HIPPOCRATIC JOURNAL OF UNANI MEDICINE

Volume 7, Number 2, April – June 2012

Hippocratic J. Unani Med. 7(2): 1-140, 2012

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

On account of the world-wide interest in the personal health and use of plant based drugs, the research activities in the traditional drugs have considerably increased. Over the years, a large number of traditional drugs, mainly herbal, have been subjected to clinical, pharmacological, phytochemical and pharmaceutical studies in an effort to validate them and prove their medical efficacy and safety. All these investigations have yielded extensive and valuable findings and insights, and there is a need for wide exchange of this information among scientists engaged in the development of new drugs of natural origin.

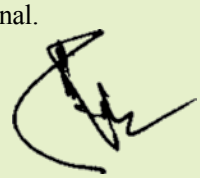
Unani system of Medicine, although originated in Greece, is one of the recognized systems of medicine of the country. Although, the Unani medicine have been in use for centuries and are known for their therapeutic efficacies, there is a need to scientifically establish their efficacy and safety in order 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 12 original research 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

Safety, Efficacy and Mechanism of Action of *Fasd* (Blood Letting through Venesection) in Cases of Osteoarthrosis —A Randomized Controlled Study

[*1]Shariq Ali Khan,
[1]Shagufta Rehman,
[2]S. Shakir Jamil
and
[3]S.M.Abbas Zaidi

[1]Regional Research Institute of Unani Medicine (CCRUM), Post Box No. 70, Aligarh – 202002, India

[2]Central Council for Research in Unani Medicine, 61-65, Institutional Area, Janakpuri, New Delhi - 58

[3]Department of Moalajat, H.S.Z.H. Govt. Unani Medical College, Bhopal-462003, India

Abstract

Osteoarthrosis is the commonest life style disorder encountered by the society. In the western countries radiographic evidences of this disease is present in majority of persons by 65 years of age and about 80% persons more than 75 years of age; despite exhaustive work, still no satisfactory answer has been placed forward by the modern medicine, conservative measures are ineffective and produce various Adverse drug reactions. Whereas, the Unani physicians e.g. *Galen*, *Ibn Sina*, *Razi*, *Majoosi*, *Akbar Arzani*, *Azam Khan* & *Kabiruddin* has suggested *Fasd* as an adjuvent regimenal therapy for various types of Arthritis. Though venesection is in vogue, but its scientific validation has not been carried out so far about its safety, efficacy and mechanism of action. Therefore, to explore new alternatives and for scientific validation of *Fasd*, this study has been designed and carried out to evaluate the safety and efficacy; and to explore the mechanism of action of *Fasd* in the cases of Osteoarthrosis.

Keywords: Bloodletting, Venesection, Fasd, Osteoarthrosis.

Introduction

As per Unani Medical doctrine derangement of the temperament is occurred due to the presence of morbid humours in the body and the blood circulation as well, which are responsible for production of the disease. Hence, the bloodletting is applied for the purpose of *Tanquia-e-mawad* (Elimination of morbid material) from the body(Arzani, ynm) in order to restore the bodily humors and hence maintaining health. There are three important modes of bloodletting described in the Unani literature namely, *Fasd* (Venesection), *Hijamat* (Cupping therapy) and *Taleeq* (Leech therapy). Jalinoos, Ibn Sina (1927), Arzani (1956), Razi (ynm), Majoosi (ynm), Arzani (ynm), Khan (ynm), (Kabiruddin, 1916; Kabeeruddin, 2003) have recommended the application of venesection as an adjuvent therapy in the treatment of *Wajaul Mafasil*. Osteoarthrosis is a kind of disease, *Wajaual Mafasil*. Hence, *Fasd* is equally applicable to Osteorthrosis as in other types of arthritis.

Osteoarthrosis is a life style disorder commonly encountered by the society, in western countries. Radiographic evidence of this disease are present in majority of persons by 65 years of age and about 80% of persons more than 75 years of age(Lawrence *et al*.,1989). Approximately 11% of persons more than 64 years of age have symptomatic O.A. of knee (Felson & Zhang, 2004). In Indian

[*]Author for correspondence

population knee O.A. is more common than any other joint; the same type is more common in caucasions than black or Chinese(Christopher *et al*.,1991).

American college of Rheumatology defines the disorder as; a heterogeneous group of conditions that lead to joint symptoms and signs which are associated with defective integrity of articular cartilage, in addition to related change in the underlying bone at the margins(Cooper,1988). This condition characterized clinically as joint pain, morning stiffness of less than 30 minutes, muscular weakness, swelling/effusion, Restriction of joint movements. Though the classics of Unani medicine have not described the disease as such but the symptomatology of O.A. has been described under the heading of 'Wajaul Mafasil'.

Despite exhaustive work in the field of management of this agony, still no satisfactory answer has been placed forward by modern medicine. The conservative treatment for subsiding the pain and stiffness produces a lot of adverse reactions. This handicap drives us to explore the safe and effective alternatives. Present work is based on this rationale.

Since the application of venesection has been recommended by various Unani physicians as an adjuvant therapy in the cases of arthritis, we selected this intervention to combat the sign and symptoms of O.A. Though this intervention is in vogue since centuries together but no scientific validation was carried out for its safety and efficacy. Therefore, we designed and carried out this study to evaluate the safety and efficacy of this regimen in the cases of Osteoarthrosis in comparison to conservative treatment of Unani system of medicine. An attempt was also done to explore its mechanism of action on scientific lines in combating the existing sign and symptoms of O.A.

Methodology

(i) Study Design

This was a prospective, single-centered, randomized controlled trial. All patients underwent a treatment period of 6 weeks. The protocol was approved by the ethics committee of Jamia Hamdard University, New Delhi. The trial was conducted under the Good Clinical Practice (GCP) guidelines. All patients gave written informed consent.

