldrich, Germany.

Drugs were administered by oral route with the help of a gastric cannula. The dosage forms were prepared freshly every day before the administration by suspending the drug in 1ml of 0.4% carboxymethyl cellulose (CMC).

### Experimental animals

The study was carried out on Wistar rats of either sex, weighing 150-200 gm. They were procured from central animal house facility, National Institute of Mental Health and Neurosciences (NIMHANS), Bangalore. The rats were housed in polypropylene cages, under controlled conditions of light (12/24 hour) and temperature ($23\pm2\ ^{0}C$) and provided standard commercial food pellets (Hindustan Lever Ltd.) and tap water *ad libitum*, under strict hygienic conditions.

The experimental protocol was approved by the Institutional Animal Ethics Committee (IAEC), National Institute of Unani Medicine, Bangalore, Karnataka, India vide Reg. No. 953/C/06/CPCSEA, dated 28th August 08.

### Aspirin-induced gastric ulcer

This test was carried out by the method of Goel *et al.* (1985), using albino rats divided into 8 groups of 8 animals each. The animals in Group I were treated with 1 ml of 0.4% CMC while those in Group II were administered 200 mg/kg

of aspirin (suspended in 1 ml of 1% CMC), and served as Plain control and Negative control, respectively. The animals in Group III and IV were treated with hydroalcoholic extract of the test drug in the dose of 160 mg/kg and 273 mg/kg (suspended in 1 ml of 0.4% CMC) daily for 5 days and served as Pre-treated test group A and B, respectively. Group V was treated with ranitidine 50 mg/kg daily for 5 days (suspended in 1 ml of 0.4% CMC) and served as Pre-treated standard group. From 6$^{th}$ day onwards aspirin (200 mg/kg) was given to all the animals except those in Plain and Negative control groups, orally for the next 5 days. After the administration of aspirin, food was withdrawn for a period of 2 hours (animals had free access to food and water thereafter). On 11$^{th}$ day after 5 days administration of aspirin, 12 hour fasted rats were sacrificed under thiopentone anaesthesia (40 mg/kg IP). While the animals in Negative control group were sacrificed on 6$^{th}$ day after 5 days of aspirin treatment and Plain control animals were sacrificed on 11$^{th}$ day.

The animals in Group VI, VII and VIII, were treated with aspirin (200 mg/kg) once daily for first five days and the food was withdrawn for two hours after each administration. From 6$^{th}$ day hydroalcoholic extract of test drug was given orally to Group VI and VII in the dose of 160 mg/kg and 273 mg/kg by oral route once daily for next five days. These two groups served as Post-treated test group A and B, respectively, whereas Group VIII received standard drug ranitidine 50 mg/kg orally, once daily for 5 days and served as Post-treated standard group. On 10$^{th}$ day after the administration of test and standard drugs the animals were kept on fasting with water *ad libitum*. Coprophagy was prevented during fasting by putting the animals in cages with grating on the floor. On 11$^{th}$ day after 24 hours of fasting, the animals were sacrificed.

In Aspirin-induced ulceration, gastric mucosa was examined for ulceration by the following method:

Abdomen of the anaesthetized animals was opened by the midline incision; stomach was dissected out carefully and opened along the greater curvature. The mucosa of stomach was washed with tap water and spread over a cardboard with the mucus surface upwards. The mucosal surface was examined for ulceration with the help of magnifying lens (10 fold magnification). The stomach of 2 rats from each group was preserved immediately in 10% formalin and sent for histopathological examination.

### Determination of the degree of ulceration

The degree of ulceration was determined by the method of Adami *et al.,* (1964).

0.0 – Absence of any detectable lesion

0.5 – Small haemorrhagic effusion

1.0 – Haemorrhagic effusion

1.5 – Mucosal ulceration of limited diffusion involving not more than 1/3rd of whole surface of stomach

2.0 – Mucosal ulceration of limited diffusion involving not more than 2/3rd of whole surface of stomach

2.5 – Mucosal ulceration of generalized diffusion

3.0 – Deep ulceration of limited diffusion

3.5 – Deep ulcerations of generalized diffusion

4.0 – Perforated ulcer

The average degree of single ulceration (ADU) for each group was determined by adding together the degree of single ulceration (DSU) and dividing it by the number of animals. On the basis of the percentage of rats with ulceration (% RU), the ulcer index was calculated by the following formula (Srimal, 1984)

$$\text{Ulcer Index} = \frac{(\text{ADU})\ (\%\ \text{RU})}{100}$$

ADU – Average degree of single ulceration

% RU – Percentage of rats with ulceration

The observations in various groups were expressed as median with range. The ulcer scores of various groups were compared with Negative control group. The group comparison was analyzed using Kruskal-Wallis post hoc Dunn's multiple pair comparison test. The difference of median was considered significant at $p<0.05$.

## Results

Median 'ulcer score' in Negative control group was found to be 2.5(1.5, 3.0). While the median score in Pre-treated test group A was found to be 1.5 (1, 2) showing non-significant result. Similarly, in Pre-treated test group B, the ulcer score was found non-significant with median score of 1.25 (1, 2). But in Pre-treated standard group where (ranitidine treated) the median score was 1 (0.5, 1.5), a significant ($p<0.01$) reduction was observed. The Post-treated group A showed non-significant result as the median score was found to be

1.25 (1, 2), whereas the median score of Group B and that of the standard group was found to be highly significant ($p<0.001$) with median score of 0.75 (0.5, 1.5) and 0.5 (0.5, 1.0), respectively.

The 'ulcer index' was found to be 2.25 in Negative Control group and 1.5 and 1.4 in Pre-treated test group A & B, respectively. In Pre-treated standard group, the ulcer index was found to be 0.94 whereas in Post-treated test group A it was found to be 1.31. In Post-treated test group B and standard group more reduction in ulcer index was found i.e. 0.81 and 0.68, respectively (Table 1 & 2; Fig. 1 & 2).

## Histopathological findings

Ulceration and necrosis was seen in the gastric mucosa of the animals of Negative control. The submucosa showed severe oedema. Few engorged blood vessels and areas of necrosis were also seen (Slide 1, Table 3).

In Pre-treated test group A, section from the biopsy revealed atrophy of the mucosa (Slide 2, Table 3). Gastric mucosa of Pre-treated test group B, showed eosinophilic gastritis with increased number of paneth cells (Slide 3, Table 3). Section from the biopsy of Post-treated test group A revealed features of gastritis with increased number of paneth cells and eosinophils (Slide 4, Table 3), while Post-treated group B showed features of gastritis only (Slide 5, Table 3).

Table 1 : Effect of the extract of *Coriandrum sativum* Linn seeds on median ulcer score in Aspirin induced-gastric ulcer

| Groups | Treatment | Median ulcer score |
|---|---|---|
| Group I<br>Plain control | 1 ml of 0.4%<br>Carboxymethyl cellulose | 0 (0, 0) |
| Group II<br>Negative control | Aspirin (200 mg/kg) | 2.5 (1.5, 3.0) |
| Group III<br>Pre-treated test group | Coriander (160 mg/kg)<br>+<br>Aspirin (200 mg/kg) | 1.5 (1.0, 2.0) |
| Group IV<br>Pre-treated test group B | Coriander (273 mg/kg)<br>+<br>Aspirin (200 mg/kg) | 1.25 (1.0, 2.0) |

| Groups | Treatment | Median ulcer score |
|---|---|---|
| Group V<br>Pre-treated standard group | Ranitidine (50 mg/kg)<br>+<br>Aspirin (200 mg/kg) | 1 (0.5, 1.5) |
| Group VI<br>Post-treated test group A | Aspirin (200 mg/kg)<br>+<br>Coriander (160 mg/kg) | 1.25 (1.0, 2.0) |
| Group VII<br>Post-treated test group B | Aspirin (200 mg/kg)<br>+<br>Coriander (273 mg/kg) | 0.75 (0.5, 1.5) |
| Group VIII<br>Post-treated standard group | Aspirin (200 mg/kg)<br>+<br>Ranitidine (50 mg/kg) | 0.5 (0.5, 1.0) |

**p<0.01, ***p<0.001 with respect to Negative control, N = 8 in each group.

Table 2 : Effect of the extract of *Coriandrum sativum* Linn seeds on ulcer index in Aspirin-induced gastric ulcer

| Groups | Ulcer incidence<br>No. % | Ulcer index |
|---|---|---|
| Group I<br>Plain control | 0/8 0% | 0 |
| Group II<br>Negative control | 8/8 100% | 2.25 |
| Group III<br>Pre-treated test group A | 8/8 100% | 1.5 |
| Group IV<br>Pre-treated test group B | 8/8 100% | 1.4 |
| Group V<br>Pre-treated standard group | 8/8 100% | 0.94 |
| Group VI<br>Post-treated test group A | 8/8 100% | 1.31 |
| Group VII<br>Post-treated test group B | 8/8 100% | 0.81 |
| Group VIII<br>Post-treated standard group | 8/8 100% | 0.68 |

N = 8 in each group.

Table 3 : Histopathological Summary of Aspirin induced-gastric ulcer Model

| Groups | Congestion | Haemorrhage | Oedema | Necrosis | Inflamm. Changes | Erosion | Ulceration |
|---|---|---|---|---|---|---|---|
| Group I | - | - | - | - | - | - | - |
| Group II | +++ | ++ | + | + | ++ | + | ++ |
| Group III | +++ | ++ | + | - | +++ | + | + |
| Group IV | ++ | + | + | - | ++ | + | - |
| Group V | + | + | - | - | + | - | - |
| Group VI | ++ | ++ | ++ | - | + | + | - |
| Group VII | + | + | - | - | + | - | - |
| GroupVIII | + | - | - | - | - | - | - |

Normal: (-), Moderate: (+), Severe: (++), Intensely severe: (+++)

Effect of hydroalcoholic extract of *Coriandrum sativum* Linn. on "Aspirin induced-gastric ulcer"

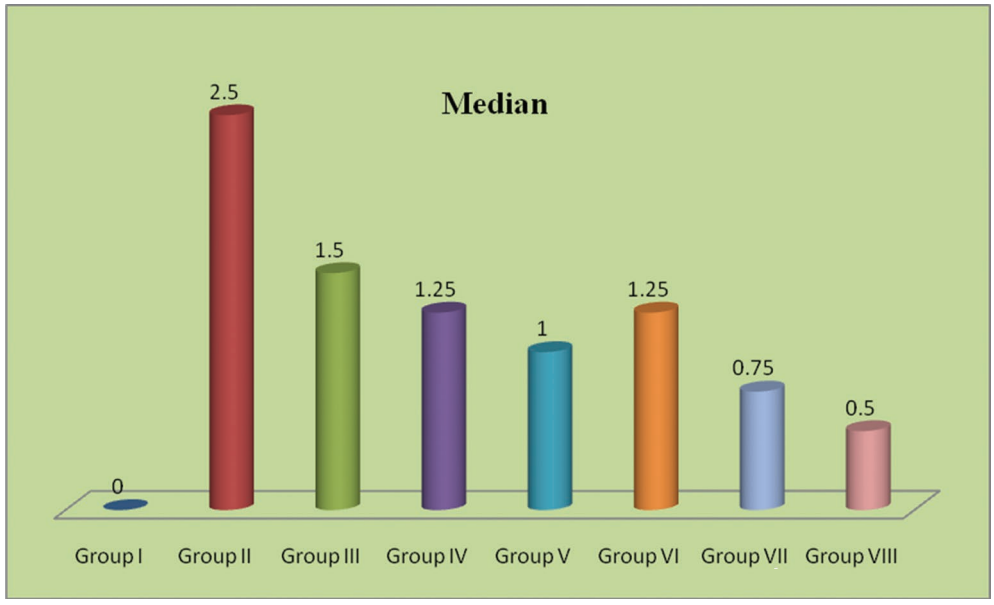



Fig. 1 : Showing ulcer score

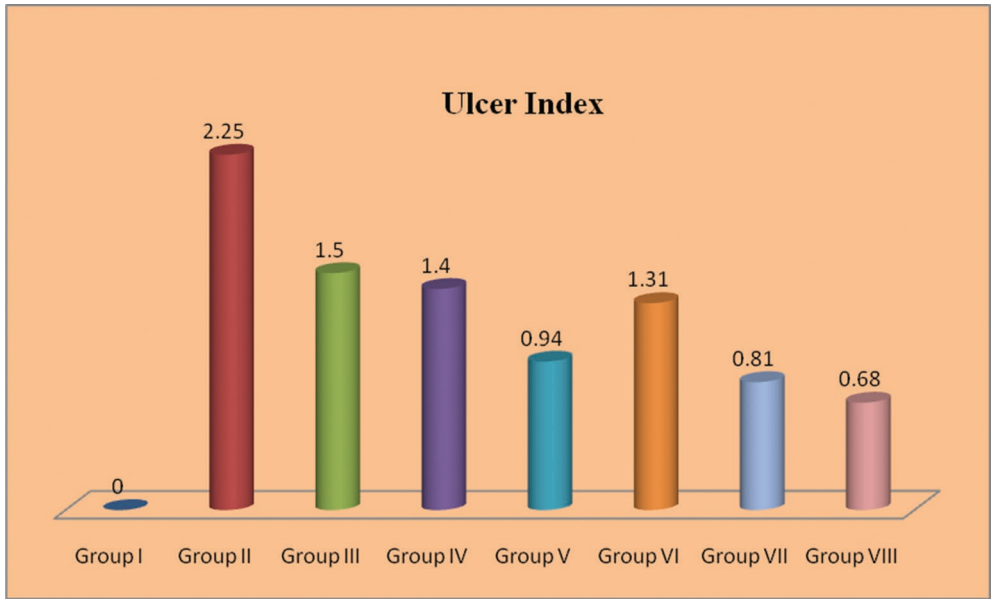
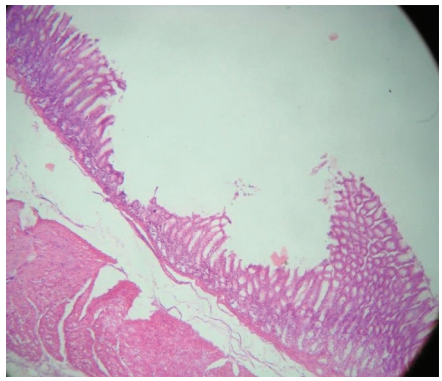
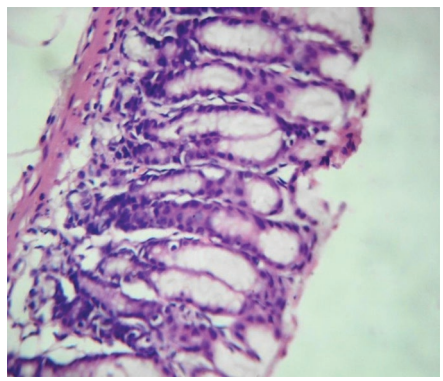


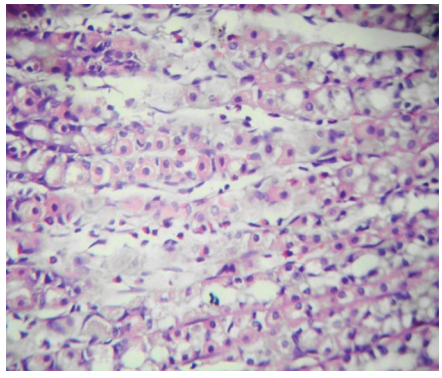

Fig. 2: Showing ulcer index



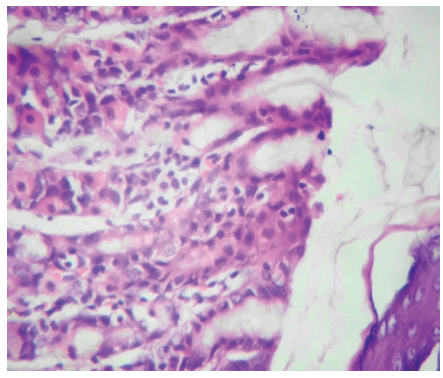
Slide No. 1 : Negative Control



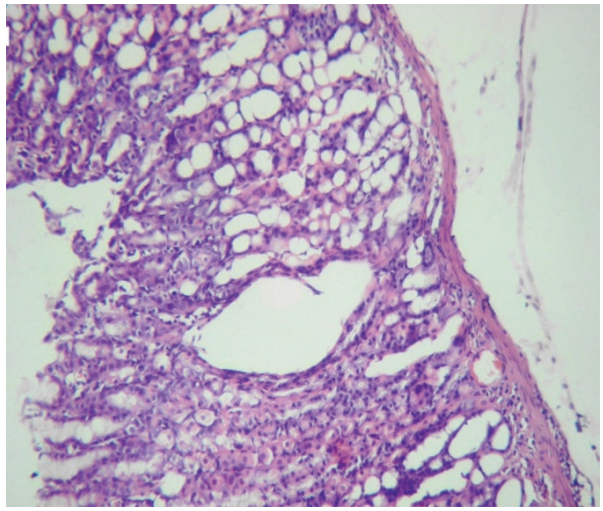
Slide No. 2 : Pre-treated group A



Slide No. 3 : Pre-treted group B



Slide No. 4 : Post treated group A



Slide No. 5 : Post treated group B

## Discussion

The findings of the study demonstrated that the pre-treatment of test drug at low and high doses did not produce significant results. Similarly, the effect of low dose in post treated group was also found non-significant. However, the high dose in post-treated group produced significant reduction in ulcer score and ulcer index suggesting that the test drug at high dose possesses significant anti ulcer activity ($p<0.001$).

The results of the study clearly indicated that the test drug at low dose does not have the healing effective in experimentally induced gastric ulcer as it failed to reduce both the ulcer score and ulcer index. But it was found effective at higher dose and the efficacy was observed only in curative group. It signifies that the test drug has healing effect at higher dose level and only as a curative agent. It means the drug cannot be used as a prophylactic measure but can be used in treating the ulcers when they are formed. The result is in conformity with the other reports suggesting that Unani drugs frequently fail to induce the desirable response at the lower doses that have been recommended in Unani literature. However when the dose is increased the desirable response is achieved (Amin, 1998). It suggests that the dose of test drug should be increased to treat the PUD.

Non-steroidal anti-inflammatory drugs (NSAIDs) like aspirin are known to induce gastric ulceration, the reason being attributed principally to the inhibition of biosynthesis of cytoprotective prostaglandins, resulting in overproduction of leukotrienes and other products of 5-lipoxygenase pathway (Ranisford, 1987). It has been proposed that aspirin induces gastric ulcers by disrupting

the gastric mucosal barrier resulting in the back-diffusion of acid (Davenport, 1967). It is a potent irreversible prostaglandin biosynthesis inhibitor and causes a dose dependent reduction in mucosal prostaglandins ($PGE_2$ and $PGI_2$) biosynthesis accompanied by an increase in the areas of gastric mucosal damage. Further, the injury following the aspirin administration has been associated with the formation of reactive oxygen species that has been reported to accumulate in gastric mucosa and cause oxidative DNA damage (Kang *et al.,* 2007). Gastric mucosal damage caused by aspirin-like drugs has been reported to evolve certain other mechanisms such as the topical irritant effect on epithelium, impairment of mucosal barrier function, reduction of gastric mucosal blood flow and interference with the repair of the superficial injury. It appears therefore that the test drug probably evolved more than one mechanism to produce anti ulcer effect against aspirin induced mucosal damage. However, since it was found to be effective as curative agent and did not show any response as a protective agent, therefore it is likely that the anti ulcer effect was mediated through the curative mechanisms. Since the constituents found in coriander have been demonstrated to possess anti-oxidant property (Ammar *et al.,* 1997) therefore its effectiveness may at least partially be associated with its anti-oxidant activity. Secondly, in Unani literature it has been described to possess healing effect (Hakeem, 2002) therefore the improvement in ulcer is also likely to be associated with healing property of the test drug. Cytoprotection is mainly induced by the release of prostaglandins. Coriander has a number of fatty acids and flavonoids, which are the sources of prostaglandins thus the cytoprotective role of the test drug is also likely. Other studies on coriander demonstrating cytoprotective and anti-oxidant effect in it (Satyanarayana *et al.,* 2003) further strengthen our proposition regarding the cytoprotective effect of the test drug. The overall effect of the test drug is in consonance with another report that demonstrated that the oral administration of the coriander powder produced dose dependant effect against the ulcers induced by the ethanol and pylorus ligation ( Al-Mofleh *et al.,* 2006).

In Unani literature the causes of gastric ulcer have been described to be *khilte haad* (hot and irritant humour), *fuzlat* (waste products), intake of hot and spicy foods, excessive use of alcohol, stress and strain, chronic gastritis and indigestion (Arzani, 2003; Ibn Hubal, 2004;Ibn Sina, 2007). The temperament of coriander is cold and dry in second degree (Ghani, ynm) so it is quite possible that it helps neutralize the *khilte haad* which has opposite temperament and the cold temperament may have arrested the secretion of corrosive *fuzlat*. Coriander has also been mentioned to possess *qabiz* (astringent), *musakkin* (sedative), *munawwim* (hypnotic), *muhallil* (resolvent)

and *munaqqi* (cathartic) properties (Ibn Sina, 2007; Ibn Baitar, 2003; Ibn Hubal, 2004). These effects may have a role in improving the gastric lesions either through the mediation of nervous system or by producing local effect of neutralization, healing and cytoprotection. Unani scholars have also mentioned it to be useful in various gastric disorders like *sue mizaj meda* (altered temperament of stomach), *wajae meda* (gastralgia), *zofe hazam* (oligopepsia), *sue hazam* (indigestion), *tukhma* (food poisoning) and *qurooh wa busoor meda* (gastric ulcers); all these conditions are associated with making the mucosal defense system weak (Arzani, 2003; Ibn Sina, 2007). Therefore, it may be assumed that coriander plays important role in improving the mucosal defense system. Some important constituents found in coriander have been reported to produce pharmacological effects that are responsible to improve the gastric lesions. The findings of the present study and the reports available on coriander and its various constituents suggest that it produces effect by evolving diverse mechanisms such as by reducing the stress, inducing cytoprotection, minimizing or neutralizing the acid secretion and by healing and anti-oxidant activity.

On the basis of above findings and discussion it can be concluded that coriander possesses significant anti-ulcer activity against aspirin induced gastric ulcers.

## References


Adami E, Marzzi-uberti E, Turba C., 1964. Pharmacological research on gefarnate, a new synthetic isopenoid with an anti-ulcer action. *Archives International Pharmacodynamic et de Therapic* 147: 113-145.

Al-Mofleh IA, Al-Haider AA, Mossa JS, Al Sohaibani MO, Rafatullah S, Qureshi S., 2006. Protection of gastric mucosal damage by *Coriandrum sativum* L. pretreatment in Wistar albino rats. *Environmental Toxicology and Pharmacology* 22(1): 64-69.

Amin, K.M.Y., 1998. Distinctive methodology for research in Tibb-e-Unani: Experiences and reflexions. Proceeding of the National Seminar on Research Methodology in Unani Medicine, 3-4 April, Jamia Hamdard, New Delhi, pp1-15.

Ammar N.M., AL Okbi S.Y., Mohamed D.A., 1997. Study of the anti-inflammatory activity of some medicinal edible plants growing in Egypt. *Journal of Islamic Academy of Sciences* 10(4): 113-122.

Andreoli, T.E., Bennett, J.C., Carpenter, C.C.J., Plum, F., Jr. Smith, L.H., 2001. Cecil Essentials of Medicine. 5th ed. Edinburgh: W. B. Saunders Company, pp. 334-343.

Andreoli, T.E., Bennett, J.C., Carpenter, C.C.J., Plum F, Jr. Smith L.H., 1993. Cecil Essentials of Medicine. 3rd ed. USA: W. B. Saunders Company, pp. 289-299.

Anonymous, 2007. The Unani Pharmacopoeia of India. Part-1 vol. Ist. New Delhi, Dept. of AYUSH, pp. 56-57.

Arzani, A. YNM. Tibbe Akbar. Faisal Publication, Deoband, p. 409.

Chaudhry, N.M.A., Tariq, P., 2006. Bactericidal activity of black pepper, bay leaf, aniseed and coriander against oral isolates. *Pak. J. Pharm. Sci.* 214-218.

Davenport, H.W., 1967. Salicylate damage to the gastric mucosal barrier. *New Eng. J. Med.* 276: 1307-1312.

Dharmanl, P., Pallt, G., 2006. Exploring Indian medicinal plants for anti ulcer activity. *Indian Journal of Pharmacology* 38(2): 95-99.

Freirich, E.J., Gehan, E.A., Rall, D.P., Schmidt, L.H., Skipper, H.E., 1966. Quantitative comparison of toxicity of anti ulcer agent in mice, rat, hamster, dog, monkey and man. *Cancer chemotherapy Report* 50(4):219-144.

Ghani, N., YNM. Khazainul Advia. Idarae Kitabul Shifa, New Delhi, pp. 704-707.

Goel, R.K., Chakrabarti, A., Sanyal, A.K., 1985. The effect of biological variables on the antiulcerogenic effect of vegetable Plantain, Banana. *Planta Medica* 51: 85-88.

Goel, R.K., Sairam K., 2002. Antiulcer drugs from indigenous sources with emphasis on *Musa sapientum*, Tamrabhasma, *Asparagus racemosus* and *Zingiber officinale*. *Indian Journal of Pharmacology* 34: 100-110.

Hakeem M., 2002. Bustanul Mufridat. Idarae Kitabul Shifa, New Delhi, pp. 282-283.

Horn, J.H., 2000. The proton-pump inhibitors: similarities and differences. *Clinical therapy* 22: 266-280.

Ibn Baitar, 2003. Al Jami Li Mufradat Al Adviya wal Aghziya, (Urdu translation), Vol IV. Ministry of Health & F.W., Govt. of India, New Delhi, pp. 165-172.

Ibn Hubal, 2004. Kitabul Mukhtarat Fil Tibb, (Urdu translation). Vol. I, II, III. Ministry of Health & F.W., Govt. of India, New Delhi, pp. 129, 187, 235.

Ibn Sina. Al Qanoon. (Urdu translation by Kintoori GH). Vol. 2nd, 3rd. New Delhi. Idara Kitabu us Shifa; 2007, pp. 133-134, 446-448.

Kang, Y.J. *et al.,* 2007. Induction of heme oxygenase-1 by traditional herb mix extract improves

MKN-74 cell survival and reduces stomach bleeding in rats by ethanol and aspirin *in vivo. Korean. J. Physiol. Pharmacol.* 11: 65-70.

Miller, L.C., Tainter, M.L., 1944. Estimation of $ED_{50}$ and its error by mean of log-probit graph paper. *Proc. Soc. Expt. Biol. Med*. 55: 261.

Ranisford, K.D., 1987. The effect of 5-lipoxygenase inhibitors and the leukotriene antagonists on the development of gastric lesions induced by non-steroidal anti-inflammatory drugs in mice. *Agents and Actions* 21: 316-319.

Saeed, S., Tariq, P., 2007. Antibacterial activities of *Emblica officinalis* and *Coriandrum sativum* against gram negative urinary pathogens. *Pak. J. Pharm. Sci.* 20(1): 32-35.

Satyanarayana, S., Sushruta, K., Sarma, G.S., Srinivas, N., Subba Raju, G.V., 2003. Antioxidant activity of the extracts of spicy food additives-evaluation and comparison with ascorbic acid in *in-vitro* systems. *Journal of Herbal Pharmacotherapy* 1-10.

Singh, S., Majumdar, D.K., 1999. Evaluation of the gastric anti-ulcer activity of fixed oil of *Ocimum sanctum* (Holy Basil). *Journal of Ethnopharmacology* 65: 13-19.

Srimal, R.C., 1984. Evaluation for anti-inflammatory activity. In: Dhawan, B.N. and Srimal, R.C. (Eds.), The use of pharmacological techniques for the evaluation of natural products, p. 380.

# Management of Chronic Rhinosinusitis with Habb-e-Shifa and Steam Inhalation

**[1]*Md. Wasi Akhtar and**
**[2]M.M.H. Siddiqui**

[1]Department of Moalejat
[2]Department of Ilaj-bit-Tadbeer,
A.K. Tibbiya College,
Aligarh Muslim University,
Aligarh-202002

## Abstract

Present study was designed to determine the efficacy of *Habb-e-Shifa* and a combined therapy of *Habb-e-Shifa* and steam inhalation in two groups of 30 patients each of Chronic Rhinosinusitis. Patients in Group I were treated with *Habb-e-Shifa* (2 tablets) orally twice daily for 14 days, whereas those in Group II were treated with steam inhalation along with *Habb-e-Shifa* (2 tablets) twice daily for 14 days. The main five symptoms of Chronic Rhinosinusitis.viz. rhinorrhoea, nasal congestion, frontal headache, nasal itching and frequent sneezing were assessed using VAS sheet. Baseline scores of symptoms were compared with final scores and analyzed statistically using Student's't' test.

In both the groups the symptoms were found to be improved significantly, however the degree of effect in respect of Group II was higher as compared to Group I. The study thus demonstrated that *Habb-e-Shifa* is an effective drug to manage the cases of Chronic Rhinosinusitis but the maximum therapeutic effect is achieved when it is combined with steam inhalation.

**Keywords:** Chronic Rhinosinusitis, *Habb-e-Shifa*, Unani Medicine, Steam inhalation, Anti-inflammatory

## Introduction

Nasal mucosa remains in continuous exposure to the environment, facing air of different temperatures, dust, pathogens, allergens and many foreign particles. This exposure makes it vulnerable to be diseased, causing different inflammatory conditions affecting nasal as well as sinus mucosa. Upper respiratory tract infections, rhinitis, sinusitis and rhinosinusitis are among the most frequent reasons to see a medical practitioner. Chronic Rhinosinusitis is an inflammatory disease of the mucosa of the nasal cavity and paranasal sinuses with symptoms lasting longer than 12 weeks or occurring at least 6 episodes per year (Benninger *et al.,* 2003).

The main clinical features of Chronic Rhinosinusitis are recurrent rhinorrhoea, nasal congestion, frontal headache, nasal itching and frequent sneezing. The diagnosis is typically clinical by identifying signs and symptoms that can be seen by anterior rhinoscopy. During acute exacerbation, on rhinoscopy or on simple nasal examination the inflamed nasal mucosa and nasal discharge, is seen in almost all patients.

[1]* Author for correspondence

Chronic Rhinosinusitis, rhinitis and sinusitis are being managed with modern as well as Unani medicines with varying degree of success. The basic principles of management of rhinosinusitis and related conditions are to reduce the inflammation, facilitate the drainage both during and after treatment, to prevent recurrence and treat any infection, if present. Pharmacological measures include the use of anti-inflammatory analgesic, antipyretic, antihistaminic, decongestant, anticholinergic drugs and also the corticosteroids (systemic/topical) and sometimes antibiotics, while adjunctive (non-pharmacologic) measures include steam inhalations, saline irrigation, and use of hot/dry air to promote drainage through the sinus ostia and ciliary function. (Druce, 1990; Meltzer, 1995).

In Unani system of Medicine drugs having *muhallil-e-auram, musakkin, mujaffif-e-ratubat, habis wa qabiz and dafe ratubaat-e-fasida* etc. effects are commonly used for the management of Chronic Rhinosinusitis and other similar clinical conditions.