(ii) Patients

We screened all our patients, aged 35 to 65 years, who attended the Unani as well as Orthopedic OPDs in Majeedia hospital, New Delhi. The patients,

who had definite osteoarthritis of the knee as defined by American College of Rheumatology, were included. In bilateral knee pain, the investigator selected the more painful knee. Additionally, only those patients were included in the study that could perform 50 ft. walk test without the support of crutches or assisted devices. Exclusion criteria included pregnant and breast feeding women, anemic individuals, diabetics, patients having past history of blood disorders, ischemic heart disease and hypertension, ESR > 40 mm/hr (Westergren), CRP > 5 mg/l, any knee surgery in the previous three months, other types of arthritis, patients with any intercurrent disease(s) or condition(s) that might interfere with the free use and evaluation of the affected knee and might predispose them to a high probability of interfering with the completion of the 6 wk. follow-up (severe osteoarthritis associated with disability, neurological problems, severe congenital defects, peptic ulcer, severe liver disease, mental state, or other clinically significant conditions). *Mizaj* (temperament) of each subject was assessed on the basis of ten classical parameters prescribed in unani medical literature.

(iii) Procedures

A total of 40 patients, 20 in each group, were randomly allocated to both groups by a non-stratified block randomization with equal block lengths. Sequentially numbered envelopes containing the treatment assignment were prepared. When a patient met the inclusion criteria and consented for participation, the investigator opened the lowest numbered envelope, which determined the group of assignments. Since the intervention was invasive, hence we could not blind our study. The trial was performed after getting prior approval by institutional committee of medical ethics Jamia Hamdard, New Delhi. Patients were informed regarding the nature of the study in detail and were provided the informed consent form.

The cases randomly selected for test group i.e. group ‘B’ were administered the oral + local drugs and venesection simultaneously.

In group ‘A’ (Control group) - (i) Cap. ‘AUJAI’ were given 2 BD after meals

(ii) Roghan Surkh – was provided to apply locally on affected joints once at night

(Both formulations from Hamdard (Wakf) Lab Delhi, a GMP certified company)

In group ‘B’ (Test group) - Same drugs and dosage was administered as group ‘A’ with application of venesection on the indicated vein. The total duration of treatment was fixed 6 weeks (42 days) for both groups.

Before application of venesection, the vein to be venesected was identified properly, then as preoperative measure the site was shaved off and cleaned thoroughly with an antiseptic solution. A tourniquet was applied then on the proximal end of the extremity to expose the vein. Keeping all the sterilization measures a small cut in the longitudinal axis was made on the targeted vein.

Since all the cases were having knee osteoarthrosis; hence either small saphenous or popliteal vein was selected for venesection. The blood was allowed to be let out till it stopped itself. Then the tourniquet was released and the wound was closed by applying a piece of gauze containing antiseptic solution. On day 14th, patients returned for the second visit; day 28th for third visit and on 42nd day the final visit took place.

Outcome Measures

The outcome measures were change in knee pain, joint stiffness, joint swelling, muscular weakness and restriction of joint movement as derived from the mean Visual Analog Score of each component. The Each question was assessed by a 10 cm horizontal VAS score. For the fifty meter walk test, patients were asked to walk, at their own naturally preferred 'comfortable' pace, across a distance of 50 feet. The time taken to complete the distance was measured using a hand-held stop watch. Three repetitions of the walk were undertaken and the mean was used for subsequent analysis. Radiological assessment of the joint was also done pre and post treatment intervention.

Tolerability

Vital signs were monitored at every visit. Laboratory investigations were also performed including hematology, liver function test (Serum Bilirubin, SGOT, SGPT and Alkaline phosphatase), Serum Creatinine, Blood Urea and Uric acid at day 0 and 42.

Statistical analysis

Standard statistical tests were employed. Mann-Whitney U test was used to see the between the group difference while Wilcoxon signed rank test was used to compare the within the group difference.

Results

The improvement in joint pain is shown in table no. 2. In group A, the mean percentage of change in grading score was reported 73.33 while in group B, it

was found 93.75. As far as the morning stiffness is concerned in group A, the mean percentage of change in grading score was reported 81.66, whereas in group 'B', it was found 85.00 (Table 3). In muscular weakness the percentage of change was 66.66 in group A, whereas 85.83 in group B (Table 4). In swelling/effusion the percentage of change was 45.83 in group A, while 55.00 in group B (Table 5). The change in restriction of movement was found 78.78 in group A, whereas 90.47 in group B after the treatment (Table 6).

The statistical significance in subsidence of clinical features between the two groups was found at P-value 0.001, 0.806, 0.020, 0.467 and 0.130 respectively in pain, morning stiffness, muscular weakness, swelling/effusion and restriction of movement. However, the reduction in all clinical features was found significant in both the groups individually at P-value <.001 (Table 1 to 7).

Table 1: Baseline characteristics of study patients (n = 40)

Variable		Test Group (n = 20)	Control Group (n = 20)
Age (years)		49.90 ± 2.79	47.85 ± 7.49
Sex	Male(n)	8	6
	Female (n)	15	11
Previous regular NSAID intake (n)		16	14
Duration of knee OA (Yrs)		4.5	3.2
BMI (kg/m2)		27.12 ± 0.31	28.47 ± 0.33
VAS Pain Score		3.4 ± 0.50	3.2 ± 0.52
VAS Stiffness Score		2.05 ± 0.82	1.80 ± 0.89
VAS Joint swelling score		1.45 ± 1.31	1.2 ± 1.28
VAS Muscular weakness score		2.0 ± 0.91	1.8 ± 0.83
VAS Restriction of joint Movement		1.70 ± 1.21	1.35 ± 1.30
Fifty Meter Walk Test		37.35± 0.58	39.71± 0.78

***** Values with plus/minus signs are expressed as means ± SD

The effect on walking time was found significant in both the groups individually and the difference in both the groups comparatively was found insignificant (Table 7).

As far as the laboratory investigations are concerned, it was noted that there was no significant change in the status of Hb%, TLC, DLC and ESR after the intervention in both groups (Table No. 8 & 9).