*Habb-e-Shifa* (Table 1) is one such pharmacopoeal preparation that possesses befitting medicinal values as required to treat the inflammatory condition of nasal and sinus mucosa. It is useful in most of the rhinorrhoea e.g. *Nazla* (Common cold)*, Nazla Shadeed* (Severe Rhinitis) and in *Nazla Balghami* (Khan, 1987; Khan, 2011). It also has analgesic effect and used in headache (Kabeeruddin, 1977). Unani Physicians are also using *Habb-e-Shifa* in different inflammatory conditions of nose and para-nasal sinuses, successfully. In some of the studies conducted in recent years it has been demonstrated to possess significant analgesic, anti inflammatory and other related effects (Tajuddin *et al.,* 2007; Haq, et al. 2009). Therefore the present study was planned to evaluate the efficacy of *Habb-e-Shifa* in patients of Chronic Rhinosinusitis. However, since inhalation is one of the most advised and commonly practiced adjunctive measures to manage upper respiratory disorders therefore the effect of *Habb-e-Shifa* was also studied in a separate group of patients who were treated with steam inhalation along with oral administration of *Habb-e-Shifa* so as to determine the differential effect of the two.

Table 1 : Ingredients of *Habb-e-Shifa*

| S. No. | Unani name | Scientific name | Parts used | Weight (gm) |
|---|---|---|---|---|
| 1. | *Jauz-e-Masil* | *Datura stramonium* Linn. | Seed | 300 |
| 2. | *Revand Chini* | *Rheum emodi* Wall. ex Meissn. | Root | 200 |
| 3. | *Zanjabeel* | *Zingiber officinale* Rosc. | Rhizome | 100 |
| 4. | *Samagh-e-Arabi* | *Acacia arabica* Willd. | Gum | 100 |

## Material and Method

This study was conducted at Department of Ilaj-bit-Tadbeer and Department of Moalejat, Ajmal Khan Tibbiya College, AMU, Aligarh on 60 patients, divided into two groups, of 30 patients each. The patients were taken up from the outpatient department of A.K. Tibbiya College Hospital and randomly allocated to both the groups. Patients in Group I were treated with *Habb-e-Shifa* (2 tablets) orally twice a day for 14 days, whereas those in Group II received *Habb-e-Shifa* (2 tablets) and Steam inhalation twice daily for the same period.

Patients were taught to mark the severity of the main five symptoms of Chronic Rhinosinusitis on VAS sheet, where 0 stands for no symptom and 3 for maximum severity. VAS sheet marking was done at the commencement of the treatment, at $7^{th}$ day and at the end of the treatment i.e. at $14^{th}$ day and the scores for all the five symptoms were noted. For each group baseline scores and final scores were analyzed statistically by applying Student's paired't' test to assess the efficacy of *Habb-e-Shifa* alone and in adjunct of steam inhalation on the signs & symptoms and on the overall clinical condition of Chronic Rhinosinusitis.

*Inclusion Criteria*

- Age between 15 years to 60 years of both sexes.
- Having typical symptoms of Chronic Rhinosinusitis viz. rhinorrhoea, nasal congestion, frontal headache, nasal itching and frequent sneezing for more than 12 weeks.

*Exclusion Criteria*

- Patients who received medication for Chronic Rhinosinusitis in last 2-3 weeks
- Use of systemic corticosteroid within 2 months or nasal corticosteroid within 2 weeks
- Gross Nasal Structure deformity, Large nasal polyp or Hypertrophic rhinitis
- Other active respiratory disorder
- Active medical disorders like Systemic infection, Haematological, Renal, Hepatic, Cardiovascular, Gastric and Metabolic disorders etc.
- Pregnant and Lactating women

## Observations and Results

Effect of the test drugs was observed in each patient on the five major signs and symptoms of Chronic Rhinosinusitis and the findings have been presented in tabular form as follows:

Table 2 : Rhinorrhoea

| Group 1 | | Group 2 | |
|---|---|---|---|
| Baseline Score | Final Score | Baseline Score | Final Score |
| 2.27 ± 0.69 | 1.10 ± 0.66 | 2.03 ± 0.61 | 0.80 ± 0.55 |
| t = 16.86 | p<0.001 | t = 15.70 | p<0.001 |

Table 3 : Nasal congestion

| Group 1 | | Group 2 | |
|---|---|---|---|
| Baseline Score | Final Score | Baseline Score | Final Score |
| 2.37 ± 0.49 | 1.17 ± 0.46 | 2.43 ± 0.50 | 0.87 ± 0.35 |
| t = 16.15 | p<0.001 | t = 17.03 | p<0.001 |

Table 4 : Frontal headache

| Group 1 | | Group 2 | |
|---|---|---|---|
| Baseline Score | Final Score | Baseline Score | Final Score |
| 2.27 ± 0.52 | 1.10 ± 0.55 | 2.33 ± 0.55 | 1.00 ± 0.37 |
| t = 13.86 | p<0.001 | t = 13.56 | p<0.001 |

Table 5 : Nasal itching

| Group 1 | | Group 2 | |
|---|---|---|---|
| Baseline Score | Final Score | Baseline Score | Final Score |
| 1.20 ± 0.76 | 0.90 ± 0.66 | 1.23 ± 0.63 | 0.70 ± 0.54 |
| t = 3.53 | p>0.001 | t = 5.76 | p<0.001 |

Table 6 : Frequent sneezing

| Group 1 | | Group 2 | |
|---|---|---|---|
| Baseline Score | Final Score | Baseline Score | Final Score |
| 1.17 ± 0.98 | 0.70 ± 0.65 | 1.53 ± 0.68 | 0.57 ± 0.50 |
| t = 4.47 | p<0.001 | t = 9.52 | p<0.001 |

Table 7 : Statistical analysis for Cumulative score

| Group 1 | | Group 2 | |
|---|---|---|---|
| Baseline Score | Final Score | Baseline Score | Final Score |
| 9.37 ± 1.79 | 4.97 ± 1.40 | 9.57 ± 1.59 | 3.93 ± 1.11 |
| t = 19.75 | p<0.001 | t = 28.94 | p<0.001 |

## Discussion

The study demonstrated that both *Habb-e-Shifa* alone and in combination with steam inhalation produced significant effect in the patients of Chronic Rhinosinusitis as all five major symptoms i.e. rhinorrhoea, nasal congestion, frontal headache, nasal itching and frequent sneezing and the overall clinical condition was found improved significantly (Table 2-7). However, the effect produced by the combined therapy (*Habb-e-Shifa* + steam inhalation) was comparatively better than *Habb-e-Shifa* alone, as is evident from the difference of't' values.

As per description contained in Unani literature, the temperament of *Jauz-e-masil* (*Datura stramonium* Linn.) is *barid yabis* (cold & dry) in 4° and is described to have *Musakkin, Mujaffif–e-ratubat Ghareeba and Habis wa Qabiz* effects (Ghani, ynm; Khan, 2013); these effects possibly reduced rhinorrhoea and headache, while *Dafe ratubaat* effect of *Zanjabeel* (*Zingiber officinale* Rosc.) and *Mujaffif-e-ratubat* effect of *Revand chini* (*Rheum emodi* Wall. ex Meissn.) may have complemented the effect of *Jauz-e-masil* in reducing the rhinorrhoea (Ghani, ynm; Khan, 2013; Hakeem, 2002). Some of the recent scientific data suggested that *Jauz-e-masil* (*Datura stramonium* Linn.) has anti-cholinergic, anti-muscarinic, analgesic, anodyne and anti-inflammatory effects (Das *et al.,* 2012; Devi *et al.,* 2011; Soni *et al.,* 2012; Chopra *et al.,* 1956), therefore, it is likely that these attributes of Jauz-*e-masil* may have played a role in reducing the inflammation and oedema of nasal/sinus mucosa and secretion from it**.** Medicinal properties of *Jauz-e-masil* have been attributed mainly to the presence of atropine and scopolamine. *Zanjabeel* (*Zingiber officinale* Rosc.) has [6]-gingerol, an active chemical constituent (Young *et al.*, 2005) that has anti-inflammatory, analgesic and oedema reducing effects (Ojewole, 2006; Raji *et al.*, 2002; Penna *et al.*, 2003), therefore, on account of having these medicinal effects *Zanjabeel* is also likely to reduce the rhinorrhoea, nasal congestion and headache. However, since all the drugs of *Habb-e-Shifa* were given in combination (pills form) therefore it is more likely that the total response of *Habb-e-Shifa* has induced the desirable effect.

Steam by virtue of having local anti-inflammatory/analgesic and soothing effects and also acting as muco-diluent and muco-evacuant effect (Ophir, 1987; Tyrrell, 1989; Georgitis, 1994; Evans, 1998; Lance *et al.*, 2000), is supposed to have increased the nasal patency and reduced the secretion to alleviate the symptoms. Thus the collective response produced by *Habb-e-Shifa* and steam inhalation was more significant as compared to the effect of *Habb-e-Shifa* alone.

Nasal discharge initiates sneezing through nasal itching that arise due to macerated and hypersensitive/inflamed nasal mucosa. The possible anti-cholinergic/anti-muscarinic and anti-inflammatory effects of complete regimen (*Habb-e-Shifa* and Steam Inhalation) might have relieved rhinorrhoea, nasal congestion and frontal headache on one hand and subsided nasal itching and frequent sneezing on the other. The preclinical and clinical studies conducted by Tajuddin *et al.* (2007) and Haq *et al.* (2009), respectively on *Habb-e-Shifa* also support the result of our study.

During the study it was noted that 8 out of total 60 patients reported dryness of mouth and 2 patients complained of mild blurring of vision, but these unwanted effects did not create any major hindrance in routine practices of the patients, as no dropout was recorded. These unwanted effects of *Habb-e-Shifa* may be due to anti-cholinergic and anti-muscarinic effect of *Jauz-e-masil* which is the chief ingredient of *Habb-e-Shifa.* But the findings pointing towards the side effect warrant that toxicity study of this drug should be conducted on relatively larger number of subjects to prepare a safety/ toxicity profile.

In the light of the findings it can be conclude that *Habb-e-Shifa* is an effective Unani formulation, useful in the management Chronic Rhinosinusitis, however it produces optimal effect when the patient is treated simultaneously with steam inhalation.

## References


Benninger, M.S., Ferguson, B.J., Hadley, J.A., Hamilos, D.L., Jacobs, M., Kennedy, D.W. et al., 2003. Adult chronic rhinosinusitis: definitions, diagnosis, epidemiology, and pathophysiology. *Otolaryngol Head Neck Surg.* 129:S1–S32.

Chopra, R.N., Nayar, S.L. and Chopra, I.C., 1956. Glossary of Indian Medicinal Plants. National Institute of Science Communication and Information Resources, New Delhi, pp. 91, 212.

Das, S., Kumar, P., Basu, S.P., 2012. Phytoconstituents and Therapeutic potentials of *Datura stramonium* Linn. *Journal of Drug Delivery & Therapeutics* 2(3): 4-7.

Devi, M.R., Bawari, M., Paul, S.B. and Sharma, G.D., 2011. Neurotoxic and Medicinal Properties of *Datura stramonium* L. – Review. *Assam University Journal of Science & Technology: Biological and Environmental Sciences* 7(1): 139-144.

Druce, H.M., 1990. Adjuncts to medical management of sinusitis. *Otolaryngology--head and Neck Surgery* 103 (5) 2: 880-883.

Evans, K.L., 1998. Recognition and Management of Sinusitis. *Drugs* 56(1) : 59-71.

Georgitis, J.W., 1994. Nasal Hyperthermia and Simple Irrigation for Perennial Rhinitis: Changes in Inflammatory Mediators. *Chest* 106(5):1487-1492.

Ghani, H.N., (YNM). Khazainul Advia, Idara Kitabus Shifa, New Delhi, pp210, 211, 701-703.

Hakeem, A.H., 2002. Bustanul Mufradat Jadeed, Idara kitabus shifa, Delhi, pp280, 312-313.

Haq, G., Aziz, I, Ahmad, G. And Kashif, M., 2009. Efficacy of Habb-e-Shifa as Pre-anaesthetic Medication. *Hamdard Medicus* 52(1): 87-96.

Kabeeruddin, M., 1977. Bayaz-e-Kabeer, Vol.2, 15th Edition. Hikmat Book Depot. Hyderabad, pp. 47-48.

Khan, A., 1987. Haziq, Beesween. Sadi Book Depot, Neta ji Subhash Marg, New Delhi, pp. 75-77.

Khan, M. A., 2013. Muheet-e-Azam, Vol. 2 (Urdu Translation by CCRUM). CCRUM, New Delhi, pp. 12-13, 793-795.

Khan, M.A., 2011. Akseer Azam, (Urdu Translation by Mohammad Kabeeruddin). Idara Kitab-us-Shifa, New Delhi, p. 214.

Meltzer, E.O., 1995. An overview of current pharmacotherapy in perennial rhinitis. *The Journal of Allergy and Clinical Immunology* 95(5): 1097-1110.

Ojewole, J.A., 2006. Analgesic, antiinflammatory and hypoglycaemic effects of ethanol extract of Zingiber officinale (Roscoe) rhizomes (Zingiberaceae) in mice and rats. *Phytother. Res.* 20 (9):764-72.

Ophir, D., Elad, Y., 1987. Effects of steam inhalation on nasal patency and nasal symptoms in patients with the common cold. *Am. J. Otolaryngol* 8(3):149-53.

Raji, Y., Udoh, U.S., Oluwadara, O.O., Akinsomisoye, O.S., Awobajo, O., Adeshoga, K., 2002. Anti-Inflammatory and Analgesic Properties of the Rhizome extract of *Zingiber officinale*. *Afr. J. Biomed. Res*. 5: 121-124.

Penna, S.C., Medeiros, M.V., Aimbire, F.S.C., Faria-Neto, H.C.C., Sertié, J.A.A., Lopes-Martins, R.A.B., 2003. Anti-inflammatory effect of the hydralcoholic extract of Zingiber officinale rhizomes on rat paw and skin edema. *Phytomedicine* 10(5): 381-385.

Soni, P., Siddiqui, A.A., Dwivedi, j. and Soni, V., 2012. Phrmacological properties of *Datura stramonium* L. as a potential medicinal tree: An overview. *Asian Pac. J. Trop. Biomed* 2(12): 1002-1008.

Tajuddin, M., Khan, N.A., Tajuddin and Afzal, M., 2007. Analgesic, anticonvulsant and antipyretic effects of a Unani compound formulation Habb-e-Shifa. *Indian Journal of Traditional Knowledge* 6(2): 315-318.

Tyrrell, D., Barrow, I., Arthur, j., 1989. Local hyperthermia benefits natural and experimental common colds. *BMJ* 298(6683): 1280-3.

Young, H.Y., Luo, Y.L., Cheng, H.Y., Hsieh, W.C., Liao, J.C. and Peng, W.H., 2005. Analgesic and anti-inflammatory activities of [6]-gingerol. *Journal of Ethnopharmacology* 96(1-2): 207-210.

# Pharmacognostic Studies of Vitex agnus-castus Linn.– Fruit

**Rajat Rashmi**

Homoeopathic Pharmacopoeia Laboratory,
Dept. of AYUSH,
Ministry of Health & F. W.,
Govt. of India, Kamla Nehru Nagar,
Ghaziabad-201002

## Abstract

Fruits of *Vitex agnus-castus* Linn. (Verbaenace) is used in Homoeopathy and Indian system of medicine. Pharmacognostic studies of fruit / berry has been carried out to lay down the standards for genuine drug. Characteristic microscopical features are loculicidal drup with exalbuminous seeds; mesocarp consists of thick walled cells; endocarp stony; lignified testa cells show conspicuous scalariform folds or thickenings. It can be characterized by the presence of flavon, sterol, alkaloid, glycoside, volatile oil, sugar, tannin and starch. Other parameters also studied include TLC, UV spectrophotometry, fluorescence behavior, ash values, extractive values etc. Based on these characters, the study will help in the correct identification of this important drug.

**Keywords**: *Vitex agnus-castus*, Pharmacognostic, Fruit / Berry, Homoeopathy.

## Introduction

*Vitex agnus-castus* Linn. (Fam. Verbenaceae) is commonly known as chaste tree, found in Baluchistan, Afghanistan, Western Asia, Mediterranean and it is cultivated in India (Chopra *et al.*, 1974; Anonymous, 1976). It is a woody, perennial, deciduous shrub or a small tree, 3-6 m high, with strong aromatic odour (Davis, 1982).

Fruits are reported to contain casticin and orientin (c-glycosyl compound), Homo-orientin and dark fixed oil (Mabry, 1968; Harborne *et al.,* 1975).

In Homoeopathic system of medicine fruits / berries are used specially for sexual debilities, impotence, gleet, nervous debility, melancholy and apathy from sexual abuse (Allen, 1976). It is also used for scanty emission without proper ejaculation and loss of prostatic fluid on straining (Boericke, 1976).

In Ayruvedic system of medicine fruit is useful in “Kapha” and ‘Vata’, pruritus, itching, burning sensation and thirst while seeds are prescribed for colic/ stomatic, abortifacient, diuretic, alexiteric, cause biliousness. In Unani system of medicine it is given for enlargement of spleen & liver and useful in inflammation, pains, dropsy. Seeds are astringent, purify brain and liver (Kirtikar & Basu, 1975; Nadkarni, 1976).

Decoction of berries is used for leucorrhoea, staining yellow and also shows flavourable effect on amenorrhoea (Amann, 1982).

It relieves pre-menstrual syndrom (PMS) including corpus luteum insufficiency, menopausal syndrom and insufficient milk production (Gurmeet *et al.*, 2011). Chaste tree berries has the effect of stimulating and normalising pituitary gland functions, especially its progesterone function (Anonymous (Internet), 2012). Oil from seeds have progesterone like effect on mature female rats (Anonymous, 1976).

Elaborate pharmacognostic studies on the fruit of this plant is not on record. In view of efficacy of drug the detailed pharmacognostic studies including phytochemical analysis, TLC profile and physical characters are worked out and reported in the present communication.

## Materials and Methods

Fruits were collected from Central Institute of Medicinal and Aromatic Plants, (CIMAP), Lucknow and Medicinal Plants Garden, Homoeopathic Pharmacopoeial Laboratory, (HPL), Ghaziabad, preserved for macro & microscopical studies.

For histological studies microtome sections of 20 µm thickness were prepared after softening the fruit in Hydrofluoric acid; for powder study 5% aqueous KOH solution was used for tissue maceration.

For anatomical / histological characterization, Esau (1960) and Metcalfe (1950) were consulted; for powder analysis method suggested by Jackson & Snowdon (1968) were followed. Fruits were dried, powdered and extracted with ethanol at room temperature in soxhlet apparatus. Extract was filtered and filterate was used for preliminary phytochemical tests. For chemical analysis (Johnsen, 1940; Youngken, 1951; Cromwell, 1955; Trease & Evans, 1983) and for physical evaluation I.P. (1970), were followed. For fluorescence behavior of drug Harborne (1973) was consulted.

## Results and Observations

Drug Evaluation

*(i) Macroscopical Evaluation*

Fruit a drupe, pepper corn like, hard, purple to dark brown outside & yellowish inside, spherical, obtuse, 4-celled; mostly enclosed in greenish-grey cup-shaped pubescent calyx, slightly larger than the calyx, each lobe containing an oblong seed, rich in fat. Odour aromatic spicy; taste bitter and peculiar (Fig. 1).

*(ii) Microscopical Evaluation*

(a) Histology

Fruit: transection shows circular in outline, locular; locules 2 to 4, bearing exalbuminous seeds (Fig. 2-A). Exocarp consists of either single layer of cuticularised cells or a zone of 5 to 9 layers of thick walled cells with cellular inclusions (fig. 2-B). Mesocarp consists of either 5 to 22 layers of thickwalled isodiametric, oval parenchymatous cells arranged tangentially in the upper half while radially in the lower half containing conducting elements or entirely of palisade parenchymatous cells with or without conducting strands (fig. 2-B). Endocarp made up of 4 to 15 layers of sclereids having elongated macrosclereids towards the inner zone extending along with septa. The inner most layer of the endocarp is thin walled, tangentially elongated, cells with cell contents. Septa made up of thickwalled, isodiametric, oval parenchymatous cells (Fig. 2-C). Seed: oval in outline; seed coat consists of single layer of lignified conspicuous sclariform folds followed by 4 to 9 layers of large tabular parenchyma cells; cotyledons 2, each consists of single layered epidermis of oval cells enclosing storage parenchyma with starch grains and oil globules, a few scattered conducting elements present (Fig. 2-D).

(b) Powder Microscopy

Powdered fruit dark brown to yellowish-brown with oily repulsive odour and oily, bitter taste. It contains elongated macrosclereids, 40 to 100 µm long, with narrow lumen and prominent pits; irregularly shaped stone cells or brachysclereid, 10 to 25 µm in length; tracheary elements with simple pits and broad lumen, 25 to 100 µm long; tracheary elements with scalariform thickenings, 20 to 55 µm in length; thick walled parenchyma cells of epicarp with prominent pits, 20 to 30 µm in diameter; cotyledonary parenchyma cells with oily globules, 10 to 25 µm or more in diameter; groups of lignified seed coat cells with scalariform folds (Fig. 2-E).

*(iii) Chemical Analysis*

Observations in respect of preliminary phytochemical analysis and Thin Layer Chromatography are presented in Table 1 and 2.

*(iv) Physical Analysis : Observations*

Fluorescence behaviour, Extractive values, Ash values, Total solids, pH (at 25°C) and UV spectrophotometry are presented in Table 3 to 5.

Table 1 : Phytochemical Tests (Preliminary colour reaction tests of fruit of *Vitex agnus-castus* Linn.)

| S. No. | Reagent | Test Performed | Result |
|---|---|---|---|
| 1. | Dragendroff's reagent | Alkaloids | + ive |
| 2. | Phloroglucinol + HCl | Lignin | + ive |
| 3. | $FeCl_3$ | Tannin | + ive |
| 4. | Molish test | Sugar | + ive |
| 5. | Molish test after hydrolysis | Glycosides | + ive |
| 6. | Alc. ext. + Acetic anhydride + $H_2SO_4$ | Saponin | – ive |
| 7. | Mg powder + Conc. HCl | Flavones | + ive |
| 8. | Libermann + Conc. HCl | Steroids | + ive |
| 9. | Sudan IV | Oils | + ive |
| 10. | Borntrager reaction | Anthraquinone | – ive |
| 11. | Weak Iodine Solution | Starch | + ive |

Table 2 : Rf values of fruit of *Vitex agnus-castus* Linn. (Mobile phase, n-Butanol : Acetic acid : water-4 : 1 : 1 v/v)

| S. No. | Colour of spots | Rf values |
|---|---|---|
| 1. | Blue | 0.49 |
| 2. | Green | 0.59 |
| 3. | Blue | 0.73 |
| 4. | Yellow | 0.92 |

Table 3 : Fluorescence behavior of fruit powder of *Vitex agnus-castus* Linn.

| S. No. | Material taken | Colour in day light | Colour under UV light (365 nm) |
|---|---|---|---|
| 1. | Entire fruit | purpulish-dark brown | dark brown |
| 2. | Dry powder | dark brown or Yellowish-brown | dirty soil coloured |
| 3. | Extracts | | |
| (a) | Petroleum Ether | light brown | yellowish light green |
| (b) | Benzene | light green | yellowish light green |
| (c) | Chloroform | greenish straw | light green |
| (d) | Acetone | greenish straw | light green |
| (e) | Alcohol | greenish straw | greenish yellow |
| (f) | Water | reddish brown | very dark reddish brown |

Table 4 : Extractive values of fruit of *Vitex agnus-castus* Linn.

| S. No. | Reagents | Values (in percentage) |
|---|---|---|
| 1. | Ethyl Alcohol | 1.69 |
| 2. | Acetone | 0.98 |
| 3. | Benzene | 1.19 |
| 4. | Petroleum Ether | 1.32 |
| 5. | Water | 2.10 |
| 6. | Chloroform | 1.26 |

Table 5 : Physico-chemical values of fruit of *Vitex agnus-castus* Linn.

| S. No. | Ash | Values (in percentage) |
|---|---|---|
| | Total ash | 3.5% |
| | Water soluble ash | 2.3% |
| | Acid insoluble ash | 0.98% |
| | Total Solids | 0.20% w/v |
| | pH | 5.60 to 6.20 |
| | UV Spectrophotometry | λmax 268, 310 nm |

A. Vetex agnus castus Linn.

B. Fruit of Vitex agnus castus Linn.

Fig. 1: (A) *Vitex agnus-castus* Linn. (Plant in flowering & fruiting)
(B) Fruit of *Vitex agnus-castus* Linn.

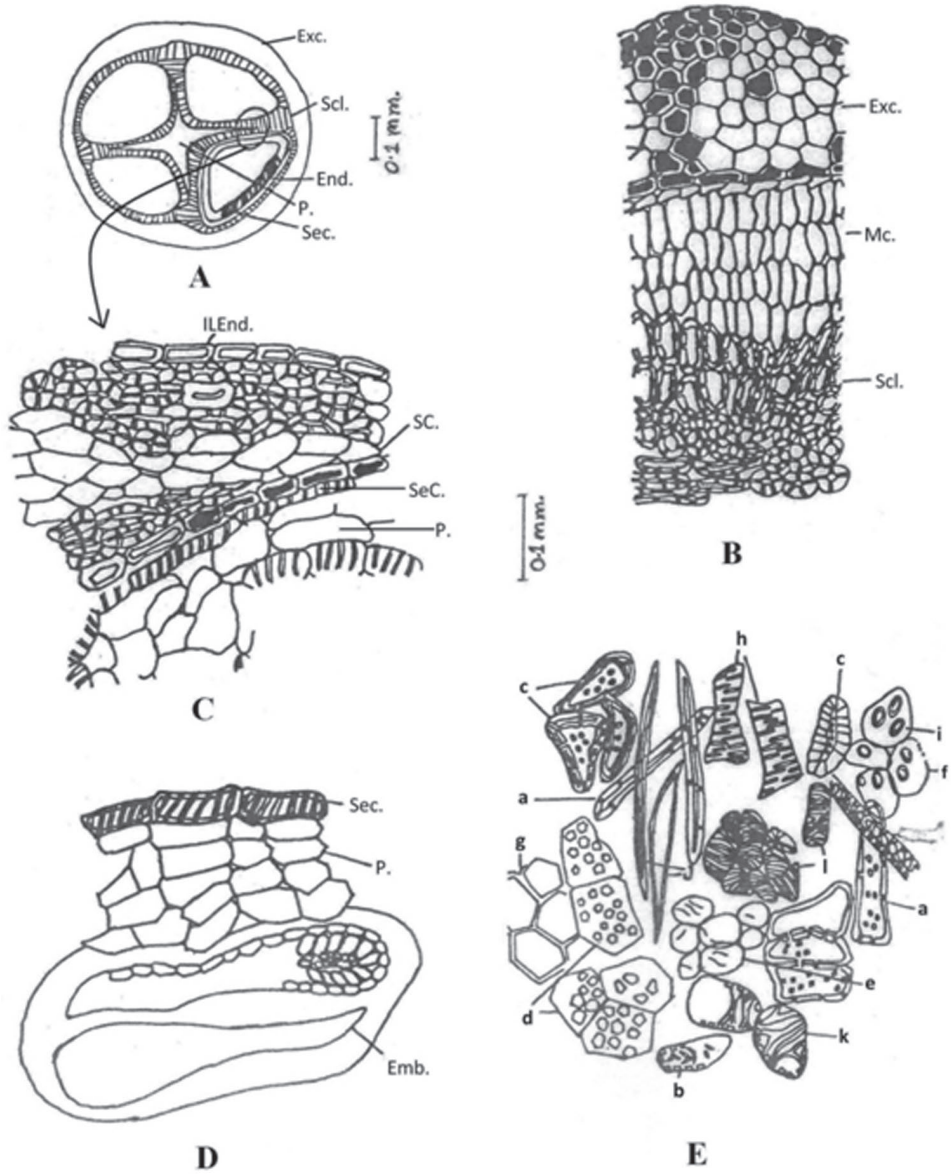



Fig. 2: (A). T.S. of Fruit (Diagrammatic); (B) T.S. of Fruit (Exocarp & Mesocarp); (C) T.S. of Fruit (Endocarp); (D) T.S. of Seed; (E) Powder Analysis of Fruit - (a) Macrosclereids, (b) Tracheary elements with simple pits, (c) Brachysclereids, (d) Epicarp parenchyma cells with pits, (e) Parenchyma cells, (f) Cotyledon parenchyma cells, (g) Thick walled parenchyma cells, (h & k) Tracheary elements with Scalariform thickenings, (i) Oil globules, (j) Fibers, (l) Lignified seed coat (Testa) cells.

Abbreviations : Emb.- Embryo; End.- Endocarp; Exc.- Exocarp; ILEnd.- Innermost Layer of Endocarp; Mc.- Mesocarp; P.- Parenchyma; SC.- Septal Cell; Se.- Seed; Scl.- Sclereids; SeC.- Seed Coat.

## Discussion

The macroscopical and microscopical characters of *Vitex agnus-castus* fruit show its distinguished tissue system. Preliminary photochemical and physical

analytical data are reproducible. All these data enable the easy identification of the drug and eliminate the possibilities of adulteration and also help in achieving desired therapeutic value of drug.

## Acknowledgement

The author is grateful to the Director, Homoeopathic Pharmacopoeia Laboratory, Ghaziabad (UP), for providing necessary facilities.

## References

Allen, H.C., 1976. Key-notes and characteristics of materia medica with nosodes, 21, Jain Publishing Company, New Delhi.

Amann, W., 1982. Favourable effect of *Agnus castus* on amenorrhoea, *ZFA (Stuttgart)* 58 (4): 228 – 31.

Anonymous, 1970. Pharmacopoeia of India, Manager of Publications, Government of India, New Delhi.

Anonymous, 1976. The Wealth of India, (raw–materials) Vol. X: 520, *C.S.I.R.*, New Delhi.

Anonymous Internet, 2012. Chaste-Tree Berries, http://beforeitsnews.com/health.

Boericke, W., 1976. Homoeopathic Materia Medica. 23-24, B. Jain Publishers, New Delhi.

Chopra, R.N., Nayar S.L., Chopra, I.C., 1974. Supplement to Glossary of Indian Medicinal Plants. Publication & Information Directorate, C.S.I.R., Hill Side Road, New Delhi – 12.

Cromwell, B.T., K., Paech and M.V. Tracey, 1955. Modern methods of Plant analysis, Vol. 4. Springer verlag, Berlin, Heidelberg.

Davis, P.H. 1982. Flora of Turkey and the East Aegean Island, Vol. 7, Edinburgh Univ. Press, Edinburgh.

Esau, K., 1960. Anatomy of Seed Plants. John Wiley, New York.

Gurmeet, S. Chhabra; Kala. S. Kulkarni, 2011. Vitex agnus-castus – An Overview. *Journal of Natural Remedies* 2:90-97.

Harborne, J.B., 1973. Phytochemical Methods. Chapman and Hall, London.

Harborne, J.B., Mabry, T.J. and Mabry, H., 1975. The Flavonoid, Part-1. 336, Academic Press, New York.

Jackson, B.P. & Snowdon, D.W., 1968. Powdered vegetable drugs. Churchil Ltd., London.

Johansen, D.A., 1940. Plant microtechnique. MC Graw Hill Book Co., New-York.

Kirtikar, K. R. and Basu, B. D., 1975. Indian Medicinal Plants, Vol. III. Bishen Singh, Mahendra Pal Singh, New Delhi (reprinted).

Mabry T.J., 1968. Recent Advances in Phytochemistry, Vol. I. 311, Appleton-Century-Crofts, Division of Meredith Corporation, New York.

Metcalfe, C.R. and I. Chalk, 1950. Anatomy of dicotyledons Vol. II. Clerendon Press, Oxford.

Nadkarni, K. M., 1976. Indian Materia Medica Vol. I. 1277, Popular Prakashan, Bombay.

Trease, G.E. and W.V. Evans, 1983. Pharmacognosy, (12th Edition). Bailiere, Tindall, London.

Youngken, H.W., 1951. Pharmaceutical Botany, (7th edition). Blackiston Company, Toronto.

# Harmonization of Indian Pharma-copoeial Standards*

[1]Nitin Rai and
[2†]Rajeev Kr. Sharma

Pharmacopoeial Laboratory for Indian Medicine, Kamla Nehru Nagar, Ghaziabad-201002, India

Pharmacopoeia Commission for Indian Medicine (PLIM Campus), Kamla Nehru Nagar, Ghaziabad-201002, India

## Abstract

Drugs & Cosmetics Act & Rules recognise Indian Pharmacopoeia, Ayurvedic Pharmacopoeia of India, Siddha Pharmacopoeia of India, Unani Pharmacopoeia of India and Homoeopathy Pharmacopoeia of India under regulatory frame work. These pharmacopoeias have incorporated a number of monographs which are common in respect of botanical source of drugs but vary in standards. The aim of harmonization of monographs is to arrive at identical requirements for all attributes of a herbal drug notable with the simplification and standardizations of quality control methods. Harmonization of monographs on common herbal drugs (botanical species) in these pharmacopoeias is needed to avoid confusion in varying specifications.

**Keywords:** Pharmacopoeial harmonization, Pharmacopoeial herbal drugs, Drugs and Cosmetics Act & Rules.

## Introduction

India is the only country which recognizes the five pharmacopoeias of different systems of medicine under regulatory frame. In Indian context Indian Pharmacopoeia (IP) is the premier pharmacopoeia having its first edition published in the year 1955 followed by the publication of other pharmacopoeias viz. The Ayurvedic Pharmacopoeia of India (1986), The Unani Pharmacopoeia of India (1998), The Siddha Pharmacopoeia of India (2008) and The Homoeopathy Pharmacopoeia of India (1971). All these Pharmacopoeias provide regulatory standards (under Drugs & Cosmetics Act & Rules) for quality control of drugs of allopathic, ayurvedic, siddha, unani and homoeopathic systems of medicine. All these pharmacopoeias have incorporated the monographs on herbal drugs along with drugs of other natural (animal and mineral–metals) and synthetic origin. To facilitate uniformity in regulatory quality specifications, harmonization of pharmacopoeial standards is timely need when acceptability of herbal drugs is accelerating. Present write-up is based on this rationale.

### Essentiality of Harmonization

Globalization and expansion in international trade present a growing need to develop global quality standards for medicines. As standards are a vital instrument for registration, market surveillance and free movement and trade of medicines among as many countries as possible, harmonization among

* Invited Paper

[2†] Author for correspondence

the national pharmacopoeias is essential to avoid confusion in regulation. To facilitate uniformity in regulatory quality specifications, some harmonization of pharmacopoeial standards will be of advantage to all. If past is prologue, one can look to present and former pharmacopoeial monographs as guideposts in any effort for future harmonization.

The details of respective pharmacopoeias published in India and incorporated monographs therein are given in Table 1-5.

Table 1 : Pharmacopoeia of India (IP) editions

| Sl. No. | Title | Year of Publication | No. of Monographs on Herbal Drugs |
|---|---|---|---|
| 1. | The Pharmacopoeia of India (1st ed) | 1955 | 237 |
| 2. | The Pharmacopoeia of India (2nd ed) | 1966 | 155 |
| 3. | The Pharmacopoeia of India (3rd ed) | 1985 | 17 |
| 4. | Indian Pharmacopoeia (4th ed) | 1996 | 21 |
| 5. | Indian Pharmacopoeia (5th ed) | 2007a | 58 |
| 6. | Indian Pharmacopoeia (6th ed) | 2010a | 89 |
| 7. | Indian Pharmacopoeia (7th ed) | 2014 | 123 |

Table 2 : Ayurvedic Pharmacopoeia of India (API) publications

| Sl. No. | Title | Year of Publication | No. of Monographs on Herbal Drugs |
|---|---|---|---|
| 1. | The Ayurvedic Pharmacopoeia of India, Pt. I, Vol. I | 1986 | 80 |
| 2. | The Ayurvedic Pharmacopoeia of India, Pt. I, Vol. II | 1999a | 78 |
| 3. | The Ayurvedic Pharmacopoeia of India, Pt. I, Vol. III | 2001 | 100 |
| 4. | The Ayurvedic Pharmacopoeia of India, Pt. I, Vol. IV | 2004 | 68 |
| 5. | The Ayurvedic Pharmacopoeia of India, Pt. I, Vol. V | 2006 a | 92 |
| 6. | The Ayurvedic Pharmacopoeia of India, Pt. I, Vol. VI | 2008 a | 101 |
| 7. | The Ayurvedic Pharmacopoeia of India, Pt. I, Vol. VIII | 2008 b | 60 |

Table 3 : Unani Pharmacopoeia of India (UPI) publications

| Sl. No. | Title | Year of Publication | No. of Monographs on Herbal Drugs |
|---|---|---|---|
| 1. | The Unani Pharmacopoeia of India, Pt. I, Vol. I | 1998 | 45 |
| 2. | The Unani Pharmacopoeia of India, Pt. I, Vol. II | 2007 b | 50 |
| 3. | The Unani Pharmacopoeia of India, Pt. I, Vol. III | 2007 c | 53 |
| 4. | The Unani Pharmacopoeia of India, Pt. I, Vol. IV | 2007 d | 50 |
| 5. | The Unani Pharmacopoeia of India, Pt. I, Vol. V | 2008 c | 52 |
| 6. | The Unani Pharmacopoeia of India, Pt. I, Vol. VI | 2009 | 48 |

Table 4 : Siddha Pharmacopoeia of India (SPI) publications

| Sl. No. | Title | Year of Publication | No. of Monographs on Herbal Drugs |
|---|---|---|---|
| 1. | The Siddha Pharmacopoeia of India, Pt. I, Vol. I | 2008d | 73 |
| 2. | The Siddha Pharmacopoeia of India, Pt. I, Vol. II | 2010b | 66 |

Table 5 : Homoeopathic Pharmacopoeia of India (HPI) publications

| Sl. No. | Title | Year of Publication | No. of Monographs on Herbal Drugs |
|---|---|---|---|
| 1. | Homoeopathic Pharmacopoeia of India, Vol. I | 1971 | 180 |
| 2. | Homoeopathic Pharmacopoeia of India, Vol. II | 1974 | 100 |
| 3. | Homoeopathic Pharmacopoeia of India, Vol. III | 1978 | 105 |
| 4. | Homoeopathic Pharmacopoeia of India, Vol. IV | 1984 | 107 |
| 5. | Homoeopathic Pharmacopoeia of India, Vol. V | 1987 | 114 |
| 6. | Homoeopathic Pharmacopoeia of India, Vol. VI | 1990 | 104 |

| Sl. No. | Title | Year of Publication | No. of Monographs on Herbal Drugs |
|---|---|---|---|
| 7. | Homoeopathic Pharmacopoeia of India, Vol.VII | 1999 b | 105 |
| 8. | Homoeopathic Pharmacopoeia of India, Vol.VIII | 2000 | 101 |
| 9. | Homoeopathic Pharmacopoeia of India, Vol.IX | 2006 b | 100 |

An overview of pharmacopoeial monographs on herbal drugs (botanical species) incorporated in these pharmacopoeias reveal that a number of herbal drugs are common in botanical sources. Each pharmacopoeia has its specific format for pharmacopoeial monographs (Table-6) and herbal drugs incorporated in these pharmacopoeias have regulatory specification on that specific format. The review of common monographs of these pharmacopoeias reveals variability in quality specifications in certain cases under regulatory framework. Therefore, harmonization of these monographs, will have desired impetus in follow-up work.

Table 6: Format of monographs in different Indian Pharmacopoeias

| Sl. No. | Parameters | Unani Pharma-copoeia of India (UPI) | Ayurvedica Pharma-copoeia of India (API) | Siddha Pharma-copoeia of India (SPI) | Homoeopathy Pharma-copoeia of India (HPI) | Indian Pharma-copeia (IP' 2014) |
|---|---|---|---|---|---|---|
| 1. | **Pharmacopoeial Title** | √ | √ | √ | √ | √ |
| 2. | **Defination-Botanical Name (family),Part used as distribution** | √ | √ | √ | Botanical Name, Family, Part used, Distribution are under independent headings | √ |
| 3. | **Synonyms** | √ | √ | √ | √ | √ |
| 4. | **Regional Language Name** | √ | √ | √ | Common Names | - |
| 5. | **Description** Macroscopic Microscopic Powder | √ | √ | √ | Description- Macroscopic Microscopic Powder-independent headings | - |
| 6. | **Identity, Purity & Strength** | √ | √ | √ | - | - |
| | Foreign Matter | √ | √ | √ | - | √ |
| | Total Ash | √ | √ | √ | - | √ |
| | Acid insoluble ash | √ | √ | √ | - | √ |
| | Alcohol/ethanol soluble extractive | √ | √ | √ | - | √ |
| | Water soluble Extractive | √ | √ | √ | - | √ |

| Sl. No. | Parameters | Unani Pharma-copoeia of India (UPI) | Ayurvedica Pharma-copoeia of India (API) | Siddha Pharma-copoeia of India (SPI) | Homoeopathy Pharma-copoeia of India (HPI) | Indian Pharma-copeia (IP' 2014) |
|---|---|---|---|---|---|---|
| 7. | Thin Layer Chromatography | √ | √ | √ | In certain monographs | √ |
| 8. | **Constituents** | √ | √ | √ | - | - |
| 9. | Properties and Action (as per system of medicine) | √ | √ | √ | - | Category |
| 10. | Important Formulations | √ | √ | √ | - | - |
| 11. | Therapeutic Uses | √ | √ | √ | - | - |
| 12. | Dose | √ | √ | √ | | |
| 13. | Identification | - | - | - | √ | Macro-scopic Micros-copic & TLC |
| 14. | **History and authority** | - | - | - | √ | - |
| 15. | **Preparation** | - | - | - | √ | - |
| 16. | **Heavy metals** | - | - | - | - | √ |
| 17. | **Loss on drying** | - | - | - | - | √ |
| 18. | **Microbial contamination** | - | - | - | - | √ |
| 19. | **Assay** | - | - | - | - | √ |
| 20. | **Storage** | - | - | - | - | √ |

Harmonization efforts in the area of pharmacopoeias started long back. World Health Organization was mandated with its Secretariat in 1948. This led to the creation of the International Pharmacopoeia. Pharmacopoeias are country specific and embedded in their respective national or regional regulatory environment. Prospective harmonization is easier in comparison to retrospective harmonization which is difficult to achieve. But present pharmacopoeial standards (pharmacopoeial texts and reference standards) subject to harmonization needs to be viewed within a long-term perspective.

Harmonization as a word covers many individual realities. The pharmacopoeias have found that prospective harmonization of yet-to-be-adopted monographs or reference standards is easier to achieve than retrospect harmonization of existing monographs that differ. Variability existing in monographs arose out of different laboratory practices and environments and different time frame of development of respective pharmacopoeia. Pharmacopoeial Discussion Group (PDG) (WHO) has defined harmonization of a pharmacopoeial monographs or general chapter as – "A pharmacopoeial general chapter or other pharmacopoeial document is harmonized when a

substance or preparation tested by the harmonized procedure yields the same results and the same accept/reject decision is reached".

Forward harmonization is a concept agreed upon by the members of the forerunner of the PDG, the British, European, Japanese and U.S. pharmacopoeias. It means selection of methods that would be acceptable well into the future that any pharmacopoeia can retain any meaningful standard even if not adopted by the others and that harmonization does not inhibit unilateral progress on the part of any pharmacopoeia. Although agreed to, this has been difficult to achieve.

## Pharmacopoeial Standardization

Pharmacopoeial standardization strategies for herbal drugs are the general definition of the plant as the active material, whether or not the active constituents are known. This concept has substantial implications. When an expiration date is assigned before which reliable performance can be expected, identity, purity and strength tests must support the definition. Pharmacopoeial monographs intrinsically are shelf-life standards, so one can expect that the pharmacopoeial monographs will select technology that will exclude definitively decomposed botanical materials.

## Description-Macroscopic and Microscopic

Description comprises pharmacognostic studies in respect of macroscopic and microscopic details of entire drug and details of cellular components of powdered drug. The first challenge is pharmacognostic description. The sine qua non for a herbal drug is identification. These are many monographs in different pharmacopoeias complete botanical description by the language of pharmacognosy is elaborated. But for the pharmacopoeias to harmonize on pharmacognostics, they face a significant challenge. It only needs diagnostic characterstics.The standard is unenforceable if industry and regulators cannot obtain analysts with the correct training to interpret a botanical description accurately.

## Botanical Reference Standards

Botanical reference materials are critical aspect of identification, for both botanical and histological parameters and for regulatory specifications. For the pharmacopoeias, the harmonization challenge is in availability of compatible reference materials so that comparison against two different reference materials does not confuse the issue in any one quality control laboratory.

## Purity and Strength

In pharmacopoeias certain general quality parameters would be expected to apply to most if not all (e.g., Total ash, acid-insoluble, water-soluble extractive, alcohol soluble extractive as-because sand or other mineral contents of drugs are a predictable in occurrence).

But eventual harmonization of these general quality characteristics is a reasonable expectation.

## Assays

Quantitative determination of active ingredients or characteristic markers may be inescapable for certain preparations and plant materials.

## Other Specifications

Limits on water and volatiles contents are also covered in some of the monographs in pharmacopoeias. Other specific herbal drug also herbal require tests for bitterness or tannins; hemolytic activity tests for saponins; or some functionality testing, such as for swelling and foaming index. There will be difficulty in harmonization on these less frequently standardized parameters.

## Chromatographic Finger-Printing

Thin-layer chromatography is for use in a wide variety of circumstances. Chromatography the active constituents of the herbal markers. Characteristic and quantifiable plant constituents to be used in quality control when actives are uncertain or not found. One can verify markers as characteristic or that a pattern of active ingredients is characteristic, by examination of a fairly large number of batches of that authentic herbal drug from more than one source. Authentic specimens will be inescapable for comparison because of the known variation in chromatographic finger printing.

## Heavy Metals

Tests for heavy metals are also required to be harmonized. It is difficult to harmonize the application of specific tests for elements, such as cadmium or lead, when instruments such as inductively coupled plasma or atomic absorption are to be used. Although toxicity-based limits is the proper way to establish specifications.

## Pesticide Residue

Herbal drugs resourced through cultivation, pesticides are ubiquitous. During postharvest treatment use of pesticides leads to contamination, so analysis for toxic residues when a drug is to be ingested is an issue of analysis to ensure the level of pesticides residue.

WHO has recommended a list of about 42 pesticides to be minimally tested in herbal drugs. WHO suggested that there be: (1) a list of pesticides not to be used in the cultivation of herbs for medicinal use; and (2) a list of those pesticides to be favored in this regard. This would greatly reduce the combinations to be coped with in the analytical laboratories worldwide in determining the absence of unwanted quantities of pesticide residues.

## Microbial Limits

The need for the absence of pathogens, such as *Salmonella, E. coli and Pseudomonas* etc. are mendentory.The application of limits for molds also is an area in which there will be differences of opinion. Some people would test strictly by chemical means for aflatoxins, and others would take the more general microbiologic approach.

Harmonization of pharmacopoeial monographs may be achieved by the decision of the expert committees/pharmacopoeial committees of each pharmacopoeia. The implementation of harmonization monographs will also depend upon their legal requirement need for translation and publication schedule. Harmonization did not completed until the text become official in all the pharmacopoeia having common monographs. The harmonized monographs are also subject of revision but not to done unilaterally. The revision should be necessitated with appropriate reason and should be taken up nothing other pharmacopoeia simultanesouly. Table 7 Pharmacopoeia in Indian Context.

Table 7 : Herbal Drugs monographs on common botanical sources in different Pharmacopoeias of India