Table 2: Effect on Joint Pain (VAS)

Groups	Items	Before treatment	After treatment	% of change
A	Mean Std. Dev. Std. Error of Mean	3.2 0.52 0.11	0.90 0.71 0.16	73.33 20.34 4.54
B	Mean Std. Dev. Std. Error of Mean	3.40 0.50 0.11	0.25 0.44 0.09	93.75 11.10 2.48
P value	< 0.001			

Table 3: Effect on Morning Stiffness (VAS)

Groups	Items	Before treatment	After treatment	% of change
A	Mean Std. Dev. Std. Error of Mean	1.80 0.89 0.20	0.30 0.47 0.10	81.66 31.48 07.03
B	Mean Std. Dev. Std. Error of Mean	2.05 0.82 0.18	0.25 0.44. 0.09	85.00 26.98 06.03
P value	< 0.806			

Table 4: Effect on Muscle weakness

Groups	Items	Before treatment	After treatment	% of change
A	Mean Std. Dev. Std. Error of Mean	1.80 0.83 0.18	0.65 0.48 0.10	66.66 31.06 6.94
B	Mean Std. Dev. Std. Error of Mean	2.0 0.91 0.20	0.30 0.47 0.10	85.83 26.08 5.83
P value	< 0.020			

The difference in change was found insignificant individually as well as between the two groups in LFTs & KFTs (Table No. 10 &11). Hence, it was concluded that the intervention is safe and tolerable.

The Radiographic assessment showed no any significant improving effect in both groups. However, Acute Soft Tissue Swelling (ASTS) was relieved in both groups after intervention.

Table 5: Effect on Joint Swelling

Groups	Items	Before treatment	After treatment	% of change
A	Mean Std. Dev. Std. Error of Mean	1.20 1.28 0.28	0.25 0.44 0.09	45.83 44.87 10.03
B	Mean Std. Dev. Std. Error of Mean	1.45 1.31 0.29	0.15 0.36 0.08	55.00 47.48 10.61
P value	< 0.467			

Table 6: Effect on Restriction of joint Movement

Groups	Items	Before treatment	After treatment	% of change
A	Mean Std. Dev. Std. Error of Mean	1.35 1.30 0.29	0.30 0.47 0.10	78.78 21.20 6.39
B	Mean Std. Dev. Std. Error of Mean	1.70 1.21 0.27	0.20 0.41 0.09	90.47 15.62 4.17
P value	< 0.130			

Table 7: Effect on Fifty meter walk test

Groups	Items	Before treatment	After treatment
A	Mean Std. Dev. Std. Error of Mean	39.71 0.78 0.52	17.20 1.60 0.36
B	Mean Std. Dev. Std. Error of Mean	37.35 0.58 0.675	16.25 1.02 0.228
P value	< 0.01		

As far as the Arthritic Profile is concerned, no case was found positive for R. Factor, ASO Titre and C-Reactive Protein. Change in Uric Acid and ESR was reported significant in both groups individually after the treatment but insignificant in between the two groups (Table No. 12 & 13).

Table 8: Effects on Haematological Parameters
(Significance in between the two groups)

	% change in Haemoglobin	% change in TLC	% change in Neutrophils	% change in Lymphocytes	% change in Monocytes	% change in Eosinophils
Mann-Whitney-U	181.50	152.00	195.50	183.00	200.00	179.00
P-value	0.617	0.194	0.903	0.645	1.000	0.663

Table 9: Effects on Haematological Parameters
(Within the group significance)

Significance	Groups	Hb% AT-BT	TLC AT-BT	Neutrophils AT-BT	Lymphocytes AT-BT	Monocytes AT-BT	Eosinophils AT-BT
P. value	A	0.001	0.008	0.026	0.471	1.000	0.001
	B	0.001	0.003	0.001	0.043	1.000	0.002

AT = After Treatment, BT = Before Treatment

Table 10: Effect on Biochemical Parameters
(Significance in between the two groups)

	Liver function tests (% change in)				Kidney function test (% change in)	
	S. Bilirubin	SGOT	SGPT	S. Alk phosphatase	Blood urea	S. creatinine
Mann-Whitney-U	187.50	99.00	47.00	144.00	175.500	190.500
P-value	0.725	0.006	0.001	0.130	0.507	0.795

Adverse Events

Neither group experienced any adverse effects as evidenced by the safety parameters.

Discussion

Since long term therapy for Osteoarthritis (OA) of the knee has limited options and treatment carries substantial risk for serious adverse effects, new therapeutic approaches should be considered. *Fasd* (venesection), although extensively used for treating various disorders in Unani system of medicine, has never been evaluated in a modern scientific context in accordance with GCP. We have followed the GCP as close as possible when conducting the study. We found that *Fasd* (Venesection) significantly improved scores of

pain, stiffness, restriction of joint movement, muscular weakness and 50 meter walk test performance over 6 weeks. OA is a disease in which compliance and persistence are known to be rather poor. In this study, venesection was found safe and well tolerated. Baseline characteristic of both the groups were comparable.

While evaluating the therapeutic effects of *Fasd* it was observed the subsidence of pain was quite significant in group B in comparison to group A, perhaps due to the expulsion of morbid materials, pain producing substances and relieving the congestion, since the drugs used in both the groups locally as well as internally were the same. Hence, venesection had an added value in relieving the pain. There was significant difference in walking time after the treatment in both groups and the difference between the groups was found insignificant.

The possible mechanism of action of venesection can be understood by exploiting the knowledge of haemodynamics; biophysical and biochemical dimensions of Biohemorrheology (Wang and Cheng Sun,1988;Poiseuille, 1835;Poiseuille,1830). Different mechanisms explain the observed effects of the venesection. After performing venesection, the hydrostatic pressure of capillaries of that local area becomes suddenly decreased, resultantly the movement of waste-metabolites and other morbid humours increase considerably from tissue spaces to the capillaries. It also increases the perfusion and relieves the engorgement of veins. O.A. leads to subchondral bone remodeling which results into subchondral irregular thickening with sclerosis and cyst formation. Increment in intraosseous pressure due to these changes in subchondral bone produces pain. Hence, relief of this pressure which is thought due to obstruction of various out flow can relieve pain. Therapeutic intervention of *Fasd* releases this pressure and is helpful in relieving pain. Furthermore, this procedure is thought to clear out the pain producing indigenous chemical stimuli (Algogenic substances) such as serotonin, substance P, Bradykinin, Prostaglandins and Histamines. It is also worth to mention here that application of *Fasd* (venesection) enhances the local blood flow, removes the stasis which helps in normalizing the local pH, removes the cell rigidity, in which the cells lost their elasticity and behave like Ghost cells of spherical nature instead of biconcavity, this phenomenon hampers the microcirculation and further increases hypoxia and acidosis. It checks the rouleaux formation and clears the already formed clumps, decreases the viscosity, and removes the acidosis and hypoxia. Hence it is helpful in relieving pain, stiffness and muscular weakness. Since the venesection's resources the hypoxia which is supposed to be an important

contributory factor in production of OA, might be helpful in delaying the destruction of articular cartilage.

Our present data suggest that re-treatments will be necessary for this therapy to become clinically valuable in the long term management of OA. Venesection, as applied in this study, was safe and well tolerated.

In conclusion, this study suggests that *Fasd* (Venesection) seems to be an effective treatment for Osteoarthrosis. However, because of the above mentioned limitations, we emphasize the preliminary nature of this study. The effectiveness of this treatment, especially when applied repeatedly, should be further evaluated in larger randomized studies. In addition, further advanced capillary haemodynamic studies are needed to have deeper and firm insight into its exact mechanism of action.

Table 11: Effect on Biochemical parameters
(Within the group Significance)

Significance	Groups	Liver Function Tests (AT-BT)				Kidney Function Tests (AT-BT)	
		S. Bilirubin	SGOT	SGPT	S. Alk phosphatase	Blood urea	S. creatinine
P-Value	A	0.5126	0.040	0.117	0.003	0.001	0.002
	B	0.452	0.001	0.001	0.001	0.003	0.033

AT = After Treatment, BT = Before Treatment

Table 12: Effects on Arthritic Profile
(Significance in between the two groups)

	% change in uric acid	% change in ESR
Mann-Whitney U	136.50	118.00
P-value	0.086	0.026

Table 13: Effects on Arthritic Profile
(Within the group significance)

Significance	Groups	Uric Acid AT-BT	ESR AT-BT
P-value	A	0.001	0.001
	B	0.001	0.001

AT = After Treatment, BT = Before Treatment

References

Arzani A, *Mufarrahul Quloob*, ynm. Urdu Translation by S.M. Baqar (Munshi Nawal Kishore Press, Lucknow), pp. 669-709

Arzani A, *Tibb-e-Akbar* (Urdu), Vol. II, 1956. Munshi Nawal Kishore Press, Lucknow, pp. 470-477

Bao Ping Wang and Fung-cheng sun, 1988. *Clin. Hemorheol,* 8(2): 269-272

Christopher R.W, Edwards & Boucher Ian A.D, 1991. *Davidson's Principles and Practices of Medicines*, 16th ed., (ELBS, UK), pp. 798-799

Cyrus Cooper, *Rheumatology*, Vol II, 1988. Mosby International, London, p. 82

Felson D.T. & Zhang, Y., 2004. An update on the epidemiology of knee and hip osteoarthritis with a view to prevention. *Rheumatology* 41(8): 1343-1355

Ibn Sina, *Al-Qanoon Fil Tibb*, Urdu Translation by G.H. Kintoori, Vol. III, 1927. Munshi Nawal Kishore Press, Lucknow, pp. 375- 387

Kabeeruddin M, *Alakseer*, Vol.2nd, 2003. Aijaz Publishing House, Delhi, pp. 1430-1448.

Kabiruddin M, *Moalijat Sharhe Asbab*, Vol. 3, 1916. Hikmat Book Depot, Hyderabad, pp. 1104-1110

Lawrence, RC, Hochberg M.C., Kelsey, J.L., 1989. Estimates of the prevalence of selected arthritis and musculoskeletal diseases in the United States. *Journal of Rheumatology* 16: 427-441

Majoosi A, ynm. *Kamilus-San'aa*, (Urdu Translation by G.H. Kintoori), Vol. II. Munshi Nawal Kishore Press, Lucknow, pp. 503-509

Poiseuille, J.L.M., 1835. Researches Sur les causes du mouvement Sang dans *Vaisseux capillaries*, *Rend. Acad. Sci*. 6:554-560

Poiseuille, J.L.M., 1830. Researches Sur les causes du mouvement Sang dans les vains. *J. Physiol. Exp. Pathol.* 10: 277-295

Razi Z, ynm. *Kitab-al-Hawi-Fil-Tibb*, Vol. XI. Dairatul Ma'arif Publications, Hyderabad, pp. 87-280

Evaluation of Efficacy of Unani Compound Formulation *"Sinugard Granules"* in the Management of Warm-e-Tajaweef-e-Anf (Sinusitis)-A Preliminary Study

*** [1]Mursaleen Naseer,**
[1]Abu Bakar Khan,
[1]Mukhtar Husain Hakim
and
[2]Yasmeen Aziz.

Department of Moalejat,
Ajmal Khan Tibbiya College,
Aligarh Muslim University,
Aligarh-202002, UP-India

Department of Jarahat,
Ajmal Khan Tibbiya College,
Aligarh Muslim University,
Aligarh-202002, UP-India

Abstract

The mucosal inflammation of the Paranasal sinuses may be acute or chronic process. The acute inflammation of the sinus mucosa commonly follows an attack of acute rhinitis as in common cold or influenza when the bacteria invade as secondary organisms (Dhingra, 2008). The effective treatment to manage this clinical entity is available in modern medicine but there is a need of the time to develop a safe and curative treatment in the Indian system of medicine.

Hence the objective of the present study is to evaluate the efficacy of Unani formulation 'Sinugard Granules'. The study was open single group uncontrolled clinical trial. In the present study forty cases of 13 to 57 years of age who were clinically diagnosed were enrolled in the study for 10 days from Moalejat and Otorhinolaryngology OPD, Ajmal Khan Tibbiya College, Aligarh Muslim University, Aligarh. The patients were treated with half sachet of 'Sinugard Granules' twice a day with lukewarm water. All the patients were assessed for subjective parameters. The study revealed that the Unani formulation has given good response on nasal congestion, tenderness and nasal discharge. Therefore, it can be concluded that the compound Unani Formulation 'Sinugard Granules' can be used for the treatment of Warm-e-Tajaweef-e-Anf (Sinusitis).