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Abrus precatorius* L. | Gunja | Seed | API- I |
| | Kunrimani | | SPI-I |
| | Jequirity | | HPI-IX |
| *Abrus precatorius* L. | Gunja | Root | API- II |
| | Ghongchi | | UPI-IV |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Acacia leucophloea* Willd. | Arimeda | Stem bark | API- II |
| | Kath | | UPI-VI |
| *Acacia nilotica* (L.) Willd. ex Del. | Samagh-e-Arabi | Gum | UPI-VI |
| | Acacia | | IP-2014 |
| *Acalypha fruticosa* Forsk. | Laghu haritamanjari | Root | API- VI |
| | Cinni ver | | SPI-II |
| *Acalypha indica* L. | Harita manjari | Whole plant | API- VI |
| | Kuppaimeni camulam | | SPI-II |
| | Acalypha indica | | HPI-VIII |
| *Achyranthes aspera* L. | Apamarga | Whole plant | API- II |
| | Nayuruvic camulam | | SPI-I |
| *Achyranthes aspera* L. | Apamarga | Root | API- III |
| | Chirchita | | UPI-IV |
| *Aconitum chasmanthum* stapf | Vatsanabha | Root | API- II |
| | Aconiturn, Aconite | | IP- 55 |
| | Beesh | | UPI-IV |
| *Aconitum heterophyllum* Wall ex. | Atees Shireen | Root | UPI-I |
| | Ativisa | | API- I |
| | Ativitayam | | SPI-I |
| *Acorus calamus* L. | Vaca | Rhizome | API- II |
| | Waj Turki | | UPI-V |
| *Adhatoda vasica* Nees | Arusa | Leaf | UPI-VI |
| | Vasa | | API- I |
| | Vasaka | | IP- 2014 |
| | Justicia adhatoda | | HPI-I |
| *Aegle marmelos* (L.) Corr. | Vilva ver | Root | SPI-I |
| | Bilva | | API- III |
| *Aegle marmelos* (L.) Correa | Belae fructus, Bael | Fruit Pulp | IP- 66 |
| | Aegle marmelos | | HPI-VI |
| | Belgiri | | UPI-I |
| | Bilva | | API- I |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Aerva lanata* (L.) Juss. ex Schult. | Cirupilaic camulam | Whole plant | SPI-I |
| | Pattura | | API- V |
| | Yavasaka | | API- II |
| | Seer (Lahsan) | | UPI-V |
| | Vellaippuntu | | SPI-II |
| | Allium sativum | | HPI-I |
| | Lasuna | | IP- 2014 |
| *Aloe barbadensis* Mill. | Kanyasara | Dried juice of leave | API- I |
| | Sibr | | UPI-I |
| | Aloe, Aloes | | IP-96 |
| *Alpinia galanga* Willd. | Kulanjana | Rhizome | API- V |
| | Perarattai | | SPI-I |
| | Khulanjan | | UPI-II |
| *Alstonia scholaris* (L.) R. Br. | Alstonia; Chhatim | Bark | IP- 55 |
| | Saptaparna | | API- I |
| | Alstonia scholaris | | HPI-IV |
| *Alternanthera sessilis* (L.) R.Br.,ex DC. | Ponnankani | Whole plant | SPI-I |
| | Matsyaksi | | API- II |
| *Althaea officinalis* L. | Bekh khatmi | Root | UPI-V |
| | Khatmi | | API- V |
| | Althea officinalis | | HPI-VII |
| *Althaea officinalis* L. | Khatmi | Seed | API- V |
| | Tukhme Khatmi | | UPI-V |
| *Amomum subulatum* Roxb. | Heel Kalan | Seed | UPI-IV |
| | Sthulaela | | API- II |
| *Anacyclus pyrethrum* DC | Akarakarabha | Root | API- II |
| | Aaqarqarha | | UPI-II |
| | Akkarakaram | | SPI-II |
| *Andrographis paniculata* Nees | Andrographis paniculata | Whole plant/ Dried aerial parts, stem and leaves | HPI-I |
| | Kalmegh | | IP- 2014 |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Anethum graveolens* L. | Anethum, Dill | Fruit | IP- 66 |
| | Shibt | | UPI-V |
| *Anethum sowa* Kurz Roxb. ex Flem | Tukhm-e-Soya | Seed/ Fruit | UPI-VI |
| | Satahva | | API- II |
| *Angelica archangelica* L. | Canda | Root | API- V |
| | Angelica archangelica | | HPI-IX |
| *Apium graveolens* L. | Coraka | Root | API- V |
| | Karaphsa | | API- VI |
| *Apium graveolens* L. | Tukhm-e-Karafs | Seed /Fruit | UPI-II |
| | Apium graveolens | | HPI-II |
| *Aquilaria agallocha Roxb.* | Agaru | Heart wood | API- IV |
| | Ood Hindi | | UPI-VI |
| *Areca catechu* L. | Areca | Seed | IPL |
| | Fufal | | UPI-I |
| | Puga | | API- I |
| | Areca catechu | | HPI- IX |
| *Aristolochia bracteolata* Lam. | Atutintappalai ilai | Leaf | SPI-II |
| | Kitamari | | API- VI |
| *Aristolochia indica* L. | Aristolochia | Root | IP- 55 |
| | Isvari | | API- III |
| | Zarawand Hindi | | UPI-V |
| *Artemisia martima* Linn ( *A. brevifolia* Wall.) | Artemisia | Flower head | IP- 55 |
| | Cina | | HPI- IX |
| *Asparagus racemosus* Willd. | Tannirvittan kilanku | Tuberous Root | SPI-II |
| | Satavari | | API- IV |
| | Satawar | | UPI-VI |
| *Asteracantha longifolia* Nees | Kokilaksa | Whole plant | API- II |
| | Hygrophilla sfinosa | | HPI-IX |
| *Asteracantha longifolia* Nees | Kokilaksa | Seed | API- II |
| | Talmakhana | | UPI-III |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Azadirachta indica* (L.) A. Juss | Veppilai | Leaf | SPI-II |
| | Neem | | UPI-IV |
| | Neem | | IP- 2014 |
| | Nimba | | API- II |
| *Azadirachta indica* A. Juss. | Azadirachta indica | Fresh Bark/ Stem Bark | HPI- VIII |
| | Neem | | UPI-IV |
| | Veppam pattai | | SPI-I |
| | Nimba | | API- II |
| *Azadirachta indica* A. Juss. | Veppam palam | Fruit | SPI-I |
| | Neem | | UPI-V |
| | Nimba | | API- V |
| *Azadirachta indica* A. Juss. | Veppam pu | Flower | SPI-I |
| | Neem | | UPI-V |
| | Nimba | | API- V |
| *Azadirachta indica* A.Juss. | Neem | Root bark | UPI-V |
| | Nimba | | API- V |
| *Bacopa monnieri* (L.) Penn. (Wettst) | Brahmi | Whole plant | API- II |
| | Pirammi valukkai | | SPI-I |
| | Brahmi, | | IP- 2014 |
| | Bacopa monnieri | | HPI-IX |
| | Jal Brahmi | | UPI-IV |
| *Balsamodendron caudata* Mauch. | Amragandhi-gugglu | Leaf | API- VI |
| | Cenkiluvai ilai | | SPI-II |
| *Barringtonia acutangula* (Linn) *Gaertn.* | Samander Phal | Fruit | UPI-VI |
| | Nicula | | API- III |
| *Benincasa hispida* (Thunb.) Cogn. | Kusmanda | Fruit | API- IV |
| | Pucinik kay | | SPI-II |
| *Berberis aristata* DC | Daruharidra | Stem | API- II |
| | Darhald | | UPI-IV |
| *Berberis aristata* DC.Var. *aristata.* | Maramancal | Stem | SPI-I |
| | Daruharidra | | IP- 2014 |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Betula utilis* D.Don | Bhojpatr | Stem Bark | UPI-V |
| | Bhurjah | | API- V |
| *Boerhaavia diffusa* L. | Mukkirattaic camulam | Whole plant | SPI-I |
| | Punarnava (Rakta) | | API- I |
| | Boerhaavia diffusa | | HPI-I |
| *Boerhaavia diffusa* Linn. | Punarnava | Root | IP- 2014 |
| | Raktapunarnava | | API- III |
| *Bombax ceiba L.* | Salmali | Stem bark | API- III |
| | Sembhal | | UPI-V |
| *Borago officinalis* L. | Gaozaban | Leaf | UPI-II |
| | Borago officinalis | | HPI-VIII |
| *Boswellia serrata* Roxb. | Kundura Dry | Exud. | IP- 2014 |
| | Kunduru | | API- IV |
| *Brassica camperstris* L. | Sarson | Seeds | UPI-V |
| | Sarsapa | | API- III |
| *Buchanania lanzan* Spreng. | Chironji | Seeds | UPI-IV |
| | Priyala | | API- II |
| *Butea monosperma* (Lam.) *Kuntze. Syn. Butea frondosa* Koeing ex Roxb. | Murukkan vitai | Seed | SPI-II |
| | Palas Papra | | UPI-VI |
| | Palasa | | API- V |
| | Palas Papra | | UPI-II |
| *Butea monosperma* (Lam.) *Kuntze* | Murukkam pu | Flower | SPI-II |
| | Gul Tesu | | UPI-V |
| | Palasa | | API- V |
| *Butea monosperma* (Lam.) *Kuntze.* | Palasa | Stem Bark | API- II |
| | Palas | | UPI-V |
| *Butea monosperma* (Lam.) Kuntze. | Palasa | Gum | API- IV |
| | Samagh-e-Dhak | | UPI-VI |
| *Caesalpinia bonduc* (L.) Roxb. | Karanjwa | Seed | UPI-V |
| | Lata-karanja | | API- V |
| *Calamus rotang* L. | Pirappan Kilanku | Rhizome | SPI-II |
| | Vetra | | API- VI |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Calotropis procera* (Ait.) R. Br. | Aak | Leaf | UPI-I |
| | Arka | | API- I |
| *Camellia sinensis* Linn. Kuntze. | Tea, Thea , Cha, | Leaf | IP- 55 |
| | Thea chinesis | | HPI-V |
| *Cannabis sativa* L. | Cannabis | Flowering tops | IP- 66 |
| | Cannabis sativa | | HPI-I |
| *Cannabis sativa* L. | Kanca | Leaf | SPI-I |
| | Qinnab | | UPI-I |
| | Vijaya | | API- I |
| | Cannabis indica | | HPI-I |
| *Capparis spinosa* L. | Himsra | Root | API- V |
| | Kibr | | UPI-V |
| *Cardiospermum halicacabum* L. | Habbul-ul- Qilqil | Seed | UPI-V |
| | Karnasphota | | API- V |
| *Careya arborea* Roxb. | Bai khumbi | Seed | UPI-V |
| | Kumbhikah | | API- V |
| *Carica papaya* L. | Eranda karkati | Fruit | API- VI |
| | Carica papaya | | HPI-VIII |
| *Carum carvi* L. | Caraway, Carum | Fruit | IP- 55 |
| | Krsnajiraka | | API- I |
| | Carum carvi | | HPI-VIII |
| | Zeera Siyah | | UPI-I |
| *Cassia angustifolia* Vahl. | Sennac folium | Leaf | IP- 66 |
| | Senna | | HPI-III |
| | Sana | | UPI-I |
| | Svarnapatri | | API- I |
| *Cassia fistula* L. | Aragvadha | Fruit | API- I |
| | Carakkonrai puli | | SPI-I |
| | Amaltas Sonhali; Cassia fistula | | IP- 2014 |
| | Khiyar Shambar | | UPI-I |
| *Cassia fistula* L. | Aragvadha | Stem bark | API- V |
| | Konraippattai | | SPI-II |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Cassia senna* L. | Nilavakai ilai | Leaf | SPI-II |
| | Senna leaf, Cassia leaf; Cassia angustifolia | | IP- 2014 |
| *Cassia tora* L. Syn. *Cassia obtusifolia* Linn. | Prapunnada | Seed | API- III |
| | Panwar | | UPI-II |
| *Cedrus deodara* (Roxb.) Loud. | Devadaru | Heart wood | API- IV |
| | Tevataruk kattai | | SPI-II |
| | Deodar | | UPI-VI |
| *Celastrus paniculatus* Willd. | Jyotismati | Seed | API- II |
| | Malkangni | | UPI-IV |
| | Valuluvai | | SPI-I |
| *Centella asiatica* (L.) Urban | Mandukaparni | Whole plant | API- IV |
| | Hydrocotyle asiatica | | HPI-I |
| *Chondodendron tomentosum* Ruiz et. Pavon. | Palladium | Root | HPI-V |
| | Pareira brava | | HPI-III |
| *Cinchona officinalis* L. | Kanakana | Bark | UPI-III |
| | Cinchona officinalis | | HPI-I |
| *Cinnamomum cassia* Blume. Syn. *Cinnamomum aromaticum* Nees & Eberm. | Qirfa | Leaf | UPI-III |
| | Ilavankap pattiri | | SPI-I |
| *Cinnamomum zeylanicum* Blume. | Darusita Taila | Oil | API- VI |
| | Oleum cinnamomi | | IP- 66 |
| *Cinnamomum zeylanicum* Blume. | Darchini | Bark | UPI-I |
| | Tvak | | API- I |
| | Cinnamomm | | HPI-II |
| | Cinnamomum | | IP- 66 |
| *Cissus quadrangularis* L. | Asthisrnkhala | Aerial part | API- VI |
| | Pirantai | | SPI-II |
| *Citrullus colocynthis* (L.) Schard. | Colocynthis | Fruit Pulp | IP- 55 |
| | Arruttumatti | | SPI-I |
| | Colocynthis | | HPI-I |
| | Shahm-e-Hanzal | | UPI-VI |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Citrullus colocynthis* Schrad. | Hanzal | Root | UPI-IV |
| | Indravaruni | | API- II |
| *Citrus limon* (L.) Burm.f. | Nimbu | Fruit | API- IV |
| | Turanj | | UPI-III |
| | Limonis cortex | | IP- 55 |
| *Claviceps purpurea* (Friles) Tul. | Prepared Ergot | Whole fungus | IP- 2014 |
| | Secale cornutum | | HPI-I |
| *Clerodendrum phlomidis* L. | Agnimantha | Root | API- III |
| | Baharangi | | UPI-VI |
| *Clerodendrum serratum* (L.) Moon | Bharangi | Root | API- III |
| | Cirutekku | | SPI-II |
| *Clitoria ternatea* L. | Aparajita | Root | API- II |
| | Kakkana ver | | SPI-I |
| *Coccinia grandis* (L.) Voigt | Bimbi | Stem | API- VI |
| | Kovai tantu | | SPI-II |
| *Coccinia grandis* (L.) Voigt | Bimbi | Leaf | API- VI |
| | Kovai ilai | | SPI-II |
| *Cocos nucifera* L. | Coconut oil | Endos. | IP- 2014 |
| | Narikela | | API- III |
| *Coldenia procumbens* L. | Ceruppataic camulam | Whole plant | SPI-II |
| | Tripaksi | | API- VI |
| *Commiphora wightii* (Arn.) Bhand. | Guggulu | Exudate | API- I |
| | Guggul Resin | | IP- 2014 |
| | Muqil | | UPI-I |
| *Corallocarpus epigaeus* Benth. ex Hook.f. | Akacakarutan kilanku | Tuber root / Rhizome | SPI-II |
| | Sukanasa | | API- VI |
| *Coriandrum sativum* L. | Dhanyaka | Fruit | API- I |
| | Kishneez | | UPI-I |
| | Kottumalli vitai | | SPI-I |
| *Crocus sativus* L. | Crocus | Style & Stigma | IP- 55 |
| | Kunkuma | | API- IV |
| | Kunkumap pu | | SPI-II |
| | Crocus sativus | | HPI-II |
| | Zafran | | UPI-VI |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Croton tiglium* L. | Habb-us-Salateen | Seeds | UPI-IV |
| | Jayapala | | API- II |
| | Nervalam | | SPI-I |
| *Cucumis melo* L. var. *utilissimus Duthie & Fuller* | Ervaru | Seed | API- II |
| | Kakri | | UPI-IV |
| *Cucumis sativus* L. | Khayar | Seed | UPI-V |
| | Trapusam | | API- V |
| | Vellari vitai | | SPI-II |
| *Cuminum cyminum* L. | Cirakam | Fruit | SPI-I |
| | Svetajiraka | | API- I |
| | Cuminum, Cumin | | IP- 55 |
| *Curculigo orchioides* Gaertn. | Nilap panaik kilanku | Tuber root / Rhizome | SPI-II |
| | Talamuli | | API- IV |
| *Curcuma amada* Roxb. | Amba Haldi | Rhizome | UPI-V |
| | Amra-haridra | | API- V |
| *Curcuma longa* L. | Haridra | Rhizome | API- I |
| | Mancal | | SPI-I |
| | Curcuma longa | | HPI-V |
| | Haridra | | IP- 2014 |
| | Zard Chob | | UPI-I |
| *Curcuma zedoaria* Rosc. | Karcura | Rhizome | API- IV |
| | Kiccalik kilanku | | SPI-II |
| *Cymbopogon martinii* (Roxb.) Wats | Izkhar | Whole plant | UPI-V |
| | Rohisa | | API- V |
| *Cynodon dactylon* (L.) Pers. | Doob | Root | UPI-IV |
| | Durva | | API- III |
| *Cynodon dactylon* (L.) Pers. | Durva | Whole plant | API- IV |
| | Cynodon dactylon | | HPI-II |
| *Cyperus rotundus* L. | Musta | Rhizome | API- III |
| | Saad Kufi | | UPI-V |
| *Dalbergia sissoo* Roxb. | Sheesham | Heart wood | UPI-V |
| | Simsapa | | API- III |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Datura metel* L. Syn. *D. alba* L. | Dhattura | Seed | API- III |
| | Dhatura | | UPI-IV |
| *Desmodium gangeticum* DC. | Salaparni | Root | API- III |
| | Desmodium gangeticum | | HPI-VI |
| *Digitalis purpurea* L. | Degitalis folium | Leaf | IP- 66 |
| | Digitalis purpurea | | HPI- VII |
| *Eclipta alba* (L.) Hassk. | Bhrngaraja | Whole plant | API- II |
| | Bhringraj, Eclipta alba | | IP- 2014 |
| | Eclipta alba | | HPI-IX |
| | Bhangra | | UPI-IV |
| *Elaeocarpus sphaericus* (Gaertn). K.Schum | Rudraksa | Seed | API- IV |
| | Uttiratcam | | SPI-II |
| *Elettaria cardamomum* (L.) Maton. | Elam | Fruit | SPI-II |
| | Heel Khurd | | UPI-I |
| | Suksmaila | | API- I |
| *Embelia ribes* Burm, *f.* | Vidanga | Fruit | IP- 2014 |
| | Embelia ribes | | HPI- IX |
| | Baobarang | | UPI-I |
| | Vaivitankam | | SPI-I |
| | Vidanga | | API- I |
| *Emblica officianalis* Gaertn. *Syn. Phyllanthus emblica* L. | Aamla | Dried fruit | UPI-I |
| | Amalaki | | API- I |
| | Emblica officinalis | | HPI-VIII |
| | Amalaki | | IP- 2014 |
| *Enicostemma axillare* (Lam.) A. Raynal | Nahi | Whole plant | API- VI |
| | Vellarukuc camulam | | SPI-II |
| *Ephedra gerardiana* (Wall) Stapf. | Ephedra | Stem | IP- 66 |
| | Ephedra vulgaris | | HPI-VII |
| *Eucalyuptus globulus* Labill. | Tailaparna | Leaf | API- V |
| | Eucalyptus globulus | | HPI-II |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Eucalyptus globulus* Labill. | Tailapar´a Taila | Eucalyptus oil | API- VI |
| | Eucalyptus oil | | IP-2014 |
| *Eugenia caryophyllata* Thunb. | Eugenia caryophyllata | Flower bud | HPI-VIII |
| | Caryophyllum | | IP- 66 |
| *Fagonia cretica* L. | Dhanvayasah | Whole plant | API- V |
| | Shukai | | UPI-V |
| *Ferula asafoetida* Linn./ *Ferula foetida* Regel Syn., *Ferula narthex, Boiss Ferula foetida* Regel. | Asafoetida | Oleo-Gum-Resin | HPI-I |
| | Hilteet | | UPI-I |
| | Hingu | | API- I |
| | Perunkayam | | SPI-I |
| | Asafoetida | | IP- 55 |
| *Ficus bengalensis* Linn. | Ficus indica | Aerial root | HPI-VI |
| | Nayagrodha Jata | | API- IV |
| | Reesh-e-Bargad | | UPI-VI |
| *Ficus hispida* L. | Kath Gular | Root | UPI-IV |
| | Phalgu | | API- III |
| *Ficus racemosa* L. | Attip pattai | Bark | SPI-I |
| | Post-e-Gular | | UPI-I |
| | Udumbara | | API- I |
| *Foeniculum vulgare* Mill. | Misreya | Fruit | API- I |
| | Foeniculum vulgare | | HPI-VIII |
| | Compu | | SPI-I |
| | Saunf | | IP- 2014 |
| *Fumaria parviflora* Lam. | Parpata | Whole plant | API- IV |
| | Shahtara | | UPI-VI |
| *Gaultheria fragrantissima* Wall. | Gandhapura Patra Taila | oil | API- VI |
| | Oleum gaultheriae | | IP- 55 |
| *Glinus lotoides* L. | Ciruceruppataic camulam | Whole plant | SPI-II |
| | Usandi | | API- VI |
| *Glycyrrhiza glabra* L. | Asl-us-Soos | Stolon & Root | UPI-I |
| | Atimaturam | | SPI-I |
| | Yasti | | API- I |
| | Yasti | | IP- 2014 |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Gossypium herbaceum* L. | Karpasa | Seed | API- I |
| | Pambadana | | UPI-I |
| *Gymnema sylvestre* R. Br. | Ciru kuruncan ver | Root | SPI-I |
| | Mesasrngi | | API- V |
| | Gurmar | | UPI-V |
| *Gymnema sylvestre* R.Br. | Gymnema sylvestris | Leaf | HPI-I |
| | Mesasrngi | | API- V |
| | Gudmar | | IP- 2014 |
| | Gurmar Buti | | UPI-II |
| *Hedychium spicatum* Ham. ex Smith | Sati | Rhizome | API- I |
| | Shati | | IP- 2014 |
| *Hemidesmus indicus* (L.) R. Br. | Nannari | Root | SPI-I |
| | Anantmula | | IP- 2014 |
| | Hemidesmus indicus | | HPI-VIII |
| | Sveta Sariva | | API- I |
| *Hibiscus abelmoschus* L. | Abelmoscus | Seed | HPI- IX |
| | Kasturilatika | | API- IV |
| *Holarrhena antidysenterica* (Roth) A.DC. | Kutaja | Stem bark | API- I |
| | Kurchi | | IP- 66 |
| | Holarrhena antidysenterica | | HPI-I |
| *Hordeum vulgare* L. | Jao | Fruit | UPI-VI |
| | Yava | | API- II |
| *Hydnocarpus pentandra* (Buch.-Ham.) Oken | Tuvaraka | Seed | API- VI |
| | Nirati muttu | | SPI-II |
| *Hyoscyamus niger* L. | Ajawain Khurasani | Seed | UPI-V |
| | Kurocani omam | | SPI-I |
| | Parasika Yavani | | API- V |
| *Illicium verum* Hook f. | Takkola | Fruit/Seed | API- VI |
| | Illicium anisantum | | HPI-III |
| *Indigofera tinctoria* L. | Avuri | Whole plant | SPI-I |
| | Nili | | API- III |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Indigofera tinctoria* L. | Avuri ver | Root | SPI-I |
| | Nili | | API- II |
| *Ipomoea digitata* L. | Badari kand | Root | UPI-V |
| | Kshiravidari | | API- V |
| *Jasminum officinale* L. | Jati | Leaf | API- III |
| | Chanbeli | | UPI-IV |
| *Juglans regia* L. | Akhrot | Fruit Kernal / Cotyledon | UPI-IV |
| | Aksoda | | API- II |
| *Juniperus communis* L. | Abhal | Fruit | UPI-IV |
| | Juniperus communis | | HPI-II |
| *Lawsonia inermis* L. *Syn. Lawsonia alba* Lam. | Madayanti | Leaf | API- IV |
| | Hina | | UPI-II |
| *Lens culinaris* Medic. | Adas | Seed | UPI-VI |
| | Masura | | API- III |
| *Linum usitatissimum* L. | Atasi | Seed | API- I |
| | Katan | | UPI-I |
| | Linum, Linseed. | | IP- 66 |
| | Linum usitatissimum | | HPI-IX |
| *Litsea chinensis* Lam. | Meda Lakri | Stem Bark | UPI-V |
| | Medasakah | | API- V |
| *Luffa acutangula* (Linn.) Roxb. | Luffa amara | Fruit | HPI-VI |
| | Laffa acutangula | | HPI-IX |
| *Lycopodium clavatum* L. | Lycopodium | Spore | IPL |
| | Lycopodium clavatum | | HPI-I |
| *Mallotus philippinensis* Muell. Arg. | Kamila | Glands & Hair of fruit /Fruit | UPI-I |
| | Kampilla | | API- I |
| *Mangifera indica* L. | Aam | Stem Bark | UPI-IV |
| | Amra | | IP- 2014 |
| | Amra | | API- III |
| | Mangifera indica | | HPI-VII |
| *Melia azedarach* L. | Bakayin | Stem bark | UPI-III |
| | Mahanimba | | API- IV |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Mentha viridis* L. | Nana pudina | Aerial part | UPI-V |
| | Pudinah | | API- V |
| *Mesua ferrea* L. | Nagakesar | Stamen | IP- 2014 |
| | Narmushk | | UPI-IV |
| | Nagakesara | | API- II |
| *Michelia champaca* L. | Canpakap pu | Flower | SPI-II |
| | Champaka | | API- IV |
| *Momordica charantia* L. | Karavallaka | Fruit | API- II |
| | Karela | | UPI-IV |
| | Momordica chirantia | | HPI-VIII |
| *Monochoria vaginalis* Presl. | Indivara | Rhizome | API- VI |
| | Cenkalunirk kilanku | | SPI-II |
| *Moringa oleifera* Lam. | Sehjana | Leaf | UPI-V |
| | Sigru | | API- II |
| *Moringa oleifera* Lam. | Murunkaip pattai | Stem bark | SPI-II |
| | Sigru | | API- IV |
| *Mucuna pruriens* (L.) DC. | Punaikkali vitai | Seed | SPI-II |
| | Konch | | UPI-II |
| | Kaunch | | IP- 2014 |
| *Musa paradisiaca* Linn. | Musa safientum | Flower | HPI-IX |
| | Kadali | | API- IV |
| *Musa paradisiaca* L. | Kadali | Rhizome | API- III |
| | Kela | | UPI-IV |
| | Valaik kilanku | | SPI-II |
| *Myrica esculenta* Buch. Ham ex D.Don | Kaiphal | Fruit | UPI-IV |
| | Katphala | | API- III |
| *Myrica esculenta* Buch. -Ham. ex D.Don. | Katphala | Stem bark | API- III |
| | Kaiphal | | UPI-IV |
| | Kaifal | | UPI-II |
| *Myristica fragrans* Houtt. | Jauzbuwa | Dried seed/ Aril Kernel | UPI-I |
| | Bisbasa | | UPI-VI |
| | Catikkai | | SPI-I |
| | Jatiphala | | API- I |
| | Nutmeg, Myristica | | IP- 66 |
| | Nux moschata | | HPI-I |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Nardostachys jatamansi* DC. | Jatamansi | Rhizome | IP- 66 |
| | Sumbul-ut-Teeb | | UPI-I |
| | Jatamansi | | API- I |
| *Nelumbo nucifera* Gaertn. | Kamala | Flower | API- II |
| | Tamarai malar | | SPI-I |
| *Nelumbo nucifera* Gaertn. | Kamala | Rhizome | API- III |
| | Tamaraik kilanku | | SPI-I |
| *Nerium indicum* Mill. | Dafli/Dafla | Root | UPI-IV |
| | Karavira | | API- III |
| *Nerium indicum* Mill. | Karavira | Leaf | API- I |
| | Kaner | | UPI-I |
| *Nigella sativa* L. | Kalonji | Seeds | UPI-I |
| | Karuncirakam | | SPI-I |
| | Upakuncika | | API- I |
| *Ocimum sanctum* L. | Rehan | Leaf | UPI-V |
| | Tulasi | | API- II |
| *Ocimum sanctum* L. | Rehan | Whole plant/ Whole plant excluding root | UPI-V |
| | Tulasi | | API- II |
| | Ocimum sanctum | | HPI-I |
| *Onosma bracteatum* Wall. | Goazaban | Dried Leaf/ Aerial part | UPI-V |
| | Gojihva | | API- III |
| *Operculina turpethum* (L.) Silva Manso | Trivrit | Root | API- III |
| | Turbud | | UPI-V |
| *Oryza sativa* L. | Perpolitiones oryzae, Rice polishing | Fine flaky per carp and seed coat frag ments, the embryo, aleurone layer, and outer adhering cells of starchy endosperm of grain/ Fruit | IPL |
| *Oryza sativa* L. | Sali | | API- III |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Oxalis corniculata* L. | Cangeri | Whole plant | API- III |
| | Puliyarai | | SPI-II |
| *Pandanus odoratissimus* Roxb. | Ketaki | Stilt Root | API- VI |
| | Talai vilutu | | SPI-II |
| *Papaver somnifera* L. | Khashkhaash | Seed | UPI-II |
| | Kacakaca | | SPI-I |
| | Khakhasa | | API- V |
| *Parmelia perlata* (Huds.) Ach. | Saileya | Lichen | API- III |
| | Charela | Lichen | UPI-V |
| *Peristrophe bicalyculata* (Retz.) Nees | Kakajangha | Seed | API- V |
| | Kakjangha | | UPI-V |
| *Phoenix dactylifera* L. | Khajur | Fruit | UPI-VI |
| | Kharjura | | API- IV |
| | Periccu | | SPI-II |
| *Phyla nodiflora* (L.) Greene | Jalapippali | Whole plant | API- V |
| | Potutalai | | SPI-I |
| *Phyllanthus amarus* Schum. & Thom. | Bhuiamla, | Dried aerial parts / Whole plant | IP- 2014 |
| | Kilkkai nellic camulam | | SPI-I |
| *Physalis alkekengi* L. | Kakanaja | Fruit | API- V |
| | Kaknaj | | UPI-V |
| *Picrorhiza kurroa Royle* ex *Benth.* | Katuku rokini | Root | SPI-I |
| | Kutki | | IP- 2014 |
| *Picrorhiza kurroa Royle* ex Benth. | Kutki | Rhizome | UPI-IV |
| | Picrorhiza | | IP- 66 |
| | Katuka | | API- II |
| *Pilocaprus jaborandi* Holmes. *Pilocarpus microphyllus* Stapf and other species of *Pilocarpus* | Jaborandi | Leaf | HPI-II |
| | Pilocarpini nitras | | IP- 55 |
| *Pimpinelia anisum* L. | Anisuna | Fruit | API- V |
| | Anisum, Anise | | IP- 66 |
| | Anisoon | | UPI-II |
| | Pimpinella anisum | | HPI-VIII |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Pinus gerardiana* Wall. | Nikocaka | Kernel | API- VI |
| | Maghz-e-Chilghoza | | UPI-VI |
| *Pinus longifolia* Roxb. | Colophonium | Exudate | IP- 55 |
| | Sarala | | API- V |
| *Pinus roxburghii* Sargent. | Sanobar | Root | UPI-V |
| | Sarala | | API- III |
| *Piper betle* L. | Nagavalli | Leaf | API- III |
| | Verrilai | | SPI-II |
| | Tambol | | UPI-VI |
| *Piper cubeba* L. | Kababchini | Fruit | UPI-I |
| | Kankola | | API- I |
| | Valmilaku | | SPI-I |
| | Cubeba officinalis | | HPI-III |
| *Piper longum* L. | Pippali | Fruit | API- IV |
| | Tippili | | SPI-I |
| | Pippali | | IP- 2014 |
| *Piper nigrum* L. | Marica | Fruit | API- III |
| | Milaku | | SPI-I |
| | Filfil Siyah | | UPI-IV |
| | Maricha | | IP- 2014 |
| | Piper nigrum | | HPI-III |
| *Pistacia lentiscus* L. | Mastagi | Resin | UPI-V |
| | Rumi Mastagi | | API- V |
| *Plantago ovata* Forsk. *Syn. Plantago ispaghul* Roxb. | Ispaghula Husk | Seed | IP- 2014 |
| | Aspaghol | | UPI-II |
| *Plumbago zeylanica* L. | Citrakah | Root | API- I |
| | Sheetraj Hindi | | UPI-I |
| *Polygonatum cirrhifolium* Royle | Mahameda | Root & Rhizome/ Rhizome | API- V |
| | Meda | | API- VI |
| *Pongamia pinnata* (L.) Pierre. | Punkan verpattai | Root bark | SPI-I |
| | Karanj | | UPI-IV |
| | Karanja | | API- II |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Pongamia pinnata* (L.) Pierre | Punkam vittu | Seed | SPI-I |
| | Karanj | | UPI-I |
| | Karanja | | API- I |
| *Pongamia pinnata* L. Pierre. | Karanj | Leaf | UPI-IV |
| | Karanja | | API- II |
| *Pongamia pinnata* L. Pierre. | Karanj | Root | UPI-IV |
| | Karanja | | API- II |
| *Pongamia pinnata* L. Pierre. | Karanja | Stem Bark | API- II |
| | Karanj | | UPI-IV |
| *Portulaca oleracea* L. | Khurfa | Whole plant | UPI-IV |
| | Kozuppa | | API- II |
| *Prosopis cineraria* Druce | Sami | Leaf | API- VI |
| | Vanni ilai | | SPI-II |
| *Prunus amygdalus* Batsch. *var. amara* DC. | Badam Shireen | Seed | UPI-II |
| | Amygdalus amara | | HPI-III |
| *Psoralea corylefolia* L. | Psoraleae semina | Seeds | IPL |
| | Psoralea corylifolia | | HPI-I |
| *Psoralea corylifolia* L. | Babchi | Fruit | UPI-I |
| | Bakuci | | API- I |
| | Karpokarici | | SPI-I |
| | Bakuci | | IP- 2014 |
| *Pterocarpus marsupium* Roxb. | Asana | Heart wood | API- I |
| | Vijayasara | | IP- 2014 |
| *Pterocarpus santalinus* L. | Sandal surkh | Heart Wood | UPI-V |
| | Cencantanak kattai | | SPI-II |
| | Raktacandana | | API- III |
| *Punica granatum* L. | Anar | Leaf | UPI-II |
| | Dadima | | API- IV |
| *Punica granatum* L. | Anar | Seed | UPI-VI |
| | Anardana | | UPI-II |
| | Dadima | | API- II |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Punica granatum* L. | Dadima | Fresh fruit | API- IV |
| | Matulam palam | | SPI-II |
| *Punica granatum* L. | Dadima | Fruit rind | API- IV |
| | Matulam palat tol | | SPI-II |
| *Quercus infectoria* Oliv. | Macikkay | Gall | SPI-II |
| | Mayakku | | API- IV |
| | Mazoo | | UPI-III |
| *Quillaja saponaria* Molina | Quillaia | Bark | IP- 66 |
| | Quillaya saponaria | | HPI-VI |
| *Raphanus sativus* L. | Turb | Seeds | UPI-V |
| | Mulaka | | API- III |
| *Raphanus sativus* L. | Turb | Root | UPI-V |
| | Mulaka | | API- II |
| | Raphanus sativus | | HPI-V |
| *Rauvolfia serpentina* Benth. ex Kurze. | Rauvolfia serpentina | Root | HPI-I |
| | Rauwolfia | | IP- 66 |
| | Sarpagandha | | API- V |
| | Asrol | | UPI-V |
| *Rheum emodi* Wall | Rheum, Rhubark | Dried rhizome & root / Root | IP- 66 |
| | Rewandchini | | UPI-II |
| *Ricinus communis* L. | Bed Anjeer | Seeds | UPI-IV |
| | Eranda | | API- III |
| | Ricinus communis | | HPI-III |
| *Rosa centifolia* L. | Gul-e-Surkh Satapatrika | Flowers | UPI-IV |
| | | | API- III |
| *Rubia cordifolia* L. | Majeeth | Stem | UPI-IV |
| | Manjistha | | API- III |
| | Manjistha | | IP- 2014 |
| *Saccharum officinarum* L. | Iksu | Stem | API- II |
| | Karumpu | | SPI-II |
| *Salvadora persica* L. | Pilu | Fruit | API- V |
| | Pilu | | UPI-V |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Santalum album* L. | Cantanak kattai | Heart wood | SPI-II |
| | Svetacandana | | API- III |
| | Sandal Safaid | | UPI-VI |
| *Saraca indica* L. | Ashoka, Ashok | Dried stem bark/ Bark | IP- 66 |
| | Janosia ashoka | | HPI-I |
| *Saussurea lappa* C.B. Clarke | Kustha | Root | API- I |
| | Qust | | UPI-I |
| | Saussurea | | IP- 66 |
| *Semecarpus anacardium* L. | Baladur | Fruit | UPI-IV |
| | Bhallataka | | API- II |
| | Cerankottai | | SPI-II |
| *Sesamum indicum* L. | Ellu | Seed | SPI-II |
| | Tila | | API- IV |
| *Sesbania sesban* (L.) Merr. | Jayanti | Leaf | API- II |
| | Karuncempai ilai | | SPI-I |
| *Sisvambrium irio* L. | Khubkalan | Seed | API- V |
| | Khaksi | | UPI-V |
| *Smilax china* L. | Madhusnuhi | Tuber root / Rhizome | API- V |
| | Parankic cakkai | | SPI-I |
| | Chob chini | | UPI-V |
| *Smilax ornata* Hook. f. | Sarsaparilla | | HPI-III |
| *Solanum nigrum* L. | Kakamaci | Whole plant | API- II |
| *Solanum nigrum* L. | Mako | Whole plant / Whole plant with fruit including root | UPI-IV |
| | Solanum nigrum | | HPI-II |
| *Solanum surattense* Burm.f. | Kantakari | Whole plant | API- I |
| | Kantan kattiric camulam | | SPI-I |
| | Solanum xanthocarpum | | HPI-VI |
| *Strophanthus gratus* (Wall. et Hook.) Franchet | Strophanthus gratus | Seed/ Seeds & wood | HPI-VIII |
| | Ouabainum, Ouabain | | IP- 55 |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Strychnos nuxvomica* L. | Azaraqi | Seed | UPI-II |
| | Etti vitai | | SPI-II |
| | Visamusti | | API- IV |
| | Nux vomica | | HPI-I |
| | Nux-vomina | | IP- 66 |
| *Strychnos potatorum* L. | Kataka | Seed | API- IV |
| | Terran kottai | | SPI-II |
| *Swertia chirata* Buch. (Ham.) | Chirata | Dried plant with flowers/ Whole plant/ Whole plant excluding root | IP- 66 |
| | Chiraita | | UPI-I |
| | Kiratatikta | | API- I |
| | Swertia chirata | | HPI-VIII |
| *Symplocos racemosa* Roxb. | Lodh Pathani | Stem bark | UPI-I |
| | Lodhra | | API- I |
| *Syzigium aromaticum* (L.) Merr. & L.M. Perry. | Lavang | Flower bud | IP- 2014 |
| | Ilavankam | | SPI-I |
| | Lavanga | | API- I |
| | Quranful | | UPI-I |
| *Syzygium aromaticum* (Linn.) Merr. and Perry | Clove bud oil | Flower bud | IP- 2014 |
| | Lavanga Taila | | API- VI |
| *Syzygium cuminii* (L.) Skeels | Jamun | Seeds | UPI-IV |
| | Jambu | | API- II |
| | Syzygium jambolanum | | HPI-I |
| | Jamun | | UPI-IV |
| *Syzygium cuminii* (L.) Skeels | Jambu | Stem bark | API- II |
| | Naval pattai | | SPI-II |
| *Tamarindus indica* L. | Cinca | Fruit pulp | API- IV |
| | Puliyam palam | | SPI-II |
| | Tamar Hindi | | UPI-VI |
| *Taxus baccata* L. | Sthauneya | Leaf/ Twig | API- III |
| | Taxus baccata | | HPI-III |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Terminalia arjuna* (Roxb) Wight & Arn | Arjuna | Stem bark | API- II |
| | Arjuna, | | IP- 2014 |
| | Marutam pattai | | SPI-I |
| | Arjun | | UPI-IV |
| | Terminalis arjuna | | HPI-I |
| *Terminalia belerica* (Gaertn.) Roxb. | Tanrikkai | Fruit | SPI-I |
| | Balela | | UPI-I |
| | Bibhitaka | | API- I |
| | Bhibhitaki | | IP- 2014 |
| *Terminalia chebula* Retz | Terminalia chebula | Fruit | HPI-II |
| | Halela Zard | | UPI-I |
| | Haritaki | | IP- 2014 |
| | Haritaki | | API- I |
| | Katukkai | | SPI-I |
| *Tinospora cordifolia* (Willd) Miers | Gilo | Stem | UPI-I |
| | Guduchi | | IP- 2014 |
| | Guduchi | | API- I |
| | Cintil tantu | | SPI-I |
| | Tinospora cordifolia | | HPI-II |
| *Trachyspermum ammi* (L.) Sprague | Yavani | Fruit | API- I |
| | Omam | | SPI-II |
| | Ajwain | | UPI-VI |
| | Ajwain | | IP- 2014 |
| *Tribulus terrestris* L. | Khar-e-Khasak Khurd | Fruit | UPI-I |
| | Nerunci mul | | SPI-I |
| | Gokhru | | IP- 2014 |
| | Goksura | | API- I |
| *Tribulus terrestris* L. | Goksura | Whole plant | API- VI |
| | Neruncil camulam | | SPI-II |
| | Tribulus terrestris | | HPI-I |
| *Tribulus terrestris* L. | Goksura | Root | API- I |
| | Nerunci ver | | SPI-I |
| | Visala | | API- V |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Trigonella foenum-graecum* L. | Hulba | Seed | UPI-II |
| | Hulba | | UPI-IV |
| | Methi | | IP- 2014 |
| | Vantayam | | SPI-I |
| | Methi | | API- II |
| *Valeriana officinalis* L. or *Valeriana wallichi* DC | Valerian Root, | Dried whole or cut underground parts (rhizome, roots and stolons) | IP- 2014 |
| | Valerians officinalis | | HPI-II |
| | Tagar | | UPI-I |
| | Tagara | | API- I |
| *Vateria indica* L. | Raal | Exud. | UPI-VI |
| | Sarja | | API- IV |
| *Vetiveria zizaniodes* (L.) Nash | Vetti ver | Root | SPI-II |
| | Usira | | API- III |
| | Khas | | UPI-IV |
| *Vigna unguiculata* (L.) Walp. | Kollu | Seed | SPI-I |
| | Kulattha | | API- I |
| | Kulthi | | UPI-I |
| *Vitex negundo* L. | Nirgundi | Leaf | API- III |
| | Nocci ilai | | SPI-II |
| | Sambhalu | | UPI-V |
| *Vitex negundo* L. Syn. *Vitex bicolor* Willd. | Sanbhalu | Fruits | UPI-III |
| | Renuka | | API- V |
| *Vitis vinifera* L. | Angoor | Fruits/dried fruit | UPI-VI |
| | Maweez Munaqqa | | UPI-IV |
| | Tiratcai | | SPI-II |
| *Withania somnifera* (L.) Dunal | Ashwagandha | Root | IP- 2014 |
| | Amukkara | | SPI-I |
| | Asvagandha | | API- I |
| | Asgand | | UPI-I |
| | Withania somnifera | | HPI- VIII |

| Botanical Name (as specified in Pharmacopoeial Monograph) | Pharmacopoeial / Monograph Title | Morphological Part specified as drug | Regulatory / Pharmacopoeial References |
|---|---|---|---|
| *Xeromphis spinosa* (Thunb) Keay | Mainphal | Fruit | UPI-I |
| | Madana | | API- I |
| *Zingiber officinale* Rosc. | Adrak | Rhizome | UPI-IV |
| | Ardraka | | API- II |
| | Cukku | | SPI-I |
| | Inci | | SPI-I |
| | Zanjabeel | | UPI-I |
| | Zingiber | | HPI-II |
| | Sunthi | | API- I |
| | Ginger, Zingiber | | IP- 66 |

Abbreviations: IP-Indian Pharmacopoeia, API-Ayurvedic Pharmacopoeia of India, SPI-Siddha Pharmacopoeia of India, UPI- Unani Pharmacopoeia of India and HPI-Homoeopathy Pharmacopoeia of India.

The role of herbal drugs is rather complex one from a regulatory standpoint. A fair number of herbal drugs which are commonly used in Ayurvedic, Siddha, Unani, Homoeopathic and modern system of medicine, have been incorporated in respective Indian pharmacopoeias. These herbal drugs (common in botanical specification / source) fall within more than one pharmacopoeia and required to be harmonized with the monographs in other pharmacopoeias. The quality of herbal drugs are always prime issue and dealt with regulatory provisions of pharmacopoeial monographs. The harmonized pharmacopoeial monographs will be yardstick to ensure the quality, safety and efficacy of herbal drugs without any ambiguity.

## References


Anonymous, 1940. Drugs & Cosmetics Act and Rules. Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 1946. The Indian Pharmacopoeia. Manager of Publications, Govt. of India, New Delhi.

Anonymous, 1955. Pharmacopoeia of India, First ed. Manager of Publications, Govt. of India New Delhi.

Anonymous, 1966. Pharmacopoeia of India, Second ed. Manager of Publications, Govt. of India New Delhi.

Anonymous, 1971. Homoeopathic Pharmacopoeia of India, Vol. I. Government of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 1974. Homoeopathic Pharmacopoeia of India, Vol. II. Government of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 1978. Homoeopathic Pharmacopoeia of India, Vol. III. Government of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 1984. Homoeopathic Pharmacopoeia of India, Vol. IV. Government of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 1985. Pharmacopoeia of India Vol-I&II. Third ed. Manager of Publications, Govt. of India New Delhi.

Anonymous, 1986. The Ayurvedic Pharmacopoeia of India, Part- I, Volume–I, First edition, Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 1987. Homoeopathic Pharmacopoeia of India, Vol. V. Government of India, Ministry of Health & Family Welfare, New Delhi.

Frank B., 1989 Botanical specifications. Deutsche Apotheker Zeitung 129: 617-623.

Anonymous, 1990. Homoeopathic Pharmacopoeia of India, Vol. VI. Government of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 1992. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, WHO/Pharm/92.559; document for discussion.

Anonymous, 1996. Pharmacopoeia of India (The Indian Pharmacopoeia), Vol-I&II. Fourth ed. Manager of Publications, Govt. of India New Delhi.

Anonymous, 1998. The Unani Pharmacopoeia of India, Part-I, Vol.-I Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 1999a. The Ayurvedic Pharmacopoeia of India, Part- I, Volume–II, First edition, Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 1999b. Homoeopathic Pharmacopoeia of India, Vol. VII. Government of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 2000. Homoeopathic Pharmacopoeia of India, Vol. VIII. Government of India,

Anonymous ,2001. The Ayurvedic Pharmacopoeia of India, Part- I, Volume–III, First edition. Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 2004. The Ayurvedic Pharmacopoeia of India, Part- I, Volume–IV, First edition. Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 2006a. The Ayurvedic Pharmacopoeia of India, Part-I, Volume–V, First edition. Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 2006b. Homoeopathic Pharmacopoeia of India, Vol. IX. Government of India, Ministry

Anonymous, 2007a. Pharmacopoeia of India (The Indian Pharmacopoeia) Vol-I, II& III. Fifth ed. The Indian Pharmacopoeia Commission, Govt. of India, Ministry of Health and Family Welfare, Ghaziabad.

Anonymous, 2007b. The Unani Pharmacopoeia of India, Part-I, Vol.-II. Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 2007c. The Unani Pharmacopoeia of India, Part-I, Vol.-III. Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 2007d. The Unani Pharmacopoeia of India, Part-I, Vol.-IV. Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 2008a. The Ayurvedic Pharmacopoeia of India, Part- I, Volume-VI, First edition. Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 2008b. The Ayurvedic Pharmacopoeia of India, Part-I, Volume-VIII. First edition. Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 2008c. The Unani Pharmacopoeia of India, Part-I, Vol.-V. Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 2008d. The Siddha Pharmacopoeia of India, Part-I, Vol.-I. Govt. of India, Ministry of Health & Family Welfare, New Delhi

Anonymous, 2009. The Unani Pharmacopoeia of India, Part-I, Vol.-VI. Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 2010a. Pharmacopoeia of India (The Indian Pharmacopoeia) Vol-I, II& III. sixth ed. The Indian Pharmacopoeia Commission, Govt. of India, Ministry of Health and Family Welfare, Ghaziabad.

Anonymous, 2010b. The Siddha Pharmacopoeia of India, Part-I, Vol.-II. Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 2014. Pharmacopoeia of India (The Indian Pharmacopoeia) Vol-I, II& III. seventh ed. The Indian Pharmacopoeia Commission, Govt. of India, Ministry of Health and Family Welfare, Ghaziabad.

Rai, Nitin, Lalit Tiwari and Rajeev Kr. Sharma, 2012. Quality standards on medicinal plants with special reference to regulatory aspects. In: Modern Technologies for Sustainable Agriculture (eds. Birendra Prasad and Sunil Kumar). Chapter 9, pp: 147-175.

Tiwari, Lalit, Nitin Rai and Rajeev Kr. Sharma, 2013. Regulatory Standards on Homoeopathic Drugs: Indian Perspective. *Int. J. Adv. Pharma. Sci. & Tech* 1(1): 1-20.

# Ethnomedicinal Practices among Rural and Tribal Populations in Dhenkanal District of Odisha, India

**[1]*Mukesh Kumar, [2]Mokhtar Alam, [1]Hakimuddin Khan, [1]Kishore Kumar, [3]Aminuddin and [1]L. Samiulla**

[1]Regional Research Institute of Unani Medicine, Bhadrak-756 100

[2]Drug Standardization Research Institute, PLIM Campus, Ghaziabad-201 002

[3]Central Council for Research in Unani Medicine (CCRUM), 61-65 Institutional Area, Janakpuri, New Delhi-110 058

## Abstract

Ethnobotanical field investigations of medicinal plants was carried out in Dhenkanal forest division, Odisha in March, 2014. During survey, 148 medicinal species were collected and identified from the study area. Of these, 21 species belonging to 20 genera and 14 families have been found to be used by local inhabitants for treating their common diseases and conditions. The information on folk medicinal uses of plants viz. botanical name, family, Unani name (if any), mode of application etc. have been presented in this paper.

**Keywords :** Ethnomedicines, Dhenkanal forests, Odisha, Medicinal plants

## Introduction

The value and importance of traditional knowledge are now being increasingly realized the world over (Pushpangdan and Kumar, 2005). And, ethnobotanical study, in particular provides immense scope and opportunities for those engaged in the bioprospecting of drugs, chemicals and gene prospecting. It is in this context that about 75% of the 120 biologically active plant-derived compounds presently in use worldwide have been derived through follow-up investigations to confirm the authenticity of field data from folk and ethnomedicinal uses (Farnsworth *et al.,* 1985). The present investigations are based on this rationale and provide first-hand information on 21 medicinal species widely used in folk treatment of various diseases and conditions by the tribals and ethnic groups of the study area (Fig. 1) with a view to provide lead material for the discovery of new drugs of plant origin.

### The Study Area

The Dhenkanal district is situated in the central part of the Odisha (Fig. 1) and covers an area of 4452 Sq Km. It lies between longitude 85° 58' to 86° 2' East and latitude 20° 29' to 21° 11' North. Most of this district is covered with dense forest and a long range of hills, which are home of wild elephant and tigers. The forests in the region are Tropical mixed deciduous forest, Tropical dry deciduous forest and Tropical Moist deciduous forest. The climate of Dhenkanal is warm and humid. May is the hottest month of the year with mean daily maximum temperature of 44.5C. The minimum temperature in December is 11C. The average minimum & maximum temperatures are 14.0C and 38.7C respectively. The average rainfall of the division is 1421 mm. The forest division is botanically under-explored for its potentially important medicinally

[1]* Author for correspondence

useful plants. Twenty six tribal communities viz. Sabara, Saora, Juanga, Saunti, Santal, Pendia, Paraja, Oraon, Munda, Mirdha, Matia, Mankidi, Mahali, Lodha, Koya, Kora, Kolha, Kishan, Kandha, Haria, Ho, Gand, Dharua, Binjhal, Bhumij and Bhuyan exist in the district.


Fig. 1: Map of the study area

The detailed ethnomedicinal study of the district has been taken up by the authors with a view to enlist to plant resources and their utilization by the natives. Ethnobotanical plants are known for their therapeutically interest in both organized system of medicine such as Unani and Ayurveda as well as unorganized system of medicine such as Folk medicine. They exhibit great chemical diversity and several of them have been listed as source of valuable drugs (Kirtikar & Basu, 1935; Khare, 2007). Our study has shown that these people have accumulated a wide knowledge in the usage of plant wealth over the centuries. The present paper gives an account of 21 plant species belonging to 14 families used by the natives in the treatment of various diseases. Most of the uses were found duly reported when compared with published literature on Indian Ethnobotany (Jain, 1991; Chopra *et al.,* 1956).

## Materials and Methods

Ethnobotanical field trip was undertaken during March, 2014 in order to explore the traditional knowledge of the inhabitants of Dhenkanal forest division and to make collections of native medicinal plants. Information regarding medicinal plants was obtained through field interviews with tribal people who practice indigenous medicine. In many cases, it was necessary to make a good

rapport with these people in order to win over their confidence. Most of the information included in this study was gathered from elderly and experienced practitioners who were very knowledgeable about medicinal plants. Our field notebook delineates all the usage procedures adopted by these tribal people. The gathered data were cross-checked for reliability and accuracy by interacting with different groups of the tribals from other areas to confirm the use, mode of administration and dosage differences of the herbal materials, if any. The medicinal plants were botanically identified by using the 'Flora of Orissa' (Saxena & Brahmam, 1994-1996) and the 'Botany of Bihar & Orissa' (Haines, 1921-25). After eliciting detailed information regarding the wild medicinal plants, the collected materials were carefully brought to the Survey of Medicinal Plants Unit, Regional Research Institute of Unani Medicine, Bhadrak, for identification and processing. Herbarium sheets for all the collected plant specimens were prepared and deposited in the Herbarium of Survey of Medicinal Plants Unit, Regional Research Institute of Unani Medicine, Bhadrak, India, for future reference and study.

## Enumeration

The medicinal plants used as folk medicine in the study area are arranged in alphabetical order. Their botanical name, family in bracket, local name, Unani name (if any), locality with collection number, part used, name of the disease(s) against which used, mode of preparation and administration and Informant who shared his valuable information are given for each recipe discussed.

*Bauhinia variegata* L. (Caesalpiniaceae); Kanchan; Nuagarh-9865; Root bark; Skin diseases & leprosy. Root bark paste is applied in skin diseases & leprosy (Jena).

*Buchanania lanzan* Spreng. (Anacardiaceae); Char; Hub-us-Samena; Bisiriduma-5957; Fruit; Nervous debility. Roasted fruits are eaten to treat nervous debility (R. Sahoo).

*Clitoria ternatea* L. (Fabaceae); Aparajita; Gengutia-9851; Seed; Leprosy & leucoderma. Powered seed is applied locally in leprosy & leucoderma (Savita Sahoo).

*Cryptolepis buchananii* Roem. & Schultz. (Periplocaceae); Gopakano; Tapovan-9843; Latex; wounds. Latex is applied locally on wounds & fungal infection during rainy season (Niranjan Mahapatra).

*Desmodium oojeinensis* (Roxb.) Ohashi (Fabaceae); Bandhan; Kapilash-9879; Stem Bark; Diabetes & Gonorrhea. Crushed stem bark is boiled with water and

juice is taken two teaspoonful daily to treat diabetes & gonorrhea (Santosh Mohanty).

*Gardenia gummifera* L.f. (Rubiaceae); Ghurudu; Ral; Bisiriduma-9761; Resin; Intestinal worms. 1-2 g. resins are taken early morning to treat intestinal worms (Vipul Nayak).

*Gmelina arborea* Roxb. (Verbenaceae); Gambhari; Bhauraguda-9796; Whole Plant; Skin diseases. Plant juice is applied locally in skin diseases (P. Behera).

*Gymnema sylvestre* (Retz.) R. Br. *ex* Schultz. (Asclepiadaceae); Merasingi; Gurmarbuti; Gengutia-9853; Whole Plant, Leaves; Liver disorders & Paralysis. Plant juice one teaspoonful is taken twice daily as liver tonic. Fresh leaves are chewed for paralyzing and cure the sweet & bitter taste (T. Sahoo).

*Holarrhena pubescens* (Buch.-Ham.) Wall. *ex* G. Don (Apocynaceae); Kurmi; Inderjo Talkh; Bankua Forest-9892; Seed; Diarrhoea & Dysentery. Crushed seed one teaspoonful is taken to treat diarrhoea & dysentery (Patra).

*Mesua ferrea* L. (Clusiaceae); Nagkesar; Narmushk; Saptasajya-9824; Flower, Oil; Aphrodisiac. Flowers & oil is used as aphrodisiac (Kondu Sahu).

*Mimusops elengi* L. (Sapotaceae); Baulo; Maulsari; Hindol-9896; Flower, Fruit; Dental Care. Flowers are used as brain tonic. Unripe fruit is chewed to strengthen and fix loose teeth (Patra).

*Pterocarpus marsupium* Roxb. (Fabaceae); Piyasal; Bijasar; Bisiriduma-9770; Gum; Liver disorders. Gum (1 g.) is taken daily on empty stomach as liver tonic (Churu Munda).

*Pterocarpus santalinus* L.f. (Fabaceae); Raktachandan; Sandal Surkh; Saptasajya-9823; Heartwood, Fruits; Mental diseases. Heartwood & fruits are used as decoction in mental problems (Sampat Sahoo).

*Pterospermum xylocarpum* (Gaertn.) S. & W. (Sterculiaceae); Giringa; Machkan; Bisiriduma-9779; Tender leaves, Flowers; Diarrhoea & Dysentery. Crushed juice of tender leaves and flowers, one teaspoonful, is used twice daily for three days to treat diarrhoea & dysentery (Bhagwan Das).

*Rauvolfia serpentina* (L.) Benth. (Apocynaceae); Patalgaruda; Asrol; Saptasajya-9832; Root; Hypertension. Powdered root one gm is taken daily to treat hypertension (Brahmam Das).

*Santalum album* L. (Santalaceae); Chandan; Sandal Safaid; Saptasajya-9828; Heartwood; Cardiac disorders. The glass made of heartwood and filled with water overnight taken early morning as cardic tonic (Nakuri).

*Saraca asoca* (Roxb.) de Wilde (Caesalpiniaceae); Ashok; Ashok; Mahisapat-9809; Flower; Diabetes. Flowers juice, one teaspoonful, is taken twice daily to treat diabetes (Rakesh Jena).

*Semecarpus anacardium* L.f. (Anacardiaceae); Bhalia; Baladur; Kapilash-9878; Fruit; Diabetes. Fruit is boiled in water for few minutes, then dried & powdered; 1 g. powder is taken in morning with water daily to control diabetes. (Jena).

*Terminalia alata* Heyne *ex* Roth. (Combretaceae); Asana; Bisiriduma-9789; Stem bark; Diabetes; Stem bark is boiled in water & one cup extract is taken daily for a month for treating diabetes and also acts as cardic tonic (R. Behera).

*Tinospora cordifolia* (Willd.) Hook.f. & Th. (Menispermaceae); Gulochi; Gilo; Gengutia-9852; Stem; Fever. Crushed stem is boiled with water till it become half. The residue, two tea spoonful is taken daily to subside chronic fever (Bhagwanpati).

*Vitex negundo* L. (Verbenaceae); Begonia, Baija; Sambhalu; Bisiriduma-9791; Leaf; Fever. Leaf juice one teaspoonful is taken twice daily for five days to treat common fever (P. Sahoo).

*Buchanania lanzan* Spreng.

*Cryptolepis buchananii* Roem. & Schultz.

*Gmelina arborea* Roxb.

*Pterospermum xylocarpum* (Gaertn.) S. & W.

*Saraca asoca* (Roxb.) de Wilde *Tinospora cordifolia* (Willd.) Hook.f. & Th.

Fig. 2 : Some Interesting Folk Medicinal Plants of The Study Area

## Results and Discussion

In the present investigation 21 medicinal plants are reportedly used by tribals and other ethnic people used for the treatment of various diseases and conditions e.g., dental care, fever, diarrhoea & dysentery, wounds, nervous disorders and diabetes etc. The utility lies through their roots, stem bark, latex, leaves, fruits and seeds. These are taken internally or applied externally in the form of infusion, juice, decoction, paste or powder. Most of the plants used in folk medicines are either mixed with other ingredients or single.

A perusal of the ethnobotanical survey records reveals that a number of outstanding botanists led several studies in the district and different parts of Odisha (Ali *et al.*, 2010; Aminuddin and Girach, 1996; Aminuddin *et al.*, 2013, Dash *et al.*, 2003; Girach *et al*., 1994, 2011; Kandari *et al.*, 2012; Mohanty *et al.*, 2011; Mohapatra and Sahoo, 2008; Mudgal and Pal, 1980, Mukesh *et al.*, 2012, 2013a, 2013b, 2014; Mund and Satapathy, 2011; Sahu and Dhal, 2012; Sahu *et al.*, 2013a, 2013b; Singh, 2012; Singh *et al.*, 2010; Tripathy and Behera, 2008 etc.). It was found that most of the folk medicinal plants are duly reported in the literature, however, their mode of application, ingredients and part used are different. Therefore, the present study represents the existing folk uses of medicinal plants of the area investigated. It would be worthwhile to subject all these folk drugs to scientific testing in the context of claims reported herein in an effort to find treatment for many diseases thus for incurable in modern medicine.

Furthermore, it has been observed that un-judicious exploration of some species by the local tribes and medicinal plants collectors have created an alarming situation for these plants resources. Besides, forest resources have been depleted fast due to rapid industrialization and urbanization of the district.

We suggest many such ethnobotanical surveys in order to get filed data about the unexploited, underexploited and threatened medicinal plants of the region.

## Acknowledgements

Authors sincerely acknowledge the encouragement and support provided by Prof. S. Shakir Jamil, Director General, Central Council for Research in Unani Medicine (CCRUM), New Delhi, to carry out this research work. We also wish to express our gratitude to all the staff of Dhenkanal forest division, Dhenkanal and tribal/ethnic people for their help, cooperation and sharing their valuable information during the ethnobotanical survey tour.

## References

Ali, Z. A., Hussaini, S. A. and Mukesh K., 2010. Traditional Phytoremedies in Health Care among the Forest Ethnics of Balasore District, Orissa. *Hippo. J. Unani Med.* 5 (1): 43-52.

Aminuddin and Girach R. D., 1996. Native phytotherapy among the Paudi Bhuinya of Bonai Hills. *Ethnobotany* 8:66–70.

Aminuddin, Hussaini, S. A., Mukesh K. and L. Samiulla, 2013. Ethnobotanical Survey of Konark Forests of District Puri, Odisha. *Hippo. J. Unani Med*. 8 (2): 83-89.

Brahmam, M., Dhal N K., Saxena H.O., 1996. Ethnobotanical studies among the Tanla of Malyagiri hills in Dhenkanal district, Orissa, India. In: Jain, S.K. (ed.) Ethnobiology in Human Welfare. Deep Publications, New Delhi pp. 393 – 396.

Chopra, R.N., Nayar, S.L. and Chopra, I.C., 1956. Glossary of Indian Medicinal Plants. Council of Scientific & Industrial Research, New Delhi.

Dash, P., Satapathy, K. B. and Dash B., 2003. Ethnobotanical Studies among Bathudi Tribes of the Keonjhar district, Orissa, India. *e-planet* 1(2): 21-26.

Farnsworth, N.R., Akerele, O., Bingel, A.S., Soejarto, D.D., Guao, Z., 1985. *Bull. World Health Organization* 63(6): 965-981.

Girach, R.D., Aminuddin, Siddiqui, P.A., Khan, S.A., 1994. Traditional Plant Remedies Among the Kondh of District Dhenkanal (Orissa). *Pharm. Biol*. 32(3): 274-283.

Girach, R.D., Aminuddin, Hussaini, S.A. and Mukesh, K., 2011. Ethnomedicinal Studies on *Alangium salvifolium* (L. f.) Wang. from Orissa. *Hippo. J. Unani Med*. 6 (1): 35-42.

Haines H.H., 1921-25. Botany of Bihar and Orissa. (Repr.1961). Botanical Survey of India, Calcutta.

Jain S.K., 1991. Dictionary of Indian Ethnobotany and Folk Medicine. Deep Publications, New Delhi.

Khare C.P., 2007. Indian Medicinal Plants: An Illustrated Dictionary. Springer (India) Private Limited, New Delhi.

Kirtikar K.R. and Basu B.D., 1935. Indian Medicinal Plants, Vol. I – IV. Periodical Experts, Delhi, India.

Kandari, L.S., Gharai, A.K., Negi, T. and Phondani, P.C., 2012. Ethnobotanical Knowledge of Medicinal Plants among Tribal Communities in Orissa, India. *Forest Res*. 1:1-5.

Mohanty, R.B., 2010. New wild edible plants from some tribal pockets of Dhenkanal district, Odisha. *Ethnobotany* 22:113.

Mohanty, R.B. & Rout, M.K., 2001. Traditional Phytotherapy for Diarrhoeal Diseases in Dhenkanal district of Orissa, India. *Ancient Science of Life* 20: 1-3.

Mohanty, N., Das, P. K., Panda, T., 2011. Use of plant diversity in household and rituals by tribal people of Dhenkanal district, Odisha, India. *Journal of Applied Pharmaceutical Science* 1(4): 79-82.

Mohapatra, S.P., Sahoo, H.P., 2008. Some lesser known medicinal plants of the Kondha and Gond tribes of Bolangir, Orissa, India. *Ethnobot. leaf.* 12:1003–6.

Mudgal, V. and Pal, D.C., 1980. Medicinal Plants used by Tribals of Mayurbhanj (Orissa). *Bull. Bot. Surv. India* 22:59–62.

Mukesh K., Hussaini, S.A., Samiulla, L., Kishore K., Khan, S. A., Aminuddin and Jamil, S.S., 2012. Ethnomedicinal Observations from the Anantprasad and Jeypur Tribal Villages of district Cuttack, Odisha, India. *J.A.P.Science* 2(11): 127-130.

Mukesh K., Hussaini, S.A., Aminuddin, Shamshad A. and Samiulla, L., 2013. Ethnomedicinal Studies in Narsinghpur Forests of Athagarh Forest Division, District Cuttack, Odisha. *Hippo. J. Unani Med.* 8 (2): 99-107.

Mukesh K., Mokhtar A., Zakir M., Khan H., Kishore Kumar, Aminuddin and Samiulla, L., 2014. Ethnopharmacological Studies in Health Care Among the Tribals of Angul Forest Division, Odisha. *Hippo. J. Unani Med.* 8 (2): 99-107.

Mund, N. K. and Satapathy, K.B., 2011. Notes on the traditional use of plants to treat snake-bite in Kalahandi district of Odisha. *Biohelica* 2: 15-20

Pushpangadan, P., and B. Kumar, 2005. Ethnobotany, CBD, WTO and the Biodiversity Act of India. *Ethnobotany* 17: 2-12.

Sahu, S.C. and Dhal, N.K., 2012. Floristic Composition, Diversity and Status of Threatened Medicinal Plants in Tropical Forests of Malyagiri Hill Ranges, Eastern Ghats, India. In : (Ed. Padmini Sudarshana), Tropical Forests, pp. 203-214.

Sahu, C.R., Nayak, R.K. and N.K. Dhal, 2013. Ethnomedicine and magico-religious beliefs of the kondh tribe in Boudh district of Odisha, India. *Life Sciences Leaflets 11: 10-22.*

Sahu, C. R., Nayak, R. K. and N. K. Dhal, 2013. Traditional Herbal Remedies for Various Diseases Used By Tribals of Boudh District, Odisha, India for Sustainable Development. *International Journal of Herbal Medicine* 1(1): 12-20.

Saxena H. O. and Brahmam M. 1994-1996. Flora of Orissa. Vol. I-IV. Regional Research Laboratory, Bhubaneswar.

Singh, H. 2012. Traditional phytotherapy for the treatment of hydrocele in Odisha, India. *Anc. Sci. Life*. 31(3): 137–140.

Singh, H., Srivastava, S.C., Krishna, G. and Kumar, A., 2010. Comprehensive Ethnobotanical study of Sundargarh District, Orissa, India. In: Trivedi P.C., (Ed.) Ethnic Tribes and Medicinal Plants. Jaipur Pointer Publishers, pp. 89–106.

Tripathy, N.K., and Behera, N., 2008. Traditional methods of crop protection used in Bolangir district of Orissa. *Ethnobotany* 20:147–9.

# Pharmacognostical Evaluation of *Fagonia cretica* Linn.

***K.P. Modi, K.N. Shah, S.K. Lahiri and M.B. Shah**

Department of Pharmacognosy,
L. M. College of Pharmacy,
Gujarat University,
Ahmedabad-380009, Gujarat, India

## Abstract

*Fagonia cretica* Linn. is widely distributed in dry lands of India. It has been used in traditional system of medicine as bitter tonic and febrifuge. The whole plant of F. cretica was subjected to macro and microscopical examination followed by physicochemical study. It is small woody herb with tortuous root, highly branched stem, elliptic leaves and purplish coloured flowers. Roots are characterized by lignified cork, cortical fibres, wide phloem and xylem. Stem shows the presence of a group of lignified fibres under epidermis, pericycle (containing discontinuous groups of the fibres and stone cells) and a wide stellar region followed by small pith. Transverse section of the leaf shows palisade cells, centric mesophyll and collateral vascular bundle in midrib. Powder shows the presence of covering trichomes, epidermis, stone cells, sclerenchyma and lignified cork. Saponins, flavanoids and alkaloids were found be major components. TLC study using silica gel plate as a stationary phase and Toluene: Ethyl formate: Formic acid (5: 4: 0.1) as a mobile phase shows the presence of isorhamnetin.

**Key words:** *Fagonia cretica*, Isorhamnetin, TLC, Zygophyllaceae.

## Introduction

*Fagonia cretica* Linn. (Syn.: *F. schweifurthii* Hadidi, *F. arabica* Hook. f., *F. indica* Burm. f.; Family: Zygophyllaceae.) is commonly known as Durlabha (Sans.); Dhamaasaa (Unani); Dhamaso (Guj.) and Khorason thorn (Eng.) (Rastogi and Mehrotra, 1990; Khare, 2007). It is a small spiny under-shrub, found in North West India, Punjab, Deccan and Afghanistan (Chopra *et al*., 1958; Chopra *et al*., 1956; Hooker, 1875).

The plant is highly valued in traditional medicine as a febrifuge, antiasthmatic and useful in skin diseases (Kirtikar and Basu, 1975; Nadkarni, 1954).

Flavonoids reported in plant include isorhamnetin 3-glucoside and isorhamnetin 3-rutinoside, herbacetin 8-rutinoside, kaempferol, quercetin and isorhamnetin (El-Negoumy *et al*., 1986; El-Hadidi *et al*., 1988). Oleanolic acid and ursolic acid are the triterpenoid saponins reported in the plant (Miyase *et al*., 1996; Rahman *et al*., 1982).

The present study aims at establishing quality parameters and TLC profile for isorhamnetin.

* Author for correspondence

## Materials and Methods

### Plant Material

Fresh, fully-grown, flowering plants of *F. cretica* Linn. were collected from Gujarat [Bhuj (A) and Jamnagar (B)] and Rajasthan [Jodhpur(C)] in the month of November, 2009. The plants collected were authenticated by taxonomist of Gujarat Ayurveda University, Jamnagar, Gujarat. Voucher specimen samples (LM 581—LM 583) were deposited at the Department of Pharmacognosy, L. M. College of Pharmacy, Ahmedabad, Gujarat. The plant materials were cleaned, dried, powdered to 60 # and used for the experimental work.

### Pharmacognostical Studies

Whole plants were studied for morphological characters. Microscopical study was performed for both entire (free-hand transverse sections of leaf, stem and root) and powdered material. Quantitative microscopy was carried out on leaf for determining the stomatal number, stomatal index and palisade ratio. The data was compared with the literature (Anonymous, 2006).

Moisture content (Anonymous, 2006a), ash values and extractive value were determined (Anonymous, 2002).

### Phytochemical Studies

Phytochemical screening (Shah *et al.*, 2010) was performed with the use of alcoholic extract and saponin (Anonymous, 2002), flavonoid, phenolic (Kalola and Shah, 2006), alkaloid (Sreevidya and Mehrotra, 2003) and carbohydrate (Hodge and Hofreiter, 1962) contents were estimated.

### TLC of Isorhamnetin

Powdered plant material of three samples (10 g) were extracted thrice with methanol separately, by sonication for 10 min and filtered. Extracts were evaporated to dryness. 5 mg of residues were dissolved in 5 ml methanol. The resulting solutions were centrifuged at 3000 rpm for 5 min and the supernatant collected were analysed for drug content by applying 3 µl of each of the solution to a plate.

A stock solution (100 µg $ml^{-1}$) of isorhamnetin was prepared by dissolving 1 mg in 10 ml methanol in a 10 ml volumetric flask.

Table 1 : Quantitative microscopy of *Fagonia cretica* Linn. leaf

| Parameters | Samples | | |
|---|---|---|---|
| | A | B | C |
| *Stomatal number:*<br>Upper surface<br>Lower surface | <br>147 ± 2<br>118 ± 2.4 | <br>224 ± 4<br>195 ± 3 | <br>177 ± 3<br>104 ± 2 |
| *Stomatal index:*<br>Upper surface<br>Lower surface | 12.52 ± 0.98<br>12.79 ± 0.30 | 17.49 ± 0.09<br>16.62 ± 0.49 | 13.19 ± 0.13<br>12.66 ± 0.96 |
| *Palisade ratio:*<br>Upper surface<br>Lower surface | 2.58 ± 0.14<br>1.83 ± 0.14 | 2.75 ± 0.25<br>2.5 ± 0.25 | 2.83 ± 0.28<br>1.83 ± 0.14 |

Number of readings = 3

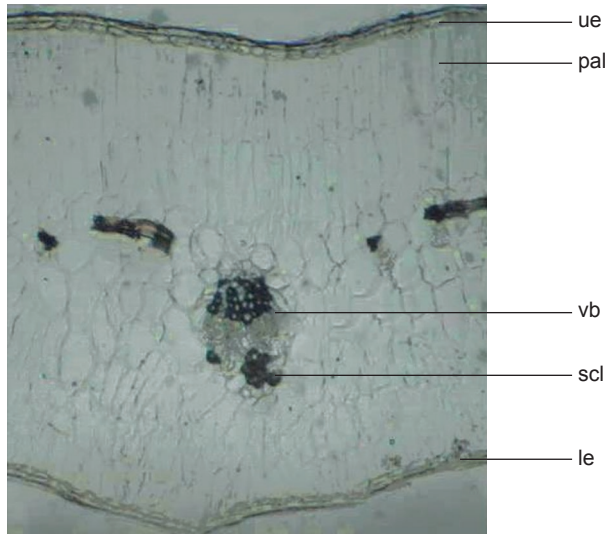
Table 2 : Physico-chemical parameters of *F. cretica* whole plant

| Particulars | Samples (% w/w ± SD) | | |
|---|---|---|---|
| | A | B | C |
| Loss on Drying | 52.72 | 54.44 | 53.89 |
| Total ash | 9.86 ± 0.85 | 9.27 ± 0.35 | 7.09 ± 0.59 |
| Water soluble ash | 4.65 ± 0.28 | 4.61 ± 0.44 | 3.02 ± 0.07 |
| Acid insoluble ash | 1.14 ± 0.16 | 0.67 ± 0.09 | 0.62 ± 0.07 |
| Water soluble extractive value | 26.6 ± 0.9 | 26.26 ± 0.01 | 29.89 ± 0.53 |
| Alcohol soluble extractive value | 22.3 ± 1.51 | 28.0 ± 0.81 | 24.46 ± 0.95 |

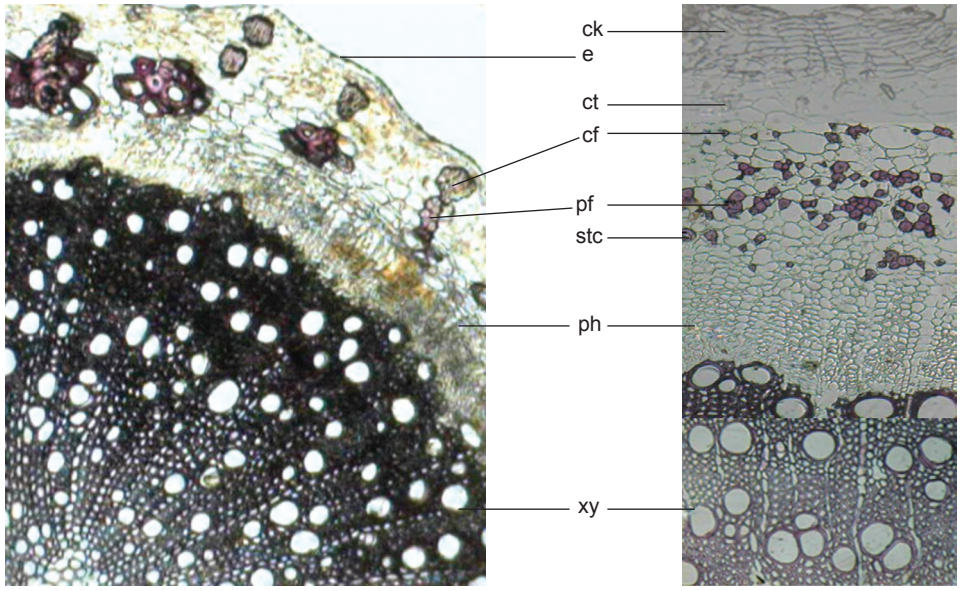
SD = standard deviation, Number of readings = 3

Table 3 : Content of phytoconstituents in *F. cretica* whole plant

| Sr. No. | Phytoconstituents | Samples (% w/w) | | |
|---|---|---|---|---|
| | | A | B | C |
| 1 | Phenolic substances | 0.327 | 0.400 | 0.612 |
| 2 | Alkaloids | 0.097 | 0.083 | 0.28 |
| 3 | Flavanoids | 0.950 | 1.411 | 2.263 |
| 4 | Saponins:<br>Froth number | 333 | 250 | 333 |
| 5 | Carbohydrates:<br>Sugar content | 3.22 | 3.77 | 4.01 |




A.