Key Words: Warm-e-Tajaweef-e-Anf, Ustukhuddus, Asalassus, Badiyan, Eucalyptus oil

Introduction

Paranasal sinuses are air-containing cavities in certain bones of skull. They are four on each side. Paranasal sinuses are lined by mucous membrane which is continuous with that of the nasal cavity through the ostia of sinuses. Paranasal sinuses develop as outpouchings from the mucous membrane of lateral wall of nose (Maqbool, 2002).

In ancient Unani literature, Warm-e-Tajaweef-e-Anf (sinusitis) is not described as such but when we go through the definitions of Nazla wa Zukam (Coryza or common cold) these seem to be quite similar to the clinical features of sinusitis (Arzani,1956). Therefore, while laid down the principles of treatment of Warm-e-Tajaweef-e-Anf we may take etiopathogenesis of Nazla wa Zukam into consideration and treat this condition accordingly.

* Author for Correspondence

The present study was carried to see the efficacy of *SINUGARD GRANULES* in Warm-e-Tajaweef-e-Anf with regards to amelioration of symptoms and signs. Although several allopathic drugs are available to treat the sinusitis but their use is hindered by adverse effects of such drugs. Therefore, we felt the necessity to find an alternative treatment in Indian system of Medicine, which could be used for a prolong interval of time without any serious complication.

Material and Methods

The present study was carried out in Moalejat and Otorhinolaryngology OPD in Ajmal Khan Tibbiya College Hospital, Aligarh Muslim University, Aligarh. The forty patients of either sex between the age group 13 to 57 years were selected whose presenting complaint was headache, facial pain, tenderness, nasal discharge and nasal congestion. Only the patients of open type frontal and maxillary sinusitis were included in this study. The diagnosis was made on the basis of history and clinical examination.

Those suffering from Diabetes Mellitus, Features of toxaemia, complications of sinusitis or who had taken any form of treatment especially antibiotics were excluded from this study. For every patient informed consent was taken.

Patients subjected for the clinical trial were given half sachet of *SINUGARD GRANULES* twice a day for a period of 10 days. The patients were followed on every 5th day.

Each sachet of SINUGARD contains 2 grams of granules and has following ingredients.

Name of ingredient	Quantity
Lavandula stoechas L. (Ustukhuddus)	550 mg
Glycyrrhiza glabra L. (Asalassus)	550 mg
Foeniculum vulgare Mill. (Badiyan)	550 mg
Menthol	60 mg
Eucalyptus oil	40 ml
Cane sugar	250 mg

Results and Observations

There was significant improvement in the subjective parameters except in the headache and facial pain.

The findings of demographic and subjective parameters were as follows.

During the course of study, patients were divided into five age groups viz. 13-21years, 22-30 years, 31-39 years, 40-48 years, 49-57 years. It was observed that maximum number of cases i.e. 14 cases (35.0%) belong to the age group 13-21 years. 13 cases (32.5%) fell in the age group 22-30 years, 4 cases (10.0%) in the age group 31-39 years, 6 cases (15.0%) in the age group 40-48 years and 3 cases (7.5%) in the age group 49-57 years.

Among the forty patients 25 cases (62.5%) were males, while 15 cases (37.5%) were females. (Table-1)

Table 1 : Showing Distribution of Patients According to Age and Sex

Total No. of Cases – 40

Age group (in years)	Number and % age of Males	Number and % age of Females	Total number and % age
13 – 21	10(25.0)	4(10.0)	14(35.0)
22 – 30	8(20.0)	5(12.5)	13(32.5)
31 – 39	3(7.5)	1(2.5)	4(10.0)
40 – 48	2(5.0)	4(10.0)	6(15.0)
49 – 57	2(5.0)	1(2.5)	3(7.5)
Total	25(62.5)	15(37.5)	40(100.0)

Patients were divided into five categories according to their occupation, student, service, labour, business and housewife. The number of cases falling in each category was 16 (40%), 6(15%), 5 (12.5%), 4(10.0%) and 9 (22.5%) respectively. Thus it was observed that maximum number of patients belong to students followed by housewives and service class. (Table-2)

Table 2 : Showing Distribution of Patients According to their occupation

Total No. of Cases – 40

Occupation	Number of Patients	Percentage
Student	16	40.0
Service	6	15.0
Labour	5	12.5
Business	4	10.0
Housewife	9	22.5
Total	40	100.0

Patients were divided into three groups on the basis of site of infection, frontal, maxillary, frontal and maxillary both. Maximum cases were found of frontal sinusitis i.e. 27 cases (67.5%) followed by 7 cases (17.5%) of maxillary sinusitis and 6 cases (15.0%) of frontal accompanied with maxillary sinusitis. (Table-3)

Table 3: Showing Distribution of Patients According to Site of Infection

Total No. of Cases – 40

Site	Number of Patients	Percentage
Frontal	27	67.5
Maxillary	7	17.5
Frontal+Maxillary	6	15.0
Total	40	100.0

The subjective parameters viz. headache, facial pain, tenderness, nasal discharge and nasal congestion were taken into consideration during the study. Out of 40 cases, facial pain, tenderness, nasal discharge and nasal congestion was found in 32 cases, 26 cases, 28 cases and 9 cases respectively, while headache was the main complaint in all the cases. At the end of study, it was observed that headache, facial pain, tenderness, nasal discharge and nasal congestion was improved by 57.5% (23 cases), 53.12% (17 cases), 69.23% (18 cases), 67.85% (19 cases) and 77.77% (7 cases) respectively. (Table-4)

Table 4 : Showing Effect of Drugs on Clinical Features of Sinusitis

Total No. of Cases – 40

Clinical Features	Follow-Up (in days)				
	Before Treatment	After Treatment			
	0 day	5th day		10th day	
	Total No. of Patients	No. of Patients	Improved % age	No. of Patients	Improved % age
Headache	40	22	45.00	17	57.50
Facial Pain	32	22	31.25	15	53.12
Tenderness	26	16	38.46	8	69.23
Nasal Discharge	28	16	42.86	9	67.85
Nasal Congestion	9	4	55.55	2	77.77

Discussion

In the present study, the efficacy of *SINUGARD GRANULES* was evaluated over a period of 10 days on the basis of improvement in the subjective parameters.

While analyzing the age group the patients were divided into five age groups. It was observed that maximum number of cases i.e. 14 (35.0%) belong to age group 13-21 years. It is well synchronized with the fact that Sinusitis usually starts in the adolescent age group (Ballyntyne,1978).