B. C.

Fig. 1: Microscopy of *Fagonia cretica*. A. Transverse Section of leaf; B. Transverse Section of stem; C. Transverse Section of root

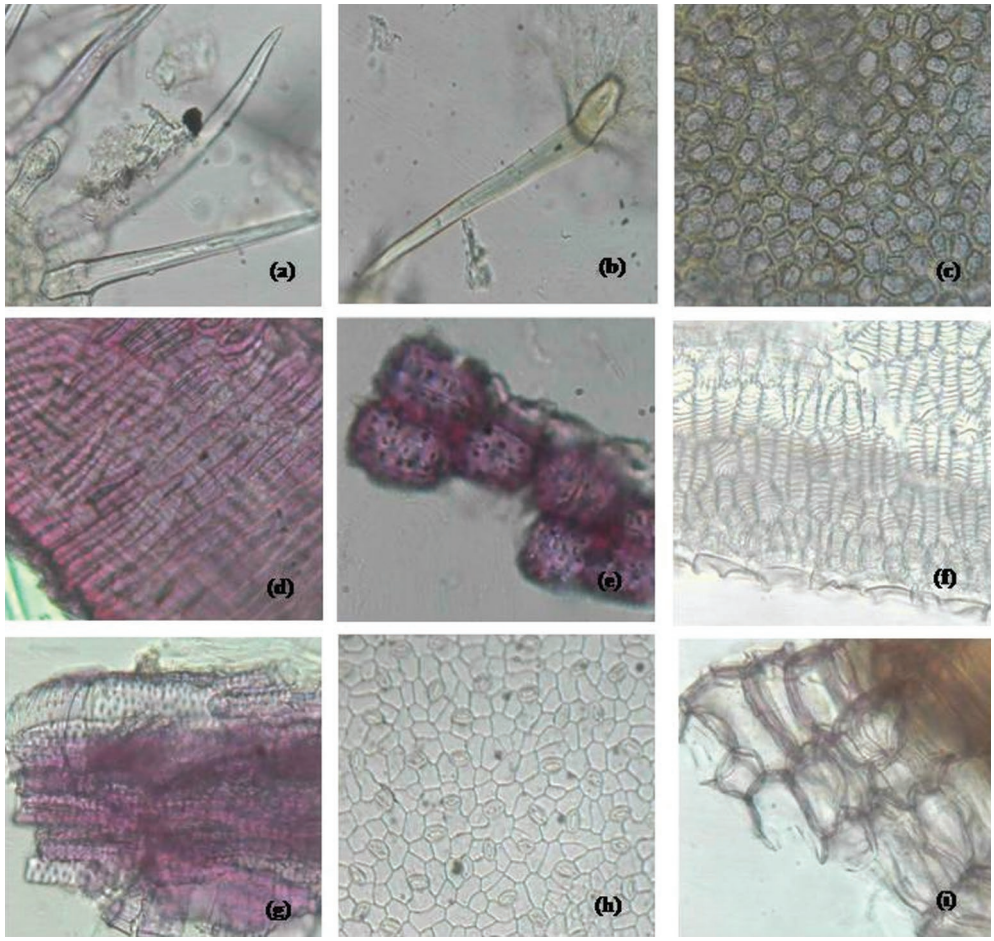



Fig. 2: Powder Microscopy of *Fagonia cretica* whole plant

a) Unicellular covering trichomes occurring in groups.
b) Isolated covering trichome with striated cuticle.
c) Fragment of testa.
d) Overlapping mesocarp and endocarp cells.
e) Stone cells.
f) Fibrous layer of anther.
g) Medullary rays and border-pitted vessels.
h) Anomocytic stomata.
i) Lignified cork.

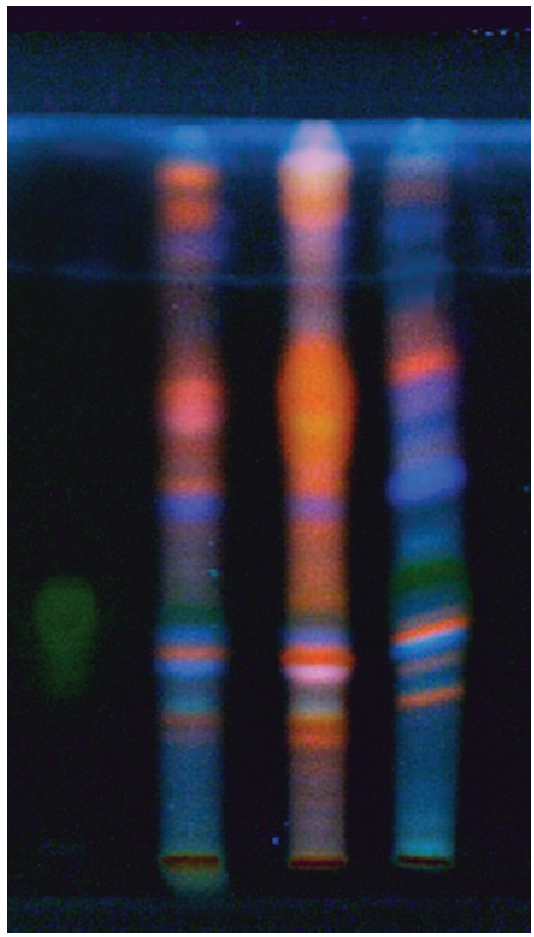


Fig. 3: Separation of isorhamnetin from *Fagonia cretica* Linn. whole plant samples (collected from Bhuj, Jamnagar and Jodhpur respectively) on TLC plate.

## Results and Discussion

### Morphological characters

*F. cretica* collected from three different places showed similar morphological characters. It is a small woody, branched and thorny under shrub, found to be growing in arid parts of northwest India. Leaf is opposite, leaflet 1.0 to 1.2 cm in length and 0.2 to 0.25 cm in width, linear to elliptic in shape, with entire margin, acute apex, glabrous surface and a small petiole; stipules spiny and arranged in whorls of 4 at node. Stem is cylindrical, glabrous, longitudinally striated with distinct nodes, internodes being 1.2–2.0 cm in length; fracture short and fibrous; yellowish brown in colour, slightly bitter and mucilaginous in taste. Root is tortuous, 0.5 to 0.8 cm in diameter, exfoliated at places, exhibiting fibrous fracture, creamish brown in colour and slightly bitter in taste. Flower is solitary, purplish-rose-coloured, petals spathulate with a marked claw, sepals imbricate,

half as long as petals; stamens 10 in number and are inserted on the disc. Fruit is schizocarp, deeply 5 partite, each one seeded cocci is compressed and pubescent with recurved peduncle, almost of the same length as that of fruit. Seeds are small, compressed, and ovate with a mucilaginous testa.

## Microscopical characters

All three samples showed similar microscopical characters and can be differentiated by quantitative microscopic parameters.

The transverse section of the leaf showed a layer of upper and lower epidermis with thin walled, tabular, tangentially running cells covered with thick cuticle, an isobilateral lamina with continuously running three layered palisade tissue (pal) with sinuous cells on the upper side, and two layered on lower side with straight walled cells; a centrally located collateral vascular bundle (vb) of the midrib associated with a group of small sclereids (scl) (Figure 1).

Transverse section of the stem showed a layer of epidermis (e), narrow band of parenchymatous cortex and pericycle traversed with groups of cortical fibres (cf) and pericyclic fibres (pf), phloem (ph) and xylem (xy) encircled by small crescent shaped, centrally located obliterated pith. Phloem wide, parenchymatous, traversed with sieve tissue and uni to triseriate medullary rays; cambium distinct; xylem wide, composed of isolated and radially arranged vessels, medullary rays, parenchyma and thin walled fibres (Figure 1).

Transverse section of the root showed centrally located wide wood, occupying the major area of the section, encircled by well developed phloem (ph) traversed with groups of thick walled fibres (cf and pf) and stone cells (stc) arranged at places in discontinuous tangential bands, a very narrow parenchymatous cortex (ct) and outermost lignified cork tissue (ck). Xylem (xy) composed of vessels, fibres and pitted parenchyma, starch grains and occasional prismatic crystals of calcium oxalate traversed throughout the parenchymatous cells of the section (Figure 1).

## Powder

Powder microscopy showed simple, covering trichomes with unicellular stalk scattered as such or attached to the epicarp and wall of ovary (a), cells of the former are covered with striated cuticle (b), simple trichomes uni- to bi-cellular, thick walled, lignified, with pointed apex and bulging base, of various sizes from fruit (a); fragments of testa in surface view showing polygonal thick walled cells (c); fragments of longitudinally cut thick walled, lignified

groups of sclerenchymatous cells of mesocarp often seen overlapping with the underlying cells of endocarp (d); isolated and groups of stone cells (e); fragments of fibrous layer of anther in surface view (f); radially longitudinally cut medullary rays crossing the bordered pitted vessels (g), anomocytic stomata (h) and lignified cork in surface view (i) (Figure 2).

Data of quantitative microscopy for leaves are entered in table 1.

### Physicochemical and Phytochemical Evaluations

Results of physico-chemical evaluation viz. ash and extractive values are given in table 2. Qualitative phytochemical examination revealed that the plant is rich in saponin and flavanoid. The study was extended to estimate saponin, flavanoid, alkaloid, phenolics and carbohydrate.

### TLC of Isorhamnetin

Both standard isorhamnetin and extracts were applied on the TLC plate and chromatographed with the mobile phase Toluene: Ethyl formate: Formic acid (5: 4: 0.1) that enabled good resolution with a sharp and symmetrical spot at $R_f$ 0.35 for each (Figure 3).

## Conclusion

The herb was woody, thorny, with petiolate leaves, glabrous stem and tortuous root. Root was characterized by lignified cork, cortical fibres in cortex, stone cells in phloem and wide zone of xylem. Stem showed hypodermis and cortex containing discontinuous groups of lignified fibres, followed by wide phloem and xylem. Characteristic diagnostic features of leaf included 2 layered palisade tissue and midrib showing a collateral vascular bundle. Powder was found to have trichomes from fruits, stone cells, overlapping cells of sclerenchyma and lignified cork. The plant showed higher water-soluble components than alcohol soluble components. Phytochemical screening revealed presence of steroid and triterpenoid, flavanoid, phenolics, saponin, alkaloid and carbohydrate. Phenolics, alkaloids, flavanoids and carbohydrates, all were found to be higher in Jodhpur sample (0.612% w/w, 0.28% w/w, 2.26% w/w and 4.01% w/w respectively) (see table 3 ).

TLC using precoated silica gel 60 $F_{254}$ plate as a stationary phase, as Toluene: Ethyl formate: Formic acid (5: 4: 0.1) mobile phase revealed presence of isorhamnetin at $R_f$ 0.35 in all samples.

## References


Anonymous, 2006. The Ayurvedic Pharmacopoeia of India, Vol. V, Part 1, 1st ed. Ministry of Health and Family Welfare, Department of Health, Government of India, Delhi, p. 23.

Anonymous, 2006a. The Ayurvedic Pharmacopoeia of India, Vol. V, Part 1, 1st ed. Ministry of Health and Family Welfare, Department of Health, Government of India, Delhi, p. 214.

Anonymous, 2002. Quality Control Methods for Medicinal Plant Materials, 1st ed. A.I.T.B.S. Publishers and distributors (WHO), Delhi, pp. 28-30, 46.

Chopra, R.N., Nayar, S.L. and Chopra, I.C., 1956. Glossary of Indian Medicinal Plants, CSIR, New Delhi, p. 116.

Chopra, R.N., Chopra, I.C., Handa, K.L. and Kapur, L.D., 1958. Chopra's Indigenous Drugs of India, 2nd ed. Academic Publisher, New Delhi, p. 507.

El-Hadidi, M.N., Al-Wakeel, S.A.M. and El-Garf, I.A., 1988. Systematic significance of the flavonoid constituents in the *Fagonia indica*. *Biochem Syst Ecol.* 16(3): 293-297.

El-Negoumy, S.I., Al-Wakeel, S.A.M., El-Hadidi, M.N. and Saleh, N.A.M., 1986. The flavonoids of the *Fagonia arabica*. *Phytochemistry* 25(10): 2423-2424.

Hodge, J.E. and Hofreiter, B.T., 1962. Methods in carbohydrate chemistry, Vol. I, Academic press, London, pp. 388-390.

Hooker, J.D., 1875. Flora of British India, Vol. 1, Reeva and Co. Ltd., London, p. 425.

Kalola, J. and Shah, M., 2006. Free radical scavenging activity of *Inula cappa, Ars Pharm* 47(4): 387-388.

Khare, C.P. (ed.), 2007. Indian Medicinal Plants, Springer-Verlag Berlin, Heidelberg, New York, p. 258.

Kirtikar, K.R and Basu, B.D., 1975. Indian Medicinal Plants, Vol. 1, 2nd ed. Lalit Mohan Basu Prakashan, Allahabad, pp. 426-428.

Miyase, T., Melek, F.R., El-Gindi, O.D., Abdel-Khalik, S.M., El-Gindi, M.R., Haggag M.Y. and Hilal S.H., 1996. Saponins from *Fagonia arabica*. *Phytochemistry* 41(4): 1175-1179.

Nadkarni, K.M., 1954. Indian Materia Medica, 3rd ed. Popular Book Depot, Mumbai, pp. 533-534.

Rahman, A., Ansari, A.A., Drexler, S.A. and Clardy, J., 1982. Isolation and structure of nahagenin. *Heterocycles* 19(2): 217-220.

Rastogi, R.P. and Mehrotra, B.N., 1990. Compendium of Indian Medicinal Plants, Vol. 5, CDRI, Lucknow, p. 366.

Shah, M.B., Marfatia, S.H., Shah, U.D., Sheth, N.R., 2010. Textbook of Pharmacognosy – II, 1st ed. Nirav and Roopal Prakashan, Ahmedabad, p. 61.

Sreevidya, N. and Mehrotra, S., 2003. Spectrophotometric method for estimation of alkaloids precipitable with Dragendorff's reagent in plant materials. *J AOAC International* 86(6): 1124-1127.

# Regulatory Requirements for Ayurvedic, Siddha and Unani Drugs : An Overview

**Vijay Kumar Garg, [1]Nitin Rai and [2*]Rajeev Kr. Sharma**

Drugs Control Cell,
Directorate of AYUSH,
Govt. of NCT of Delhi,
Karol Bagh, New Delh-110011

[1]Pharmacopoeial Laboratory for Indian Medicine, Kamla Nehru Nagar, Ghaziabad-201002

[2]Pharmacopoeia Commission for Indian Medicine, Kamla Nehru Nagar, Ghaziabad-201002

## Abstract

The drug legislation in India is governed by Drugs & Cosmetics Act 1940 and Rules 1945. During the British rule the drugs were imported in the country and Government regulated the drugs under the provisions of Poisons Act, 1919 and Dangerous Drug Act, 1930. To strengthen the regulation then Government appointed Drug Enquiry Committee under the chairmanship of Lt. Col. R.N. Chopra in 1931 to enquire into the extent to which drugs and chemicals of impure quality or of defective strength, particularly those recognized by the British Pharmacopoeia, are imported, manufactured and sold in British India and the necessity of controlling such import, manufacture and sale in the public interest and to make recommendations thereof. The committee categorically recommended; (i) Regulate the standards of drugs and medicines including patent and proprietary medicines; (ii) Compilation of a National Pharmacopoeia; (iii) Development of the Pharmacy profession; (iv) Standardization of indigenous drugs and; (v) Development of drug industry.

These recommendations prompted the Government of India to pass the Drugs & Cosmetics Act in 1940, partly implementing the Chopra Committee's recommendations to regulate, manufacture, distribute and sale of drugs in India. The drugs of Ayurvedic, Siddha and Unani are also under regulatory requirements laid in the Act and its compliance is mandatory. This communication provides genesis of the Drugs and Cosmetics Act and a synoptic account of regulatory requirements of ASU drugs in the country to educate and help manufacturers of ISM drugs.

**Key words** : Regulatory affairs, Drugs & Cosmetics Act 1940 and Rules 1945, Ayurvedic, Siddha and Unani Drugs.

## Introduction

Drugs of Ayurvedic, Siddha and Unani systems of medicine are under regulation of Drugs & Cosmetics Act, 1940 and Rules thereunder. Drug regulations are the only tool to ensure the quality, safety and efficacy of drugs. Healthcare industry in the country is being significantly regulated under this Act alongwith other prevalent regulatory norms, it paves the way to ensure the industry to comply all the regulation and laws pertinent to their business. Industry has to tune with the Central Government, State Government and local regulatory agencies for the compliance of regulations. Drugs & Cosmetics Act is Central law regulated at country and State level with defined mechanism.

[2*] Author for correspondence

## Genesis

In the beginning of 20th century, the drug industry was almost non-existent to meet out the demand of drugs. During and after the First World War cheap drugs were imported in the country. Increasing demand of drugs resulted in production of cheaper and inferior drugs by some Indian companies to compete with imported drugs flooded in the market.

To control this situation, the Government passed the Poisons Act and Dangerous Drug Act in 1919 and 1930 respectively. Debates were held in the then legislative assembly and the council of State on the prevalence of spurious and substandard drugs and resolutions were passed urging the Government 'to take immediate measures to control the craze for medicinal drugs, through legislation, thereby ensuring standardization of the preparations and sale of such drugs'. But to have a comprehensive legislation, the Indian Government appointed a Drug Enquiry Committee, under the chairmanship of Lt. Col. R.N. Chopra in 1931, to make recommendations about the ways and means to control production and sale of drugs and pharmaceuticals in the interest of public health.

Chopra Committee made comprehensive recommendations to the Government suggesting the creation of Drug Control Machinery at the Centre with branches in provinces. The Committee also recommended the establishment of well–equipped Central Drugs Laboratory with competent staff and experts. Creation of Central Pharmacy Council and Provincial Council to train young men and women were also suggested by the Chopra committee.

In 1937, Bills were introduced in Central Legislative assembly to give effect to the recommendations of Drug Enquiry Committee to regulate the import of drugs into British India. In turn provincial Government got the resolution passed from the provincial legislative and sent them to the Central Government for getting through the bill to regulate the import, manufacture, distribution and sale of drugs. Bill was introduced in the Central Legislative Assembly and it received the assent of the Governor General on 10th April 1940 with the promulgation of Drugs & Cosmetics Act, 1940.

In 1985 the Narcotic Drugs and Psychotropic Substances Act was enacted by repealing the Dangerous Drugs Act, 1930 and Opium Act, 1878.The Drugs Rules were framed in 1945 to give effect to provision of Act.

Chapter IV-A in the Act comprises the provisions relating to Ayurvedic, Siddha and Unani drugs. It was inserted by Act 13 of 1964 (with affect from 01.02.1969) and substituted by Act of 68 of 1982, S.2 (with effect from 01.02.1983).

## Regulatory requirements Law, Act and Rule

Regulatory affairs are concerned to law. Law is a procedure established by custom, agreement, or authority. In other words, it is the body of rules and principles governing the affairs of a society. Law constitutes Acts, Statutes, Amendments, Notifications, Rules and Bills in Parliament, State Laws, Central Acts, Legal Opinions, and Advices.

Legislation that has been passed by both the Houses of Parliament and has been approved by the President is termed as Act. In other words, bills passed in the Parliament become Acts. Act is the intention of law describing its applicability, definitions governing provisions, fines and penalties and the way they are to be applied. Rules are the standard methods and procedures in relation to any provision contained in the act and these are framed by the inherent powers given in the act. In case of any contradiction in Rules and Acts, the provisions of Act prevail and apply accordingly.

## Statutory Basis of Drugs and Cosmetics Act & Rules

The Drugs and Cosmetics Act, 1940 & Rules 1945 is the set of rules and regulations governing the regulatory affairs in India. This Act was amended time to time to make it more effective. The list of amending Acts & adaption orders so far is:

i. The Drugs (Amendment) Act, 1955

ii. The Drugs (Amendment) Act, 1960

iii. The Drugs (Amendment) Act, 1962

iv. The Drugs & Cosmetics (Amendment) Act, 1964

v. The Drugs & Cosmetics (Amendment) Act, 1972

vi. The Drugs & Cosmetics (Amendment) Act, 1982

vii. The Drugs & Cosmetics (Amendment) Act, 1995

viii. The Drugs & Cosmetics (Amendment) Act, 2008

## The Objectives of the Drugs & Cosmetics Act are:

i. To regulate the import, manufacture and sale of drugs and cosmetics through licensing.

ii. Manufacture, distribution and sale of drugs and cosmetics by qualified personals only.

iii. To prevent manufacture and sale of substandard drugs & cosmetics.

iv. To regulate the manufacture and sale of Ayurvedic, Siddha and Unani drugs.

v. To establish Drugs Technical Advisory Board (DTAB) and Drug Consultative Committee (DCC) for allopathic and allied drugs and cosmetics.

The detail of contents and chapters of Act are summarized in Table 1 & 2.

Table 1 : Contents of Drugs & Cosmetics Act & Rules thereunder

| Drugs and Cosmetics Act 1940 | Drugs and Cosmetics Rules 1945 |
|---|---|
| Chapter: 5 (I, II, III, IV-A, V) | Parts: 19 (part I to V,VI, VI-A, VII, VII-A, VIII, IX, IX-A, X, X-A, X-B, XI to XV, XV-A, XVI, XVI-A, XVII, XVII & XVIII |
| Section: 38 (I-1 to 4, II-5 to 7, 7A, III-8 to 15, IV-16-33, 33-A, IV- A, 33-B to 33-O and V-33-P to 38) | Rules: 169 (Rule 9-20, 42-67, 98-101,116-118 omitted) |
| Schedules: 2 (First and Second) | Schedules & Sub-schedules: 44 (Sch. E, I, L., W omitted) |

Table 2 : Chapters of Drugs & Cosmetics Act and their details

| Chapters | Subjects |
|---|---|
| Chapter I: | Introductory-scope, definition etc |
| Chapter II: | The Drug Technical Advisory Board, The Central Drugs Laboratory & The Drugs Consultative Committee. |
| Chapter III: | Important of drugs & Cosmetics |
| Chapter IV: | Manufacture, sale and distribution of Drugs and Cosmetics |
| Chapter IVA: | Provision Relating to Ayurvedic, Siddha & Unani Drugs |
| Chapter V: | Miscellaneous Schedules |

## Administration of the Act and Rules

Under the Drugs and Cosmetics Act, the regulation of manufacture, sale and distribution of Drugs are primarily the concern of the State authorities while the Central authorities are responsible for approval of new drugs, clinical trials in the country, laying down the standards for drugs, control over the quality of imported drugs, coordination of the activities of State Drug Control

Organisations and providing expert advice with a view of bringing about uniformity in the enforcement of the Drugs and Cosmetics Act. In a broader sense the Central Government has responsibilities for Legislation farming, Policy making, Review on monitoring and Maintaining uniformity whereas responsibilities of Implementation rests with State Government. The major aspect of Act is as follows:

(a) Advisory

- Drug Technical Advisory Board (DTAB)
- Drugs Consultative Committee (DCC)

(b) Analytical

- Central Drugs Laboratory (CDL)
- State Drug Testing Laboratories
- Government Analysts

(c) Executives

- Licensing authorities
- Controlling authorities
- Drugs Inspectors

Synopsis of Regulatory Requirements for Ayurvedic, Siddha and Unani Drugs

The regulations of Ayurveda, Siddha and Unani Drugs have been dealt in detail under Chapter I and IV A of the Drugs and cosmetics Act 1940 and also under Part XVI, Part XVI (A), Part XVII, Part XVIII, and Part XIX of the Drugs and Cosmetics Rules, 1945. The synoptic enumeration of different provisions regulating drugs of Ayurvedic, Siddha and Unani are given below in Table 3 & 4.

Table 3 : Drugs and Cosmetics Act, 1940 & Rules, 1945 in respect of Ayurvedic, Siddha and Unani drugs – Quick guide to relevant provisions in respect of Ayurvedic, Siddha and Unani drugs

| Subject | Regulations |
|---|---|
| *1. Definitions* | |
| i) Application of Chapter IVA Ayurvedic, Siddha or Unani Drugs | 33-B |
| ii) Ayurvedic, Siddha and Unani (ASU) Classical Drugs | Section 3(a) |
| iii) Authoritative Books | First Schedule |
| iv) Patent & Proprietary Medicine | Section 3(h) (i) |

| Subject | Regulations |
|---|---|
| 2. *Empowerment* | |
| i) Central Govt. to make rules | u/s 33-N |
| ii) Licensing Authority, State Govt. | R. 152 |
| iii) Ayurvedic Siddha and Unani Drug Technical Advisory Board (ASUDTAB) | u/s 3(aa) (i), 33-C |
| iv) Ayurvedic, Siddha and Unani Drugs Consultative Committee (ASUDCC) | u/s 3(aa) (ii), 33-D |
| v) Power of Central Govt. to prohibit manufacture | u/s 33EED |
| vi) Power to amend First Schedule | u/s 33-O |
| vii) Power to give direction | u/s 33-P |
| 3. *Manufacturing* | |
| i) License Application for grant/renewal | R. 153 |
| ii) Loan License Application for grant/renewal | R. 153-A |
| iii) Conditions for grant/renewal of License | R. 157 |
| iv) Duration of License | R. 156, 156-A |
| v) Guideline for issue of Licence | R. 158 (B) |
| vi) GMP Certification | Schedule T, R155-B |
| vii) Certificate of Renewal | R. 155, 155-A |
| 4. *Manufacture for sale or for Distribution of Ayurvedic, Siddha and Unani Medicine* | |
| i) Regulation of manufacture for sale | u/s 33-EEB |
| ii) Prohibition of manufacture and sale of ASU drugs | u/s 33-EEC |
| iii) Manufacture on more than one set of Premises | R. 151 |
| iv) Licensing Authorities | R. 152 |
| v) Application for license to manufacture Ayurvedic (including Siddha) or Unani drugs | R. 153 |
| vi) Loan license | R. 153-A |
| vii) Form of license to manufacture Ayurvedic (including Siddha) or Unani drugs | R. 154, F25-D |
| viii) Form of loan license to manufacture for sale of Ayurvedic (Including Siddha) or Unani drugs. | R. 154-A, F25-E |
| ix) Certificate of Renewal | R. 155, F26-D, 26-E |
| x) Certificate of Renewal of a loan license | R. 155-A, F26-E |
| xi) Certificate of award of good manufacturing practice Ayurveda, Siddha and Unani drugs | R. 155-B, F 26 E1 |
| xii) Duration of license | R. 156 |
| xiii) Duration of loan license xiv) Condition for the grant or renewal of a license in form 25D | R. 156-A |
| xv) Maintaining of record of raw materials | R. 157 |
| xvi) Condition of license | R. 157-A |
| xvii) Condition of loan license | R. 158 |
| xviii) Guidelines for issue of license | R. 158-A |
| xix) Cancellation and suspension of license | R. 158-B |
| xx) GMP Certification | R. 159 |

| Subject | | Regulations |
|---|---|---|
| | xxi) Provision of free sale certificate and non-conviction certificate | Schedule-T, R155-B |
| | xxii) Identification of raw materials | R. 158-C |
| | xxiii) Authoritative Books | Rule 160 |
| | xxiv) Standards to be complied with, in manufacture | First Schedule<br>R. 168, u/s 33EEB |
| *5.* | *Ingredients* | |
| | i) Poisonous substance | Schedule-E1 |
| | ii) Extract | R. 158 (B) |
| | iii) Permitted excipients | R. 169 |
| | iv) Classical formulations | First Schedule : List of Books of Ayurveda, Siddha & Unani |
| *6.* | *Packing, labeling & sale of Ayurvedic, Siddha and Unani (ASU) Drugs* | |
| | i) Labelling, packing and limit of alcohol. | R. 161 |
| | ii) Exemption in labeling and packing provisions for export | R. 161-A |
| *7.* | *Shelf life or date of expiry* | R. 161-B |
| *8.* | *Quality Control* | |
| | i) Specifications | Pharmacopoeias & Formularies S -1, R. 160, 168,169 |
| | ii) Misbranded Drugs | u/s 33 E |
| | iii) Adulterated Drugs | u/s 33 EE |
| | iv) Spurious Drugs | u/s 33 EEA |
| | v) Lab Reports | F. 13, F. 50 |
| | vi) Central Drugs Laboratory | R. 163-A, 163-B |
| | vii) Private Drug Testing Laboratory | R.160-A to160-J |
| *9.* | *Penalty* | |
| | i) Cancellation & Suspension of license | R159 |
| | ii) Prohibition of manufacture and sale | u/s 33EEC |
| | iii) Prohibition of manufacture and sale (Power of Central Govt.) | u/s 33 EED |
| | iv) Offences by companies | u/s 34 |
| *10.* | *Approval of Institutions for carrying out tests on Drugs & raw materials* | |
| | i) Application for grant of approval for testing drugs | R. 160-A, F 47 |
| | ii) Form in which approval to be granted | R. 160-B, F 48 |
| | iii) Duration of approval | R. 160-C |
| | iv) Conditions of approval | R. 106-D |
| | v) Inspection before grant of approval | R. 160-E |
| | vi) Report of inspection | R. 160-F |
| | vii) Procedure of approving authority | R. 160-G |

| Subject | Regulations |
|---|---|
| viii) Application after rejection<br>ix) Renewal<br>x) Withdrawal and suspension of approvals | R. 160-H<br>R. 160-I, F 49<br>R. 160-J |
| *11. Standards of Ayurvedic, Siddha and Unani (ASU) Drugs*<br>i) Standards of Drugs<br>ii) Permitted excipients | <br>R. 168<br>R. 169 |
| *12. Drugs Inspectors, State Licensing Authority*<br>i) Drugs Inspectors<br>ii) Duties of Inspectors, specially authorized to inspect the Manufacture of drugs<br>iii) Confiscation<br>iv) Disclosure of name of manufacture etc.<br>v) Maintenance of records & furnishing of information<br>vi) Cognizance of offences<br>vii) Qualification for State Drug Licensing Authority<br>viii) Procedure for dispatch of sample to Government Analyst<br>ix) Drug Inspectors, power and procedures<br>x) Qualification of Inspector<br>xi) Recording of condition of seals<br>xii) Report of result of test or analysis<br>xiii) Fees<br>xiv) Signature on certificates<br>xv) Method of test or analysis to be employed | <br>u/s 3(e), 33-G, 22, 23<br>R. 162<br><br>33-K<br>33-KA<br>33-KB<br><br>33-M<br>R. 162-A<br><br>R. 163, 163-C<br><br>Ch. IV u/s 22,23,24,25<br>R.167<br>R. 163-D<br>R. 163-E<br>R. 163-F<br>R.163-G<br>R. 164 |
| *13. Government analyst*<br>i) Govt. Analyst<br><br>ii) Qualifications of Government Analyst<br>iii) Duties of Government Analyst | <br>u/s 3 (c), 33-F, Rule 165-166<br>R.165,<br>R.166 |

u/s- under section, R-Rule, Ch-Chapter.