During the study, students dominated followed by housewives. It may be due to high level of awareness among the students about this disease and secondly hospital is situated in the vicinity of university campus. Housewives get exposed to dust and various allergens while doing house hold work, which may triggers the development of Sinusitis (Dhingra, 2008).

While distributing the patients according to site of infection, cases of frontal sinusitis were more than the maxillary one and it is contradictory to the text in which maxillary sinusitis is more common than frontal (Maqbool, 2002).

When the distribution of patients according to their clinical presentation was studied, it was found that the most consistent presentation was headache in all the cases while facial pain in 32 cases, Nasal discharge in 28 cases, Tenderness in 26 cases and Nasal congestion in 9 cases was recorded.

At the end of study, maximum benefit was observed in the Nasal congestion i.e. 77.77% improvement. Anti-inflammatory property of Ustukhuddus (Baghdadi, 2005, Hakim, 1924, Anonymous, 1992) and Aslusoos (Kritkar, Basu, 1996) may be attributed to this effect of drug. Glycyrrhizin inhibited thrombin induced platelet aggregation which indicates anti-inflammatory activity (www.krishnaherbals.com). Nasal congestion was also improved due to the presence of menthol in the formulation because most of menthol's uses are related to its stimulation of the cold receptors. This property makes menthol to produce a cooling effect, which help to relieve the congestion (www.wisegeek.com). Moreover, it is used in pharmaceutical preparations to disguise the taste of evil-smelling and unpleasant drugs (Chopra, 1958).

There was 67.85% improvement in the patients of Nasal discharge, which may be due to the antiseptic property of Ustukhuddus (Ahmad, 1985), Aslusoos (Rastogi, 1985-89) and eucalyptus oil. Cineole (eucalyptol) is the most important ingredient of eucalyptol oil from the medical point of view. Australol and cryptol have also been found to be efficient antiseptic (Chopra, 1958).

The headache, facial pain and tenderness were improved by 57.50%, 53.12% and 69.23% respectively at the end of study. Analgesic property of Ustukhuddus, Aslusoos and Badiyan may be attributed to this effect of drugs (Anonymous, 1998, Gazrooni, 1887).

Conclusion

This study shows the encouraging effect of Unani formulation with a potential in sinusitis management and no major adverse effects; and there is tolerance to this therapy. Further, long term studies to determine the relapse rate and the effect of Unani formulation on facial pain and headache along with standardization of active ingredients, purity and concentration are suggested.

Acknowledgement

I am grateful to Prof. M. M. H. Siddiqui, Chairman, Department of Ilaj Bit Tadbeer, A.K. Tibbiya College, Aligarh Muslim University, Aligarh, for his cooperation during the study. I am also thankful to ALDIN Herbal Research and Pharmaceutical Laboratory, Aligarh, for facilitating the study.

References

Anonymous, 1992. Standardisation of single drugs of Unani Medicine, Part II. CCRUM, New Delhi, pp.287

Ahmad, shameem, 1985. Clinical trial of Ustukhuddus (*Lavandula stoechas*) in chronic sinusitis. Thesis for M.D. (Ilmul Advia), Department of Ilmul Advia, A.K. Tibbiya College, A.M.U., Aligarh (U.P.)

Arzani,Akbar, 1956. Tibb-e-Akbar (Translated by M. H. Siddiqui). Matba Munshi Naval Kishore, Lucknow, pp.99-100

Anonymous, 1998. The Wealth of India-Raw Materials, vol. VI, CSIR. Publications & Information Directorate, New Delhi, pp.305-308

Ballyntyne, John C., 1978. A synopsis of otolaryngology. K.M. Varghese company, Bombay, pp. 216-235

Baghdadi, Ibn Hubal, 2005. Kitab al-Mukhtarat fit Tib (Urdu Translation), part-II. CCRUM, New Delhi, pp. 57.

Chopra, R.N., Chopra, I.C., Handa., K.L.,Kapur.,K.D., 1958. Indigenous Drugs of India, (2nd Ed.,). U.N. Dhur and Sons Pvt. Ltd., Calcutta, pp.167,168,196,19

Dhingra, P L, 2008. Diseases of Ear, Nose and Throat, (reprint fourth edition). Elsevier, New Delhi, pp. 181-185

Gazrooni, Al-sadeedi (Ynm.) Vol. II. Matba Munshi Naval Kishore, Lucknow, pp.141, 142,159,189

(http://www.krishnaherbals.com/glycyrrhiza glabra.html accessed on 10th Nov. 2011)

Hakim, Abdul Hakeem, 1924. Bustanul Mufridat, Khursheed Book depot, Lucknow, pp.60

(http://www.wisegeek.com/what-is-menthol.html accessed on 20th Jan., 2012)

Kritkar, K.R and Basu, B.D, 1996. Indian Medicinal Plants, Vol-3. International Book Distributers, Dehradun, pp.1973

Lubhaya, Ram, 1982. Goswami Bayan-ul-Advia, (2nd Ed.). Goswami Pharmacy, Delhi, Vol. 1, pp. 20

Maqbool, Mohd., 2002. Textbook of Ear, Nose and Throat Diseases, (reprinted 9th edition). Jaypee publishers, New Delhi, pp.184-188

Rastogi, R. P., 1985-1989. Compendium of Indian Medicinal Plants, Vol-3. CDRI, Lucknow and Publication and Information Directorate, New Delhi, pp. 319

Therapeutic Evaluation of Safuf Mudir and Sharbat Bazuri Motadil in Urinary Tract Infections (Tadiya Majra-e-Baul)

***Juwairia Ashraf, Tabassum Latafat and M.Mohsin**

Department of Moalijat, Ajmal Khan Tibbiya College, Aligarh Muslim University, Aligarh-202002, U.P., India

Abstract

Urinary tract infection is an inflammatory response of urothelium to bacterial invasion. These infections fall into two anatomic categories; the lower urinary tract infections comprising of urethritis and cystitis and the upper urinary tract infections comprising of pyelonephritis, prostatitis, and intrarenal and perinephric abscesses. In patients of such ailments Safuf mudir and Sharbat Bazuri motadil plays a drastic role. This study is therefore carried out to assess the efficacy and safety of the said drugs. Sixty patients satisfying the inclusion criteria were selected for the randomized single blind standard controlled study in the department of Moalijat Ajmal Khan Tibbiya College and hospital. All the patients were divided into test and control groups by random table numbers. 6 gm of Safuf Mudir and 20 ml of Sharbat Bazuri motadil were prescribed twice daily for 21 days to 40 patients (Group A). The study was designed by a control group of 20 patients in which Ofloxacin 200 mg was prescribed twice daily for the same duration (Group B). The assessment was carried out at weekly intervals. The data were analysed biostatstically.

Key words: Urinary tract infection, Safuf Mudir, Sharbat Bazuri

Introduction

Urinary tract infections (UTIs) account for a vast majority of patients attending the outpatients department. Throughout the world, there are about 150 million cases of symptomatic UTI per year. Such infections have plagued mankind since even before the establishment of urology as a separate branch of medicine. They affect both males as well as females, but females are at a higher risk due to the anatomy of their urinary tract. The prevalence of UTI in females is about 3% at the age of 20, increasing by about 1% in each decade (Boon, 2006). It may be defined as an inflammatory response of the urothelium to bacterial invasion. Although the concept of infection was not so clearly mentioned in Unani literature, their clinical presentations are vividly described by our ancient Unani physicians. It has been mentioned by various names in Unani text like warm-e-kulliya, warm-e-masana, and hurqatul baul. The names are either according to the site of infection or according to one of the most distressing symptoms. They may be collectively known as tadiya majra-e-baul. According to modern medicine UTIs fall into two general anatomic categories: the lower urinary tract infections comprising of urethritis, and cystitis, and the

* Author for correspondence

upper urinary tract infections comprising of pyelonephritis, prostatitis, intrarenal and perirenal abscesses. From a microbiologic perspective, it has been defined as the presence of more than one lakh organisms per ml in a midstream clean catch urine sample (Fauci *et al.*, 2008). The Infectious Diseases Society of America (IDSA) gave a slightly more relaxed consensus definition, requiring 10^3 organisms /ml to diagnose cystitis and 10□/ml for pylonephritis. In women with symptoms of uncomplicated cystitis, significant bacteriuria is now defined as 100 or more CFU (colony forming units) /ml in midstream urine plus pyuria, while in patients with uncomplicated pylonephritis and in men with UTI significant bacteriuria is defined as 10□ CFU/ml plus pyuria. In patients with complicated UTI 10□ or more CFU /ml with or without pyuria is taken into consideration (Goldman Lee, 2004). It is commonly caused by gram negative bacilli. Nearly 80% of infections are caused by *E.coli*, followed by *Proteus, Klebsiella,* and *Pseudomonas* species. Gram positive cocci play a lesser role. They include *Staphylococcus aureus, Sterptococcus epidermidis,* and *Enterococci*. The patient may present with dysuria, urgency, increased frequency of micturition, pain in abdomen, fever with chills nausea, vomiting, diarrhea, tachycardia, hematutria, pyuria (Fauci *et al*, 2008). According to the unani concept it is due to the disturbance in asbab-e-sitta zaruria and weakening of tabiyat mudabbir-e-badan, which may be regarded as the predisposing factors for derangement in kamiyat (quantity) and kaifiyat (quality) of akhlat or humors (Ahmad, 1980). This derangement may favour the growth of ajsam-e-khabisa. Among its causes weakness of excreatory function and inflammation of the neck of urinary bladder are also mentioned (Kanturi, 1889). Hippocrates, in his treatise Al-fasul, described taqtirul baul and stated that this disease is characterized by increased frequency of micturition which is due to the debility of the urinary bladder. Burning micturition as well as sepsis of the urinary tract also occurs (Razi, 2002). Tadia majra-e-baul may also occur due to exposure to cold and rain water. Other causes include consumption of alcohol and certain toxic drugs. Renal trauma and pregnancy may also predispose to the disease. Sometimes it occurs as a complication of certain infectious diseases like humma-e-mewi (tyhoid), khasra (measles), humma-e-ajamia (malaria), sarsam (meningitis) and khunnaq (diphtheria). Ufoonat-e-dam is also included among its causes. Warm-e-masana haad (acute cystitis) occurs due to deranged safra that is bile (Kabiruddin, 2009). Dysuria, burning micturition, cystitis and nephritis are not only described in detail but their management was also not beyond the approach of Unani scholars. Several regimes are mentioned in Unani pharmacopoea both in single as well as in compound formulations which have been in practice by Unani physicians. Now it is the need of the hour to test these drugs on modern parameters and to

make them evidence based. We therefore undertook this study to clinically evaluate the efficacy and safety of Safuf Mudir and Sharbat Bazuri Motadil, in the patients of UTIs. Composition of both the drugs is given in table-6.

Material and Method

This study was an experimental randomized controlled trial performed over the period extending from 2010 to 2011 i.e. one year at the outpatients and inpatients department of Moalijat, A.K. Tibbiya College & Hospital, AMU, Aligarh. All the GCP-ICMR guidelines were followed before and during the trial. Informed written consent was taken from the patients before their participation into the study. Sixty diagnosed patients, who met the criteria of age between 10-60 years, and belonged to either sex were selected for the study. Patients were diagnosed on the basis of subjective parameters like burning micturition, urgency, increased frequency of micturition, fever with chills, pain/tenderness in suprapubic region and loin. Objective parameters included haemogram, urine-routine and microscopic examination as well as culture, X-ray abdomen, random blood sugar, and USG abdomen. Liver function tests and kidney function tests were also done before and after the treatment. Patients below 10 years and over 60 years of age, those suffering from diabetes mellitus, hypertension, nodular hypertrophy of prostate and other concomitant diseases of the urinary tract were excluded from the study. Mentally retarded persons, pregnant and lactating mothers were also excluded from the study. All the patients were randomly divided into two groups, with forty patients in the test group and twenty patients in the control group. Safuf mudir (6 g) and Sharbat bazuri motadil (20 ml) were orally administered twice daily to the patients of the test group, while ofloxacin 200 mg was prescribed to the patients of the control group. Safuf Mudir is a herbomineral formulation, prepared at the pharmacy of Ajmal Khan Tibbiya Hospital, while Sharbat Bazuri Motadil is a herbal formulation from Bayaz-e-kabir Vol.II. Duration of treatment was three weeks and assessment was done at weekly intervals. Follow up was also maintained up to one month even after termination of the therapy in both the groups to observe any recurrence or re-infection. The data were analysed biostatistically by applying X^2 test.