Pharmacopoeia is a book of regulatory standards for drugs manufactured and sold in a political zone. It consist the specifications for identity, purity and strength to ensure quality of drugs. Pharmacopoeia is prepared by recognized authority appointed by the Government of a particular country. Ayurveda, Siddha, Unani, Homoeopathy and modern systems of medicine have independent pharmacopoeia (Table-4). Ayurvedic and Unani Pharmacopoeia have two parts comprising many volumes. Part one consists of standards for single drugs (ingredients) and part two consists standards for classical formulations including their standard operating procedures to manufacture (Anonymous, 1978- 2012; 1981-2008; 1986-2011; 1992-2011; 1998-2009; 2008 & 2011; 2008-2010; 2009 & 2010 and Rai *et al.* 2012)

Table 4 : Pharmacopoeias and Formularies

| Ayurvedic System of Medicine | Siddha System of Medicine | Unani System of Medicine |
|---|---|---|
| Pharmacopoeia (Single Drugs)<br>Part-I, Eight Volumes<br>(600 monographs) | Pharmacopoeia (Single Drugs)<br>Part-I, Two Volumes<br>(139 monographs) | Pharmacopoeia (Single Drugs)<br>Part-I, Six Volumes<br>(298 monographs) |
| Pharmacopoeia (Formulations)<br>Part-II, Two Volumes(<br>152 monographs) | Pharmacopoeia (Formulations)<br>Nil | Pharmacopoeia (Formulations) Part-II,<br>Two Volumes<br>(100 monographs) |
| Formulary<br>Three Parts<br>(986 formulations) | Formulary<br>One Part<br>(399 formulations) | Formulary<br>Six Parts<br>(1231 formulations) |

## Other Relevant Applicable Regulations

*Central Drugs Laboratory* – Under Rule 163-B, the functions of the Central Drugs Laboratory in respect of Ayurvedic, Siddha and Unani Drugs shall be carried out at the Pharmacopoeial Laboratory for Ayurvedic, Siddha and Unani medicine, Ghaziabad (Uttar Pradesh) and the functions of the Director in respect of the said drugs shall be exercised by the Director of the said laboratory.

*Drugs and Magic Remedies (Objectionable Advisements) Act, 1954* - Ayurvedic, Siddha and Unani medicines are also covered under the purview of the Drugs & Magic Remedies (Objectionable Advertisement) Act 1954.“Magic Remedy” includes a talisman, mantra, kavacha and any other charm or any kind which is alleged to possess miraculous powers for or in the diagnosis cure, mitigation, treatment of prevention of any disease of human being or animals of for the affecting or influencing in any way the structure or any organic function of the body of human beings or animals. Section 3 prohibits advertisement of certain drugs for treatment of certain disease and disorders (Table-5). Section 7 deals with penalty clause, whoever contravenes any of the provision of Drugs and Magic Remedies (Objectionable Advertisement) Act 1954 & Rules 1955 there under shall, on conviction, be punishable in the case of a first conviction, with imprisonment which may extend to six months or with fine or both and in the case of subsequent conviction, with imprisonment which may extend to one year, or with fine, or with both.

Table 5 : Diseases/disorders prohibited under Drugs and Magic Remedies (objectionable advertisement) Act 1954.

| | | | |
|---|---|---|---|
| 1. | Appendicitis | 28 | Hydrocele |
| 2. | Arteriosclerosis | 29 | Hysteria |
| 3. | Blindness | 30 | Infantile Paralysis |
| 4. | Blood poisoning | 31 | Insanity |
| 5. | Bright's disease | 32 | Leprosy |
| 6. | Cancer | 33 | Leucoderma |
| 7. | Cataract | 34 | Lockjaw |
| 8. | Deafness | 35 | Locomotor ataxia |
| 9. | Diabetes | 36 | Lupus |
| 10. | Diseases & disorders of the brain | 37 | Nervous debility |
| 11. | Diseases & Disorders of the optical system | 38 | Obesity |
| 12. | Diseases & disorders of the uterus system | 39 | Paralysis |
| 13. | Disorders of menstrual flow | 40 | Plague |
| 14. | Disorders of the nervous system | 41 | Pleurisy |
| 15. | Disorders of the prostatic gland | 42 | Pneumonia |
| 16. | Dropsy | 43 | Rheumatism |
| 17. | Epilepsy | 44 | Ruptures |
| 18. | Female disease (In general) | 45 | Sexual impotence |
| 19. | Fevers ( In general) | 46 | Small pox |
| 20. | Fits | 47 | Stature of persons |
| 21. | Form and structure of the female bust | 48 | Sterility in women |
| 22. | Gallstones, kidney stones and bladder stones | 49 | Trachoma |
| 23. | Gangreen | 50 | Tuberculosis |
| 24. | Glaucoma | 51 | Tumors |
| 25. | Goiter | 52 | Typhoid fever |
| 26. | Heart disease | 53 | Ulcers |
| 27. | High or low blood pressure | 54 | Venereal diseases including Syphilis, Gonorrhoeia, Soft Cancer, Venereal granuloma and Lymphogranuloma. |

State Licensing Authorities are responsible to initiate action against manufactures/persons who violate the DMR (OA) Act 1954 and Advertise about the prohibited disease/disorders.

At present, the following other Acts and Rules have impact on the manufacture, export and Clinical research of Drugs and Cosmetics in India:

i. Pharmacy Act, 1948
ii. Narcotic Drugs and Psychotropic Substances (Excise Duties) Act, 1955
iii. Drugs (Prices Control) Order 1955 (under the Essential Commodities Act).
iv. Bio-diversity Act, 2002
v. Wild Life Protection Act 1972
vi. Indian Forest Act, 1927

There are also some other laws which have a bearing on manufacture, distribution, sale and cosmetics drugs in India. The important ones are:

i. Industries (Development and Regulation)Act, 1951
ii. Trade and Merchandise Markets Act, 1958
iii. Indian Patents and Design Act, 1970
iv. Factories Act, 1948
v. Weights and Measures Act, 1976

There are circulars (F.No.K-11020/5/97-DCC (AYUSH) dated 14.10.2005 and 14.12.2005 from Govt. of India, Ministry of Health & Family Welfare, Department of AYUSH regarding heavy metals namely Arsenic, Lead, Mercury and Cadmium which are to be tested in the drugs of Ayurvedic, Siddha and Unani by licensee.

## Conclusion

Herbal medicines have, of recent, received renewed attention of scientists in India and abroad with growing acceptability for their medical efficacy in curing a number of diseases and conditions. This has drawn attention of Govt. of India to lay down standards for their safety and quality. It's in this context, various pharmacopoeias of Ayurvedic, Siddha and Unani drugs, and Drugs & Cosmetics Act are now in place to enforce production of genuine medicines. This envisages bringing within its purview various aspects of manufacturing Ayurvedic, Siddha and Unani drugs, their quality control measures, legal provisions and penal actions at one place concerning these drugs. Therefore, various pharmacopoeias related to Ayurvedic, Siddha and Unani drugs and, Drugs & Cosmetics Act, dealing with good manufacturing practices are available to create general awareness among the stakeholders and public at

large. This would ensure enforcing regulatory and recommendatory standards for most of these drugs. The present communication is an endevour in this direction and provides abstracted information compiled from related portions of various Ayurvedic, Siddha & Unani pharmacopoeias of India, and Drugs & Cosmetics Act. For legal purpose or any controversy, the relevant pharmacopoeias and Acts may be referred to.

## References


Anonymous, 2008-10. The Ayurvedic Pharmacopoeia of India, (Formulations), Part-II, Volume-I to III, First edition. Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 1978-2012. The Ayurvedic Formulary of India, Part-I to III. Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 1981-08. National Formulary of Unani Medicine, Part-I to VI. Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 1986-11. The Ayurvedic Pharmacopoeia of India, (Single Drugs), Part-I, Volume-I to VIII, First edition. Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 1992-2011. The Siddha Formulary of India, Part-I & II. Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 1998-09. The Unani Pharmacopoeia of India, (Single Drugs), Part-I, Vol.-I to VI. Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Anonymous, 2008-10. The Ayurvedic Pharmacopoeia of India, (Formulations), Part- II, Volume–I to III, First edition. Govt. of India, Ministry of Health & Family Welfare,

Anonymous, 2008 & 11. The Siddha Pharmacopoeia of India, (Single Drugs), Part-I, Vol.-I to II. Govt. of India, Ministry of Health & Family Welfare, New Delhi

Anonymous, 2009-10. The Unani Pharmacopoeia of India, (Formulations), Part-II, Vol.-I & II. Govt. of India, Ministry of Health & Family Welfare, New Delhi.

Malik, Vijay, 2013. Law relating to Drugs & Cosmetics (23rd ed.). Eastern Book Company, Lucknow.

Rai, Nitin; Lalit Tiwari & Rajeev Kr. Sharma, 2012. Quality standards on medicinal plants with special reference to regulatory aspects. *In*: (Eds. Birendra Prasad and Sunil Kumar), Modern Technologies for Sustainable Agriculture Chapter 9, pp. 147-175.

# Standardization and HPTLC Fingerprinting of a Unani Compound Formulation Habb-e-Paan

**[1]*N.M.A. Rasheed,**
**[1]Atiya Rehana,**
**[1]Maqbool Ahmed,**
**[1]Kashif Husain,**
**[1]M.A. Waheed,**
**[2]Shamsul Arfin and [2]Aminuddin**

[1]Central Research Institute of Unani Medicine, A. G. Colony Road, Erragadda, Hyderabad-500038

[2]Central Council for Research in Unani Medicine, 61-65 Institutional area, Janakpuri, New Delhi-110058

## Abstract

With global realization that use of synthetic drugs is not safe on the long run, the medical fraternity at large is looking at alternatives from natural sources to combat diseases particularly those in which conventional modern system of medicine has little to offer. This realization on the one hand has increased demand for herbal drugs and on the other hand need for quality standardization of these drugs has gone up. Central Research Institute of Unani Medicine, Hyderabad being engaged in multidisciplinary research in Unani Medicine, working on standardization of herbal drugs used in this system of medicine. One such drug "Habb-e-Paan" which is prescribed in Unani system for Aatishak (Syphillis), Fasad-e-Dam (Putrefaction of Blood) has been taken up for standardization by modern techniques, so as to ascertain its quality. The parameters which were carried out are pharmacognostic studies, physico-chemical parameters, phytochemical screening, High performance thin layer chromatography, microbial load, aflatoxins, heavy metals, and pesticidal residues revealing specific identities for the particular drug and to evaluate pharmacopoeial standards. Results suggest that the drug is safe for therapeutic use and its batch to batch identification for quality control is possible on the basis of present study.

**Keywords:** Habb-e-Paan, Standardization, Physico-chemical analysis, HPTLC.

## Introduction

Recently there has been a shift in universal trend from synthetic to herbal medicine, which we can say 'Return to Nature'. Medicinal plants have been known for millennia and are highly esteemed all over the world as a rich source of therapeutic agents for the prevention of diseases and ailments (Sharma *et al*., 2008). The global resurgence of interest in herbal medicines has led to an increase in their demand leading to a decline in their quality, primarily due to a lack of adequate regulations pertaining to drugs (Rajini and Kanaki, 2008). WHO has emphasized the need to ensure quality control of medicinal plant products by using modern techniques and by applying suitable parameters and standards, In order to overcome certain inevitable shortcomings of the Pharmacopoeial monograph other quality control measures must be explored (Pifferi *et al*., 1999; Shinde, 2009; Singh and Soni, 2004; Street *et al*., 2008). Curative efficacies of compound herbal medicine are reliant on the quality and the quantity of the constituent single drugs as they contain specific bio-active marker species with specific pharmacological actions. Though, it is very difficult

[1]* Author for correspondence

to identify the ingredients after the formulation is prepared and the organoleptic parameters like taste, odour, colour etc. will not establish the standard quality of the medicine.

A herbal formulation, Habb-e-Paan (Fig. 1) taken for the present study is a Unani compound formulation mentioned in National formulary of Unani medicine of India, Part-III, 1.41. The drug is prescribed in Unani system of medicine for Aatishak (Syphillis), Fasad-e-Dam (Putrefaction of Blood) and has its action as blood purifier. In order to standardize and to lay down the standard operating procedures (SOP's) and pharmacopoeial standards, the formulation was prepared in three batches at laboratory scale. It was subjected to analysis for microscopic study, physico-chemical parameters, microbial load, heavy metals, aflatoxins, pesticide residues and high performance thin layer chromatographic studies (Anonymous, 2009). The present paper describes the salient features of preparation, phytochemical screening, safety evaluation studies and High performance thin layer chromatographic studies for the drug.

## Materials and Methods

### Collection of material

Ingredients of formulation were procured from the pharmacy of Central Research Institute of Unani Medicine, Hyderabad, and identified with the help of a botanist. Arq-e-Paan has been prepared at in house laboratory by steam distillation method.

Preparation of the formulation (Bayaz-e-Kabir. II, pp.35).

It is prepared according to the composition of the formulation given in National Formulary which is as follows:

| S. No | Name of the drug | Botanical Name | Part Used | Qty |
|---|---|---|---|---|
| 1. | Sammul Far | White oxide of arsenic | Mineral | 3g. |
| 2. | Tabasheer | *Bambusa bambos* Druce | Crystals | 3g. |
| 3. | Kath Safaid | *Acacia leucophloea* Willd | Bark extract | 3g. |
| 4. | Arq-e-Paan | *Piper betle* Linn | Hydrodistillate. | Q.S. |

### Processing of raw material

Take all the ingredients of pharmacopoeial quality and clean all the ingredients. *Summul far* (Sankhiya) fine powder is immersed in sufficient quantity of fresh *Aab-e-Leemu* (Lemon juice) and ground in a mortar of china clay or glass till

the juice is completely absorbed. This process is repeated seven times to obtain *Summul far* or *Sankhiya mudabbar*. Ground the powder of each drug separately to obtain fine powder and pass through 80 mesh sieve. Mix the fine powders thoroughly with Arq-e-pan and prepare Huboob by mechanical process. Store the huboob so obtained in dry containers to protect from light and moisture.

### Preparation of the Tablets

The tablets were prepared as per the procedure described by Bayaz-e-Kabir. II, p.35. The granules were made into 500mg tablets (excluding binding material weight) using rotary tablet punching machine (Cadmach-GMP model).

### Chemical analysis

Physico-Chemical parameters of the prepared compound formulation Habb-e-Paan were studied such as total ash, acid insoluble ash, water soluble ash, solubility matter in alcohol and water, loss on drying at $105^0$C, microbial load, aflatoxins, pesticide residue and GBC-908 AA model Atomic Absorption Spectrophotometer (AAS) was used to determine the concentration of heavy metals as per the methods described in WHO guidelines (Anonymous, 1998). Phytochemical screening was carried out in different solvents extracts such as petroleum ether, Chloroform, Ethyl acetate, methanol, Ethanol, and aqueous as per the methods described by Trease and Evans (1972).

### HPTLC analysis

DESAGA Sarstedt Gruppe system is used for analysis along with Automatic TLC applicator and UV visible cabinet as imaging system, the instrument had Proquant 1.6 version as software system for documentation.

### Preparation of Extract of the drug for HPTLC analysis

Five grams fine powder of Habb-e-Paan was reflux on water bath for 30 min in different solvent separately through sohxlet. Later the contents were removed and filtered through Whattmann No. 41 filter paper and evaporated the solution to 20 ml. Thus the solution so obtained was used as sample for the determination of components.

### Development and determination of the solvent system

| | | |
|---|---|---|
| Sample Applied | : | Sample drug solution of about 10µl. |
| Solvent system | : | Toluene: Ethyl acetate: Methanol (5: 4: 1) |

The sample was spotted with the help of Automatic TLC applicator system of the DESAGA Sarstedt Gruppe on Precoated Aluminium Sheets of Silica Gel 60 $F_{254}$ (Merck) After trying with various solvent systems with variable volume ratios, the suitable solvent system as stated above is selected in its proportional ratio and developed in the Twin through chamber of TLC to the maximum height of the plate so that it can be able to separate the components on the polar phase of silica gel and that of mobile phase of solvent system. The formulation and its ingredients were spotted separately and developed the TLC plate.

## Development of HPTLC technique

After developing, TLC plates were dried completely and detected with the suitable detection system like UV Cabinet system for detection of spots at 254, 366nm and also under iodine vapours and after derivatizing with anisaldehyde sulphuric acid reagent as shown in the figure 3. Further it was scanned with the Densitometer CD60 of DESAGA Sarstedt Gruppe system under the UV range of 254nm, 366nm, 580nm and the overlay densitogram at 254nm and also Densitogram of ethyl acetate extract at 254nm as shown in the figure 4 in which peaks appeared for the corresponding spots being detected in the densitometer while scanning and the peaks areas under the curve correspond to the concentration of the component in the sample. The separation of the components in the compound formulation and its ingredients are corresponding compared with respect to Rf values.

Table 1 : Physico-chemical parameters of the compound formulation 'Habb-e-Paan'.

| S. No | Parameters | Sample I | Sample II | Sample III |
|---|---|---|---|---|
| 1 | Ash values<br>Total Ash (%) | 31.38-31.48 | 31.63-31.74 | 31.70-31.74 |
| | Acid insoluble ash (%) | 26.38-26.65 | 26.80-26.83 | 26.95-27.00 |
| 2 | Alcohol Soluble matter (% w/w) | 6.93-7.34 | 7.87-7.89 | 7.69-7.75 |
| 3 | Water soluble matter (% w/w) | 12.56-12.65 | 12.72-12.73 | 12.72-12.81 |
| 4 | PH of 1% aq. Solution | 4.13 | 4.12 | 4.10 |
| | PH of 10% aq. Solution | 3.58 | 3.57 | 3.58 |
| 5 | Disintegration time in min. | 12 | 12 | 12 |
| 6 | Loss on drying at 105°C (%w/w) | 5.29-5.31 | 5.33-5.36 | 5.43-5.58 |

Table 2 : Phytochemical screening of the nature of compounds present in different solvent extracts of *Habb-e-Paan*.

| S. No. | Phyto constituent | Pet. ether ext. | $CHCl_3$ ext. | E.A. ext. | Meth ext. | ethanol ext. | Aqueous ext. |
|---|---|---|---|---|---|---|---|
| 1. | Alkaloid | - | - | - | + | + | + |
| 2. | Carbohydrates | - | - | + | + | + | + |
| 3. | Glycosides | - | - | - | - | - | - |
| 4. | Phenols | - | - | + | ++ | ++ | ++ |
| 5. | Steroids | - | + | ++ | ++ | ++ | ++ |
| 6. | Tannins | - | - | + | ++ | ++ | ++ |
| 7. | Flavonoids | - | - | - | - | - | - |
| 8. | Saponins | - | - | - | - | - | - |
| 9. | Starch | - | - | - | - | - | - |

Table 3 : Peak list of densitogram of the Solvent extracts of Habb-e-Paan at UV 254nm.

| Peak no | Sammul Far | Katha | Tabasheer | Arq-e-paan | PE ext | $CHCl_3$ ext | EA ext | MeOH ext | Aq. ext |
|---|---|---|---|---|---|---|---|---|---|
| 1 | - | 0.04 | - | 0.03 | 0.03 | 0.03 | 0.03 | 0.03 | 0.03 |
| 2 | - | - | - | - | - | - | 0.20 | - | - |
| 3 | - | 0.35 | - | - | - | - | 0.34 | 0.34 | 0.32 |
| 4 | - | - | - | - | 0.67 | 0.64 | 0.67 | 0.64 | 0.61 |
| 5 | - | - | - | - | 0.80 | 0.77 | 0.79 | 0.82 | - |
| 6 | 0.95 | - | 0.94 | 0.93 | 0.91 | 0.94 | 0.96 | 0.93 | 0.94 |

Table 4 : Peak list of densitogram of the Solvent extracts of Habb-e-Paan at UV 366 nm.

| Peak no | Sammul Far | Katha | Tabasheer | Arq-e-paan | PE ext | $CHCl_3$ ext | EA ext | MeOH ext | Aq. ext |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 0.01 | 0.02 | - | 0.02 | 0.02 | 0.02 | 0.02 | 0.02 | 0.02 |
| 2 | - | - | - | - | - | - | 0.09 | 0.09 | - |
| 3 | - | - | - | - | - | - | 0.12 | 0.11 | - |
| 4 | - | 0.35 | - | - | - | - | 0.35 | 0.35 | - |
| 5 | - | - | - | - | - | - | 0.69 | 0.67 | - |
| 6 | - | - | - | - | - | 0.74 | 0.75 | 0.76 | - |

| Peak no | Sammul Far | Katha | Tabasheer | Arq-e-paan | PE ext | $CHCl_3$ ext | EA ext | MeOH ext | Aq. ext |
|---|---|---|---|---|---|---|---|---|---|
| 7 | - | - | - | - | 0.80 | 0.80 | 0.80 | 0.82 | - |
| 8 | - | 0.94 | - | - | 0.92 | 0.93 | - | - | - |
| 9 | - | - | 0.95 | 0.98 | - | 0.95 | 0.97 | - | 0.97 |

Table 5 : Peak list of densitogram of the Solvent extracts of Habb-e-Paan at 580nm under iodine vapour detection.

| Peak no | Sammul Far | Katha | Tabasheer | Arq-e-paan | PE ext | $CHCl_3$ ext | EA ext | MeOH ext | Aq. ext |
|---|---|---|---|---|---|---|---|---|---|
| 1 | - | 0.02 | - | - | - | 0.03 | 0.03 | 0.03 | 0.03 |
| 2 | 0.34 | 0.34 | - | - | - | 0.34 | 0.34 | 0.35 | 0.34 |
| 3 | - | - | - | - | - | - | 0.42 | - | - |
| 4 | - | 0.49 | 0.49 | - | - | - | 0.49 | 0.49 | 0.50 |
| 5 | - | - | - | - | - | - | 0.57 | 0.57 | - |
| 6 | - | - | - | 0.77 | 0.77 | 0.77 | 0.77 | 0.78 | - |
| 7 | - | - | - | - | 0.84 | - | - | - | - |

Table 6 : Peak list of densitogram of the Solvent extracts of Habb-e-Paan after derivatized with anisaldehyde sulphuric acid reagent at 580 nm.

| Peak no | Sammul Far | Katha | Tabasheer | Arq-e-paan | PE ext | $CHCl_3$ ext | EA ext | MeOH ext | Aq. ext |
|---|---|---|---|---|---|---|---|---|---|
| 1 | - | 0.02 | - | - | - | 0.03 | 0.03 | 0.02 | 0.02 |
| 2 | - | 0.34 | - | - | - | - | 0.34 | 0.35 | - |
| 3 | - | 0.49 | - | - | - | - | 0.49 | 0.49 | 0.50 |
| 4 | - | - | - | - | 0.77 | 0.77 | 0.77 | 0.78 | - |

Table 7 : Microbial Contamination

| S. No | Parameter analyzed | Results | Permissible limits as per WHO |
|---|---|---|---|
| 1 | Total *Bacterial* Load | $39 \times 10^3$ | Not more than $10^5$ / g |
| 2 | *Salmonella Spp*. | Nil | Nil |
| 3 | Escherichia. Coli | Nil | Nil |
| 4 | Total *Fungal* count | $1 \times 10^2$ | Not more than $10^3$/g |

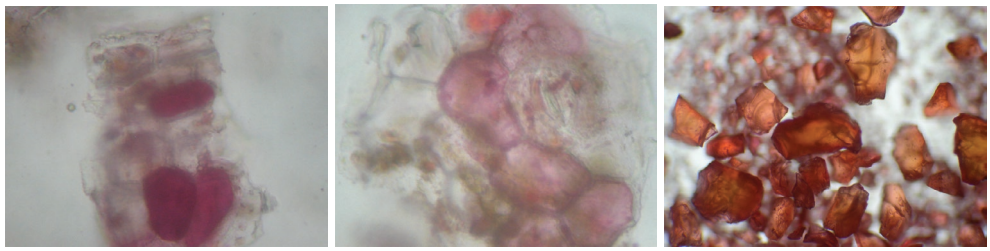
Table 8 : Aflatoxin Contamination

| S. No | Parameter analyzed | Results | Permissible limits as per WHO |
|---|---|---|---|
| 1 | B1 | Nil | Not more than 0.50 ppm |
| 2 | B2 | Nil | Not more than 0.10 ppm |
| 3 | G1 | Nil | Not more than 0.50 ppm |
| 4 | G2 | Nil | Not more than 0.10 ppm |

Table 9 : Heavy Metal Analysis

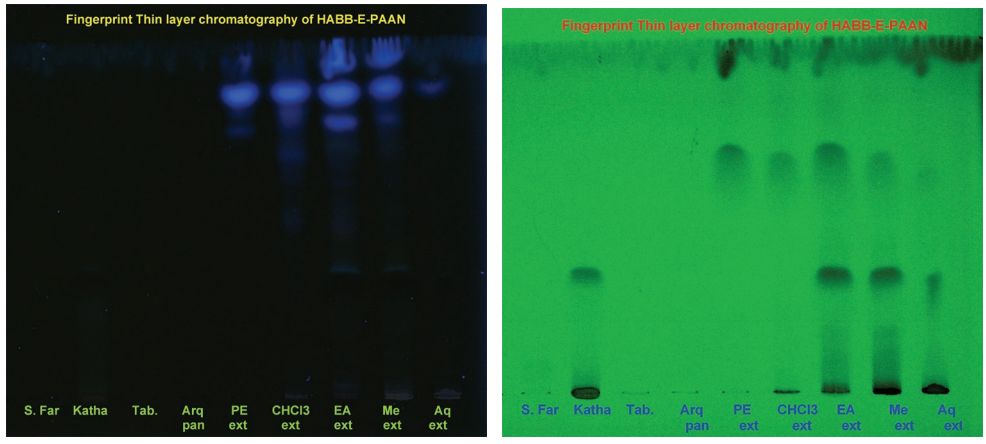
| S. No | Parameter analyzed | Results | Permissible limits as per WHO |
|---|---|---|---|
| 1 | Arsenic | Nil | Not more than 3.0 ppm |
| 2 | Cadmium | Nil | Not more than 0.3 ppm |
| 3 | Lead | Nil | Not more than 10.0 ppm |
| 4 | Mercury | Nil | Not more than 1.0 ppm |

Fig. 1: Finished Formulation Habb-e-Paan.

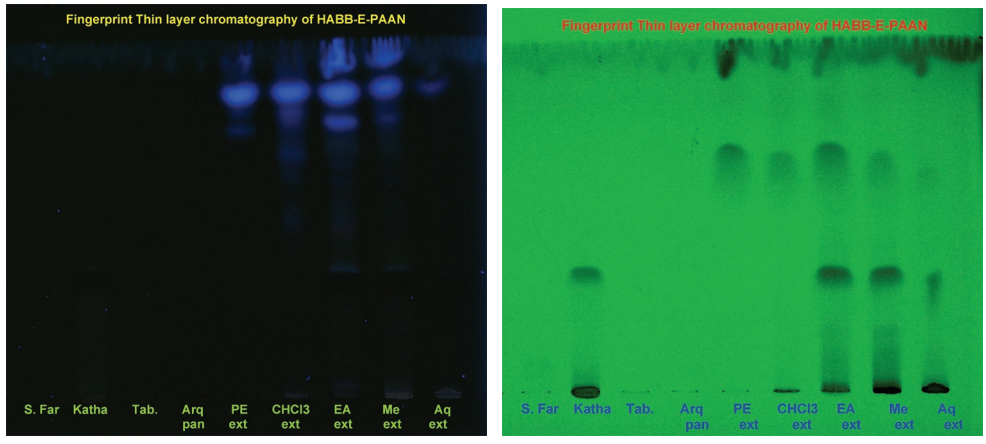


Parenchyma cells with reddish tannin content | Sac like Parenchymatous cells | Abundant Resin content

Fig. 2: Powder microscopic properties of the formulation Habb-e-Paan




A) At UV 366 nm | B) At UV 254 nm




C) Exposed to $I_2$ vapours | D) Derivatized with anisaldehyde sulphuric acid reagent.

Fig. 3. TLC plates of different solvent extracts of Habb-e-Paan and its ingredients Summul far, Katha, Tabasheer, Arq-e-paan A) At UV 366 nm, B) At UV 254 nm, C) Under Iodine vapours D) At visible region after derivatizing with Anisaldehyde sulphuric acid reagent.

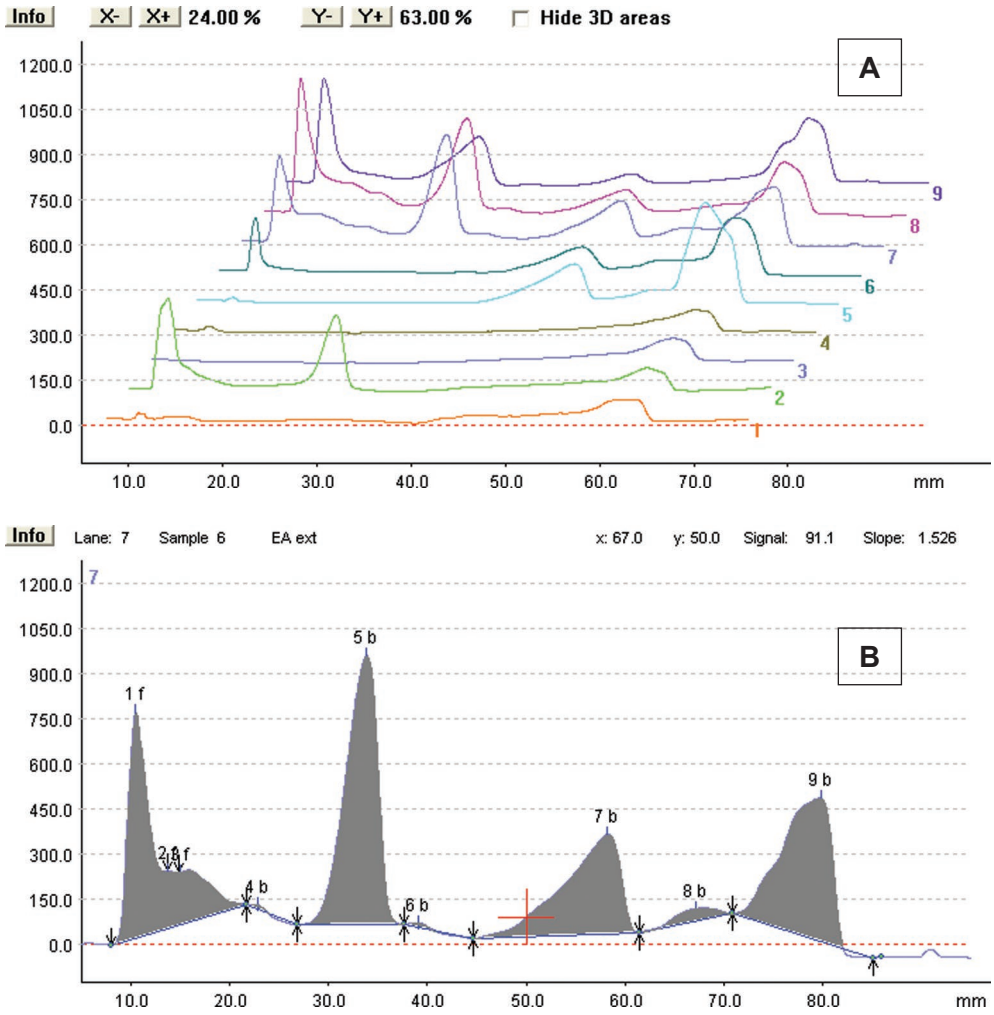



Fig. 4. A) Overlay Densitogram of Habb-e-Paan and its ingredients as spotted on TLC plate (1-9), B) Densitogram of Habb-e-Paan ethyl acetate extract at 254 nm.

## Results and Discussion

### Analytical Profile

*Organoleptic Characters*

Light brown coloured Unani pills with white spots pleasant smell and sweet taste.

### Identification

*Powder Microscopy*

Take fine powder of six tablets and immersed in the water for half an hour. Material was stirred with a glass rod and supernatant was discarded. Residue

was taken on glass slide, treated with iodine solution, Safranin and mounted with glycerine. The prepared slide was subjected for microscopical studies. Microscopical observations clearly showed the presence of abundant resin cells, scarcely starch grains, reddish tannin content and sac like parenchymatous cells as shown in figure 2.

## Physico-Chemical Standards

The Physico-Chemical Parameters data as given in table 1 is expressed as mean values of the three readings calculated. Total ash was found to be 31.38-31.74, and acid insoluble ash 26.38-27.00gm%; whereas Alcohol soluble matter in terms of %w/w is found to be 6.93-7.89 and water soluble matter as 12.56-12.81; The moisture content i.e., Loss of weight on drying at $105^0$C found to be 5.29-5.58 gm%. $P^H$ of the 1% aqueous solution observed as 4.10-4.13 and 10% aqueous solution observed as 3.57-3.58; and Disintegration time of tablet was 12min. Phytochemical screening for the phytoconstituents were carried out and are represented in the table 2. The results of total bacterial load and total fungal count of the microbial studies were within the permissible limits and the other parameters were found to be absent in the drug. The analysis of aflatoxins and heavy metal analysis showed that the drug was free from any contaminations. These findings as observed for microbial load, aflatoxin contamination and heavy metal analysis are given in tables 7, 8 and 9 respectively.

## HPTLC Analysis

HPTLC fingerprint studies of methanolic extract of Habb-e-Paan along with its ingredients was carried out and TLC plate developed and detected using the UV visible chamber which clearly showed various spots at UV 254nm and 366nm in the densitogram and also under iodine vapours and after derivatizing with anisaldehyde sulphuric acid reagent. The corresponding Rf values under each detection is illustrated in the tables 3,4,5 and 6. The corresponding $R_f$ values of the compound formulation in different extracts where coinciding with corresponding position of spot with the ingredients and its Rf values. Detection under 254nm Rf values of Sammul Far (0.95), Katha (0.04,0.35), Tabasheer (0.94) and Arq-e-paan (0.03,0.93) are correspondingly coinciding with the formulations Rf values indicating the presence of constituents form the ingredients. Similary at UV 366nm. Upon exposure of TLC plate to Iodine vapours shows Rf values of Sammul Far (0.34), Katha (0.02, 0.34, 0.49), Tabasheer (0.49) and Arq-e-paan (0.77) are correspondingly coinciding with the formulations Rf values indicating the presence of constituents

form the ingredients. The same in respect of detection after derivatizing with anisaldehyde sulphuric acid reagent. Thus the established HPTLC fingerprinting profile helps to authenticate the formulation in batch to batch consistency and quality control analysis of formulation as a reference.

## Conclusion

The drug under study was subjected to Physico-chemical analysis, which is helpful in establishing the standard along with the other parameters such as phytochemical screening, microscopic study, HPTLC analysis. Safety evaluation of drug such as Heavy metal analysis, aflatoxins contamination analysis was done and found absent; microbial load was found within the permissible limits of WHO guidelines. Modern technique of HPTLC analysis was employed in respect to standardization and to separate the compounds which can be isolated for further studies. Consequently, the drug was brought up in determining and ascertaining its quality standard**.** The study is likely to help in the quality assurance of drug used in the Unani System of Medicine and in development of standard parameters. The development of this traditional system of medicines with the perspectives of safety, efficacy and quality will help not only to preserve the traditional heritage but also to rationalize the use of natural herbal products in the healthcare.

## Acknowledgement

The authors conveys their sincere thanks to Director General, CCRUM, New Delhi, for providing necessary facilities for present investigation.

## References

Alok Sharma, Shanker C, Lalit Kumar Tyagi, Mahendra Singh and Rao Ch V., 2008. Herbal Medicine for Market Potential in India: An Overview. *Academic Journal of Plant Sciences* 1(2): 26-36.

Anonymous, 1998. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, pp. 25-28.

Anonymous, 2009. The Unani Pharmacopoeia of India, Part-I, Vol.VI. Ministry of Health & Family Welfare, Govt. of India, New Delhi, pp. 119-35.

Giorgio Pifferi, Paola Santoro, Massimo Pedrani, 1999. Quality and functionality of excipients, II. *Farmaco* 54: 1-2, 1-14.

Mohammad K.H., 1977. Bayaz-e-kabir, Vol. II. 15th Edition, Hikmat Book Depot, Hyderabad, p. 35.

Rajini, M. and Kanaki, N.S., 2008. In : Ramawat K.G. and Merillon, J.M. (Eds.), Phytochemical Standardization of Herbal Drugs and Polyherbal Formulations: Bioactive Molecules and Medicinal Plants. Springer, pp. 349-69.

Street, R.A., Stirk, W.A., Van Staden, J., 2008. South African traditional medicinal plant trade-Challenges in regulating quality, safety and efficacy. *Journal of Ethnopharmacology* 119(3): 705-10.

Surinder Singh and Soni, G.R., 2004. WHO Expert Committee on Biological Standardization. *Indian J. Med. Res.* 120: 497-98.

Trease, G.E. & Evans, W.C., 1972. Pharmacognosy, 10th edn. Bailliere Tindel, London.

Vaibhav, M., Shinde, Kamlesh Dhalwal, Manohar Potdar, Kakasaheb R Mahadik, 2009. Application of Quality Control Principles to Herbal Drugs. *International Journal of Phytomedicine* 1: 4-8.

# An Ethno-pharmacological Study of Ramnagar Forest Division of Nainital District, Uttarakhand

***Zaheer Anwar Ali, Sarfraz Ahmad, Wasiuddin and Latafat Ali Khan**

Survey of Medicinal Plants Unit, Regional Research Institute of Unani Medicine (CCRUM), Post Box 70, Aligarh-202001 (U.P.)

## Abstract

The present report deals with the results of an ethnopharmacological survey carried out during October of 2003 in the Ramnagar forest division of Nainital district in Kumaon region of Uttarakhand. In all, 26 plant species belonging to 20 families of angiosperms, used by the indigenous people against different ailments of humans as well as livestock, have been enumerated. Each entry provides the information on correct botanical and prevalent local names, the part used, claimed medicinal use(s) and mode of administration. The study has revealed new uses of many plants and highlighted the potential of ethnopharmacological research as well as the need for documentation of traditional knowledge pertaining to the utilization of plants as medicine. The data presented are first-hand and not published earlier in present form.

**Keywords:** Ethnopharmacological survey, Traditional Medicine, Ramnagar, Nainital, Kumaon region.

## Introduction

Kumaon is one of the richest floristic regions of western Himalayas in northern India and is well known for its ancient heritage of traditional herbal medicine. From different parts of Nainital district of the region, the use of diverse native floras in traditional medicine of various cultures has been extensively reported (Agnihotri *et al.*, 2003, 2012; Ali *et al.*, 2008, 2013a, 2013b, 2013c; Anonymous, 2001, 2008; Bisht *et al*., 1999; Gupta, 1960; Mathur and Joshi, 2013; Pant and Pandey, 1998; Singh, 1993, 2003; Singh *et al.,* 1987; Singh and Maheshwari, 1990, 1993, 1994). However, no ethnopharmacological study of Ramnagar forest division, Nainital, had previously been reported. The present report, therefore, communicates first-hand information on commonly used traditional herbal preparations recorded during an ethnopharmacological survey of the study area carried out in October, 2003.

The area of study forms a part of Nainital district and lying between 29˚ 13′ 30″ - 29˚ 24′ 15″ N latitude and 79˚ 06′ 00″ - 79˚ 33″ E longitude in the foothills of Siwalik ranges (Fig. 1). It is spread over an area of 48736.90 hectare in the Sub-Himalayan region of southern Kumaon. There are five forest ranges viz. Dechori, Fatehpur, Kaladhungi, Kosi and Kota. Dense forest areas, in which various indigenous castes and communities are living, cover the major part of the division. These people still rely on traditional medicines for their own healthcare and to treat different diseases and conditions of cattle.

* Author for correspondence

## Methodology

Fieldwork was carried out in October 2003. Information on folk medicinal uses of local plants was obtained by the authors through interviewing reliable informants who were traditional healers and other knowledgeable village elders. Data on the common name of the plant or the crude drug, medicinal use(s), part used, other ingredients added (if any), method of drug preparation, mode of administration, dosage and duration of treatment, etc. were recorded for each claim. Botanical specimens of all the plants along with relevant field information were collected. These were later identified with the help of related floras (Gupta, 1968; Hooker, 1872-1897; Osmaston, 1972). The botanical names were updated following Uniyal *et al.* (2007). Voucher herbarium specimens were prepared and deposited in the Herbarium of the Survey of Medicinal Plants Unit, Regional Research Institute of Unani Medicine, Aligarh (U.P.), India, for future reference and study.

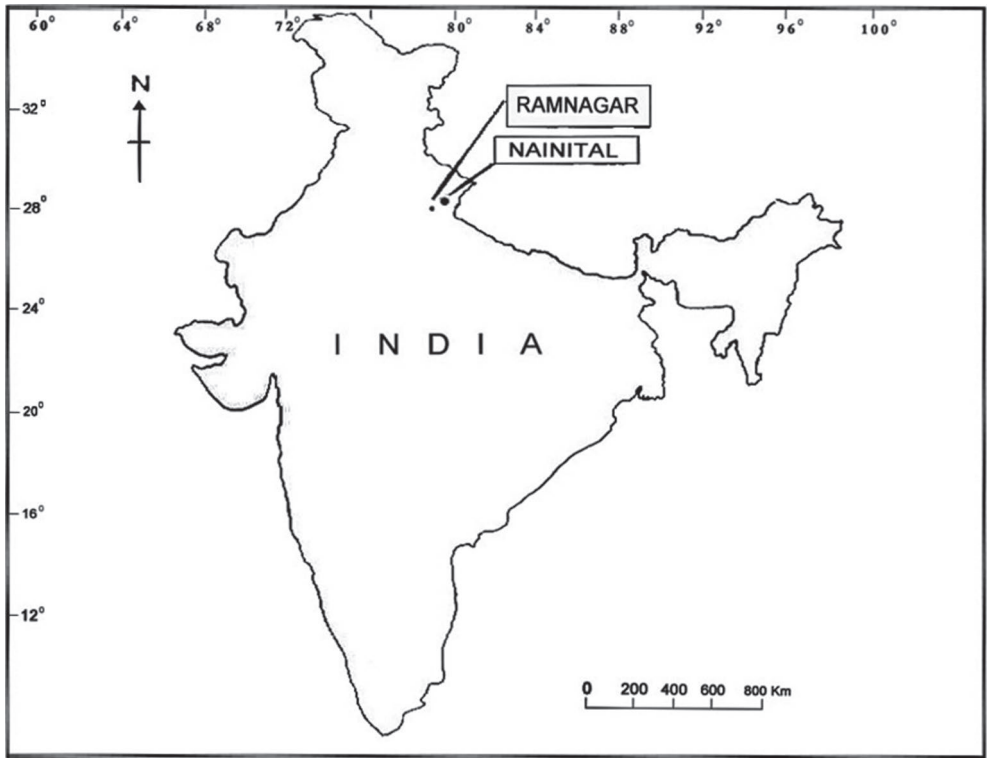



Fig. 1 : Map showing location of study area

## Observations

In the following enumeration medicinal plants are listed in alphabetic order by their scientific names together with respective family (in parentheses), local name, locality, voucher specimen number followed by folk medicinal use(s) and

mode of administration. As far as possible, the probable dosage and duration of these crude drugs are also given.

*Abutilon indicum* L. (Malvaceae), 'Kanghi', Kosi (*SMPA7090*). For treating piles, a freshly made paste of the leaves (10g), obtained by crushing, is given orally two times a day and also applied locally till the cure is obtained.

*Achyranthes aspera* L. (Amaranthaceae), 'Chorchitta', Baluti (*SMPA6943*). Ashes of the fruits mixed with honey are given in breathlessness.

*Alstonia scholaris* (L.) R. Br. (Apocynaceae), 'Chhation', Pawalgarh (*SMPA7046*). Pieces of the fresh stem bark mixed with fodder are given to cattle for treating pustules.

*Bombax ceiba* L. (Bombacaceae), 'Semal', Musabangar (*SMPA7018*). The tap root of the young plant is collected, dried and ground to make a powder. About 10g of this powder are given with milk once daily for 40 days in sexual weakness.

*Callicarpa macrophylla* Vahl (Verbenaceae), 'Daya', Kelakhur (*SMPA7067*). Fruit paste mixed with curd is given for stomatitis.

*Cissampelos pariera* L. (Menispermaceae), 'Pari', Baluti (*SMPA6946)*. Leaf juice coagulates on being allowed to stand in a cup for about 4-5 hours. It is given to children as general tonic.

*Cissus repanda* Vahl (Vitaceae), 'Shikari Jar', Kelakhur (*SMPA7064*). Root paste is applied externally on sharp cut and wound for healing.

*Cynoglossum zeylanicum* Thunb. ex Lehm. (Boraginaceae), 'Chatkura', Fatehpur (*SMPA6985*). Paste, prepared by pounding the aerial parts, is applied externally on boils to speed up suppuration and healing.

*Dendrobium crepidatum* Lindl. (Orchidaceae), 'Hadjora', Narni (*SMPA7064*). For treating bone fracture, paste of the plant is plastered around the limb after setting the bones right. Splints and bandage are used to hold the bones and plaster in position.

*Flemingia strobilifera* (L.) Ait. & Ait. f. (Fabaceae), 'Bhatola', Kelakhur (*SMPA7056*). Fresh seeds are chewed to treat stomatitis.

*Holarrhena pubescens* (Buch.-Ham.) Wall. ex G. Don (Apocynaceae), 'Kura'/'Dudhi', Kathgodam (*SMPA695*6). About 10g of the stem bark powder are mixed with water and given twice daily for 5 days to treat dysentery.

*Jatropha curcas* L. (Euphorbaceae), 'Indi', Kathgodam (*SMPA6966*). Latex is applied externally to treat dhobie itch.

*Lannea coromandelica* (Houtt.) Merr. (Anacardiaceae), 'Jhingan', Baluti (*SMPA6959*). Fresh stem bark pieces are crushed and squeezed to obtain the juice. It is applied externally on wounds.

*Litsea glutinosa* (Lour.) Robins. (Lauraceae), 'Meda', Kelakhur (*SMPA7056*). Inner stem bark paste is applied as plaster for treating bone fracture.

*Mallotus philippensis* (Lam.) Muell.-Arg. (Euphorbiaceae), 'Rohini', Baluti (*SMPA6952*). Fresh juice of vegetative buds is applied on injured hoofs of cattle.

*Mimosa pudica* L. (Mimosaceae), 'Lajjai', Fatehpur (*SMPA6969*). In cases of scorpion sting, root paste, prepared by grinding the root in water, is applied locally, then duly bandaged. It is claimed to provide relief from stinging pain.

*Oroxylum indicum* (L.) Vent. (Bignoniaceae), 'Pharkat', Fatehpur (*SMPA6970*). Powder of the seeds mixed with fodder is given to cattle for treating pustules on the body.

*Pogostemon benghalenses* (Burm. f.) Kuntze (Lamiaceae), 'Kali Basing', Baluti (*SMPA6960*). Fresh leaf juice is applied externally to check bleeding from fresh cuts and healing the wounds.

*Premna latifolia* Roxb. (Verbinaceae), 'Aguni', Fatehpur (S*MPA6971*). Dried root is rubbed in little water on stone and the resulting paste is applied on ringworm.

*Rauvolfia serpentina* (L.) Benth. ex Kurz. (Apocynaceae), 'Sarpgandha' Musabangar (*SMPA7017*). Root paste is administered orally in snake bite.

*Sapindus mukorossi* Gaertn. (Sapindaceae), 'Reetha', Kaladhungi (*SMPA7026*). The saponaceous pericarp of the dried fruits is ground to make a powder. Pills of gram size are prepared; three pills are given once daily for two weak in scabies.

*Scindapsus officinalis* (Roxb.) Schott (Araceae), 'Gajpipal', Kaladhungi (*SMPA7036*). Powder of the fruit is mixed with honey and licked in cough.

*Solanum erianthum* D. Don (Solanaceae), 'Asidh', Sitabani (*SMPA7073*). Leaves are fed to cattle for worm infestation.

*Solanum nigrum* L. (Solanaceae), 'Geewian', Chonsla (*SMPA7001*). Leaf paste is applied externally on burns.

*Tamarindus indica* L. (Mimosaceae), 'Imli', Fatehpur (*SMPA7008*). About 20g of the fruit pulp mixed with leaves of 'sana' (*Cassia angustifolia* Vahl) are ground and taken orally for chronic constipation.

*Trichosanthes tricuspidata* Lour. (Cucurbitaceae), 'Elaru', Laxampur (*SMPA7054*). Seed paste is applied externally on lower abdomen of the children to treat anuria.

## Results and Discussion

This report documents significant information on 26 plant species from 20 families of angiosperms which are traditionally used to treat 22 common ailments of humans and a few complaints of domestic animals in the Ramnagar forest division of Nianital. The data are authentic and based on direct field interviews of reliable informants who have long been using these herbal drugs with positive effects. These traditional uses were analysed and compared with the available literature on medicinal and economic plants of the country (Anonymous, 1948-1976; 2001; Chopra et al., 1956; Jain, 1991; Kirtikar and Basu, 1935; Nadkarni, 1954; Watt, 1889-1892) and it was found that uses of many plant species (e.g. *Bombax ceiba, Callicarpa macrophylla, Holarrhena pubescens, Litsea glutinosa, Pogostemon benghalensis, Rauvolfia serpentina, Solanum erianthum, Tamarindus indica*) were similar to those already published. Further, only a few medicinal plants described herein were found to have similar uses as reported by earlier workers from other parts of Nainital district and its adjoining areas (Ali *et al.*, 2013a, 2013b, 2013c; Anonymous, 2008; Mathur and Joshi, 2013; Pant and Pandey, 1998; Singh *et al.*, 1987; Singh and Maheshwari, 1990, 1993, 1994). For other plants the reported therapeutic uses were found to be new or less known. Such medicinal plants might give some useful leads for further pharmacological investigations in the search of new drugs of plants origin.

During the course of fieldwork it was observed that traditional healers and other elderly people have good knowledge regarding the utilization and preparations of various ethnomedicines while the younger generation is not interested to hold this invaluable traditional knowledge. This may be due to the erosive effect of modernization and rapid socio-economic as well as cultural changes among the native people. In this situation the continuation of this ancestral knowledge is in danger as the transmission between the older and younger generations no longer exists. Similarly, there is a threat to some of the forest species of medicinal plants due to destruction of natural plant habitats as a result of expansion of agriculture, invasion of some foreign weed

species, excessive grazing, forest fire, over exploitation of natural resources, etc. Therefore, proper documentation of indigenous knowledge on medicinal plants through such field studies among the traditional societies of other ethnopharmacologically unexplored or under explored forest areas of this region in particular and in other areas of Uttarakhand in general is important for the conservation and sustainable utilization of biological resources.

The present study reports first-hand information on indigenous phytotherapy involving 26 medicinal plants from the Ramnagar forest division of Uttarakhand with a view to contribute material to the rich herbal heritage of Kumaon region of Uttarakhand in the search of new plant-based pharmaceuticals.

## Acknowledgements

We are highly grateful to the Director General, Central Council for Research in Unani Medicine, New Delhi, for supporting this field study. We should like to thank Mrs Neena Grewal, Divisional Forest Officer, and Mr. A.K. Kukshal, Subdivisional Forest Officer, Ramnagar Forest Division, Nainital of the Uttarakhand Forest Department for giving us facilities and permission to work in this area. We express sincere thanks to all the informants who have willingly shared their traditional knowledge with us.

## References

Agnihotri, A.K., Sikarwar, R.L.S., Khatoon, S., Rawat, A.K.S. and Mehrotra,S., 2003.Some common medicinal plants used by the local people of Haldwani forest division of Uttaranchal. 2nd World Cong. on “Biotechnological Development of Herbal Medicine” (NBRI), Lucknow, U.P., India, p. 110.

Agnihotri, AK., Tiwari, L., Rai, N., Sharma, Rajive Kr., Sikarwar, R.L.S., 2012. Traditional healthcare uses of wild plants prevalent in Haldwani forest area, Central Himalaya. *Research & Review: Journal of Pharmaceutical Science and Technology* (in press).

Ali, Z.A., Ahmad, S. and Khan, I.U., 2008. A contribution to the ethnopharmacology of Nainital forests of Kumaon region, Uttaranchal (India). *Hippo. J. Unani Med.*3(1):35-45.

Ali, Z.A., Ahmad, S. Wasiuddin and Khan, L.A., 2013a. Ethnopharmacological survey of west tarai forest division, Ramnagar, Nainital in Kumaon region of Uttarakhand. *Hippo. J. Unani Med.*8(1):79-88.

Ali, Z.A., Ahmad, S. Wasiuddin and Khan, L.A., 2013b. Ethnopharmacological study of medicinal plants in east tarai forest division Haldwani, Uttarakhand. *Hippo. J. Unani Med.* 8(2): 67-74.

Ali, Z.A., Wasiuddin and Zaidi, S.T.H., 2013c. Ethnopharmacological survey of central tarai forest division Haldwani, Nainital, Uttarakhand. *Hippo. J. Unani Med.* 8(3): 141-148.

Anonymous, 1948-1976. The Wealth of India (Raw Materials), Vol. I-XI. CSIR, New Delhi.

Anonymous, 2001. Medicinal Plants in Folklores of Northern India. Central Council for Research in Unani Medicine, New Delhi.

Anonymous, 2008. Unani Medicinal Plants of Tarai Forests in Kumaon Region of Uttarakhand. Central Council for Research in Unani Medicine, New Delhi.

Bisht, G., Tewari, K.C. and Bisht, L.S., 1999. Study on the medicinal plants of Bhimtal block in relation to their cultivation, Ayurvedic preparations and medicinal uses. National Seminar on "Drugs from Himalayan Herb: present status and future strategies". Kumaon University, Nainital, India, p. 32.

Chopra, R.N., Nayar, S.L. and Chopra, I.C., 1956. Glossary of Indian Medicinal Plants. CSIR, New Delhi.

Gupta, R., 1960. Some useful and medicinal plants of Nainital in Kumaon Himalayas. *J. Bombay Nat. Hist.* Soc. 59(2): 309-329.

Hooker, J.D., 1872-1897. The Flora of British India. Vol.1-VII. L. Reeva and Co. London.

Jain, S.K., 1991. Dictionary of Indian folk medicine and ethnobotany. Deep Publications, New Delhi.

Kirtikar, K.R. and Basu, B.D., 1935. Indian Medicinal Plants, Vol. I-IV. Periodical Experts, Delhi, India.

Mathur, A and Joshi, H., 2013. Ethnobotanical studies of the Tarai region of Kumaun, Uttarakhand, India. *Ethnobotany Research & Applications*11:175-203.

Nadkarni, A.K., 1954. Indian Materia Medica.Vol. I & II, 3rd Edition, Popular Book Depot, Bombay.

Osmaston, A.E., 1927. A Forest Flora for Kumaon. Govt. Press United Provinces, Allahabad.

Pant, S.C. and Pandey, G.C., 1998. Ethnobotanical studies on medicinal flora of Tharu tribal pockets in Kumaon region in Uttar Pradesh. *Bull. Med Ethnobot. Res.* 16(1-2): 1-10.

Singh, H. and Maheshwari, J.K., 1993. Phytotherapy for diphtheria by the Bhoxas of Nainital district, Uttar Pradesh, India. *Ethnobotany* 5(1 & 2): 63-65.

Singh, H., 1993. Traditional conservation of forest flora by the Bhoxas of Nainital district, Uttar Pradesh. In: U. Dhar (Ed.) Himalayan Biodiversity Conservation Strategies. Gyanodaya Prakshan Nainital, pp.401-406.

Singh, H., 2003. Herbal recipies for spermatorrhoea by Boxa tribe of Uttaranchal. Ethnobotany 15 (1-2): 115-117.

Singh, K.K. and Maheshwari, J.K., 1990. Plant wealth in the life and economy of the Tharus of Nainital district, U. P. *Indian Forester* 116: 636-642.

Singh, K.K. and Maheshwari, J.K., 1994. Traditional phytotherapy of some medicinal plants used by the Tharus of the Naintial district, Uttar Pradesh, India. *Int. J. Pharmacog.* 32: 51-58.

Singh, K.K., Saha S. and Maheshwari J.K., 1987. Observation on the ethnobotany of Boxa tribe of Bajpur block of Nainital district, Uttar Pradesh. *Him. Res. Dev.* 6(I-II):25-29.

Uniyal, B.P., Sharma, J.R., Choudhery, U. and Singh, D.K., 2007. Flowering Plants of Uttarakhand (Checklist). Bishen Singh Mahendra Pal Singh. Dehradun.

Watt, G., 1889-1892. A Dictionary of the Economic Products of India, Vol. I-VI. (Repri. 1972). Periodical Experts, Delhi.

**Short Research Communication:**

# Bio-Active Molecules

There are several examples of bio-active molecules isolated from animal sources, say, snakes, bees, toads, leeches and some mammals, which have found medicinal applications. These applications have been highlighted in this article.

Thus some of the snake venoms have pain relieving action. This property has been exploited in alleviating the extreme pain of the patients in the terminal stages of cancer. Cobra venom (cobrotoxin), for example, is reported to be a superior alternative to morphine in its pain relieving action. The toxins, derived from vipers, have been employed in the treatment of arthritis and rheumatism. Crotalus toxin (i.e. the venom derived from rattle snake and pit vipers) is claimed to be useful in the treatment of the periodic throbbing headache (migraine). Snake venoms usually produce two different types of effects, namely, enhance the blood clotting or inhibit it. Based on this property the patients afflicted with haemophilic disorder (i.e. prolonged bleeding following even minor injuries) can be treated with blood clotting venoms. These also find application as haemostatic agents in surgery and in the treatment of other hemorrhagic conditions. Likewise the anti-coagulant action of some snake venoms has been successfully employed in the case of patients having the formation of blood clots (thrombosis) in their veins and arteries. These venoms are also described to be useful in the case of 'angina pectoris; - a condition when the patient has a severe but temporary attack of cardiac pain. An interesting use of the venom derived from rattle snake is in the treatment of epilepsy.

The bee venom, 'melittin' is the bioactive molecule which is reported to provide relief to the patients suffering from the pain of muscles and joints, arthritic and rheumatic disease.

Leech saliva contains two powerful enzymes, called 'Hirudin' and 'hementin', which are reported to prevent and even break the blood clot formation within the blood vessels. These enzymes have a potential use in the treatment of cerebral and heart diseases.

Another enzyme, 'Orgetase' is reported to attack and destroy the built-up of jelly in the eyes of a glaucoma patient. This, therefore, holds a great promise for the cure of blindness due to glaucoma.

The skin gland secretions of toad contain a variety of bioactive molecules, viz. 'batrachotoxin', bufotenine, bufotalin etc. The use of dried and powdered toad skins, for the treatment of heart disease dates back to ancient times. This practice is prevalent even today in some East and South-East Asian countries.

A class of biologically active compounds referred to as 'Prostaglandins', have been isolated from the seminal fluid of mammals. These compounds are capable of inducing abortion and also widen the tubular portion of the blood vessels.

The enzymes, a-amylase, isolated from the pancreas of swine, finds therapeutic application and as a digestive aid enzyme and also is an anti-inflammatory agent.

The liver of a large flat fish, 'halibut' is a source of oil which is rich in Vitamin A and D. Thus, the patient suffering from ill-health due to deficiency of these vitamins, could be corrected by the oral administration of halibut liver. Likewise the liver extract of mammals – rich in folic acid and vitamin B-12 finds application in the treatment of anaemia. The extract of heart muscle of calf embryos is reported to dilate the chocked blood vessels of heart patients.

The hormone, 'Andrenaline' secreted by the glands, located near the mammalian kidney, has found useful application as a heart stimulant and provides relief from persistent coughing. For the treatment of acute heart attack the use of enzymes 'hyaluronidases' (isolated from testicles of mammals) have shown encouraging results. Another enzyme called 'Lysozyme' is found in egg white and in high concentration in tear fluid, mucus and in some organs, like heart, spleen and liver. It is used as an antibiotic and in the treatment of cancer and hemorrhagic conditions.

Finally, it may be pointed out here that Unani System of Medicine relies heavily on animal based products. The examples cited above provide support to the claims of Hakeems in respect of the efficacy of some of the animal based products as medicine. A considerable amount of work has been reported about the isolation of a large number of bioactive molecules from plant source. In this context it may be pointed out here that the animal sources have not been fully explored and exploited. Thus there is a great scope for research in this area and there are good chances of isolating organic molecules with very interesting pharmacological activities.

## Reference

Vohra, S.B. and M.S.Y. Khan, 1978. Animal Origin Drugs in Unani Medicine. Jamia Hamdard, New Delhi.

**Durga Nath Dhar**

44, Duplex-1, Rajat Vihar
Sector-62, Noida, U.P.

# HIPPOCRATIC JOURNAL OF UNANI MEDICINE

## Instructions to contributors

1. The paper(s) should be submitted in duplicate. Submission of a paper will be taken to imply that it is unpublished and is not being considered for publication elsewhere.

2. Papers should be written in English language and typed with double spacing on one side of A-4 size paper leaving top and left hand margin at least 1" (One inch) wide. Length of the paper should normally not exceed 12 pages.

3. Papers should be headed by a **title**, the initial(s) and surname(s) of author(s) followed by address.

4. Each paper should bear **abstract,** 2 to 5 **keywords, introduction, methodology, observations, results and discussion** followed by **acknowledgements and references.**

5. In all studies of plants or animals proper identification should be made as to the materials used.

6. While submitting the paper(s) for publication, Author(s) should decode the drugs specially in case of clinical studies.

7. Bibliographical references should be listed in alphabetical order of the author at the end of the paper. Authors should be cited in the text only by their surname(s) but their initial(s) should be shown in the bibliography.

8. References to periodicals should include the name(s) and initial(s) of author(s), year of publication, title of the book, periodical, title of the article, volume number (Arabic numerals), issue number where appropriate, first and last page number. Reference to books should include name(s) and initial(s) of the author(s), year of publication, exact title, name(s) of publisher, place of publication, page number.

9. Reference should be cited in the text in parentheses by the name(s) of author(s) followed by the year of publication, e.g. "(Jain,1991)" except when the author's name is part of the sentence, e.g. "Jain (1991) has reported that." If there are more than two authors it is in order to put " *et al*." after the first name, e.g., Khan *et al.*, 1981.

10. Each table should be typed on a separate sheet of paper. Tables should be numbered consequently in Arabic numerals e.g. “Table 1, Table 2” etc., and attached to the end of the text. Tables should be provided with headings and kept as simple as possible and should be referred to in the text as “table 1” etc.

11. Figures (including photographic prints, line drawings on strong white or transparent paper, and maps) should be numbered consequently in Arabic numerals, e.g. “Fig. 1 etc.” and attached to the text behind the tables. Graphs and diagrams should be large enough to permit reduction to a required size, legends for figures should be listed consequently on a separate sheet of paper. Photographs should be on glossy printing paper.

12. The editors reserve the right to refuse any manuscript submitted, whether on invitation or otherwise, and to make suggestions and modifications before publication.

13. Paper accepted by the editorial board will become the property of the CCRUM. No article or any part thereof may be reproduced in whatever form, without the written permission of the Editor-in-Chief.

14. The editors and publisher are not responsible for the scientific contents and statements of the authors of accepted papers.

R.N.I. Registration No. DELENG/2006/18866

# HIPPOCRATIC JOURNAL OF UNANI MEDICINE

This is a peer-reviewed publication and included in the abstracting and indexing of Medicinal and Aromatic Plants Abstracts (MAPA); Biological Abstracts; Chemical Abstracts; Contemporary Researches in Traditional Drugs & Medicinal Plants : Unani Medicine Abstracts etc.

**CENTRAL COUNCIL FOR RESEARCH IN UNANI MEDICINE**
**Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)**
**Ministry of Health & Family Welfare, Government of India**
**61 - 65 Institutional Area, Janakpuri, New Delhi – 110 058, India**
Tel.: +91-11-28521981, 28525982, 28525831/52/62/83/97, 28520501, 28522524, Fax : +91-11-28522965
Website : http://unanimedicine.com Email : unanimedicine@gmail.com & ccrum@rediffmail.com