Result and Discussion

Clinical evaluation was carried out on the basis of subjective and objective parameters. However, during the course of study it was observed that out of 60 patients enrolled in the study, the highest incidence (51.66%) was found in

the age group of 21-30 years, while the least incidence (6.6%) was found in the age group of 51-60 years. Gender wise 20 (33.33%) patients were males, while 40 (66.66%) patients were females. This shows female preponderance and it is in accordance with the established fact (Table -1). Also, 38 (63.33%) patients were married and 22 (36.66%) patients were unmarried. According to the socioeconomic status 44 (73.33%) patients belonged to the low income group (LIG), 15 (25%) belonged to medium income group (MIG), while, only 1 (1.6%) belonged to the high income group (HIG). High incidence among the LIG may be attributed to poor personal hygiene. Various nutritional deficiencies also predispose to develop UTIs. Out of 60 patients 35 (58.3%) had a previous history of UTI while 25 (41.6%) patients had no such history (Table-2). This may be due to re-infection rather than relapse. As far as temperament is concerned the highest incidence (53.33) was found in the patients belonging to the safrawi temperament, followed by damwi (23.3%), balghami (20.00%) and the least incidence (3.33%) was found in the patients of saudawi temperament (Table-3). This also in accordance with the established fact as most of the unani physicians maintain that it is mainly caused by Safra.

Table 1: Distribution of patients according to age and sex

Age groups (in years)	Males		Females		Total	
	No	% age	No	% age	Total	% age
10-20	3	5	5	8.3	8	13.3
20-30	10	16.7	21	35	31	51.7
30-40	4	6.7	5	8.3	9	15.0
40-50	2	3.3	6	10	8	13.3
50-60	1	1.7	3	5	4	6.6
Total	20	13.3	40	66.7	60	100.0

Effect of the drugs on dysuria (Table-4)

During the study maximum number of patients complained of dysuria. 95% patients in the test as well as in the control group had this complaint at the outset. But after the treatment 84.21 % patients in the test group and 84.12% in the control group showed improvement. The effect in the test group may be attributed to the soothing and cooling properties of tukhm-e-khayarain, tukhm-e-kharpaza, and bekh-e-kasni (Baitar, 2000; Chopra, 1958; Chugtai, 2000; Sala, 2003).

Table 2: Distribution of patients according to Social status, Marital Status, and H/O previous UTI

Social status	No.	% age
LIG	44	73.3
MIG	15	25.0
UIG	1	1.7
Total	60	100.0
Marital status		
Married	38	63.3
Unmarried	22	36.7
Total	60	100.0
H/O Previous UTI		
Present	35	58.3
Absent	25	41.7
Total	60	100.0

Effect of the drugs on Fever (Table-4)

In the test group 27 (67.50 %) had fever before the commencement of the treatment which was relieved in 70.37% cases after the treatment. It may be due to the antipyretic and cooling properties of tukhm-e-khayarain, tukhm-e-kharpaza (Baitar, 2000; Sala, 2003). In the control group, 13 (65%) patients had the same complaint, which was relieved in 84.81% cases.

Table 3: Distribution of patients according to Temperament

Temperament	No.	% age
Damwi	14	23.3
Balghami	12	20.3
Safrawi	32	53.3
Saudawi	2	3.3
Total	60	100.0

Effect of the drugs on pain and tenderness (Table-4)

About 45% patients in both the groups presented with pain in lower abdomen before the treatment. There was improvement in 72.22% and 88.88% patients

in the test and the control groups respectively. However, tenderness was present in 26 (65%) patients of the test group and improvement was observed in 76.92% patients. In the control group, tenderness was observed in 12 (60%) patients and it was improved in 83.333% patients after the treatment. The improvement in the test group may be due to the anti-inflammatory effect of tukhm-e- khayarain, tukhm-e-kharpaza, and heel kalan (Khan, YNM).

Effect of the drugs on pus cells and urine culture (Table-5)

Pus cells were present in 67.50% cases in the test group, which after the treatment became normal in 66.66% patients. While in the control group, they were present in 70% cases and became normal in 78.57% patients ($X^2 = 0.03$). Urine culture being a reliable objective parameter was positive in 34 (85%) cases in the test group, which after the termination of therapy became negative in 64.71% cases. In the control group it was positive in 18 (90%) patients and became negative in 77.77% cases after the termination of therapy ($X^2 = 0.29$).

In addition to the above-mentioned results, regression in other symptoms like urgency, nausea, vomiting and foul smelling urine was also noted. In the beginning urgency was present 15 (37.5%) and 6 (30%) of patients in the test and the control groups respectively. After the treatment, it was relieved in 66.6% and 83.3% patients in the respective test and control groups. Foul smelling urine was observed in 5 (12.5%) patients of test group and 4 (80%) patients were relieved by the test drug. While, 3 (15%) patients in the control group had this complaint and after the treatment there was 100% cure. Nausea and vomiting were present in least number of patients. Only two (5%) patients of test group complained it and one patient in the control group had this symptom. However, after the treatment with the test drug it was relieved in both the patients, that is, the cure was 100%, but it was not relieved in the patient of the control group. The effect may be attributed to the digestive properties of shora qalmi, jawakhar, heel kalan, and barg-e turb (Khan N.G. YNM). Above all, the effect of the test drug may be due to nuzuj and tanqiya as they are the main principles described by various eminent unani physicians. As far as UTI is concerned, the tanqiya may be mainly in the form of diuresis and most of the drugs in both the said compounds are diuretic like shora qalmi, jawakhar, barg-e-turb, tukhm-e-khayarain, tukhm-e-kharpaza, bekh-e-kasni and bekh-e-badiyan (Baitar, 2000; Khan, 1313H; Khan, YNM; Kirtikar, 1981; Lubhaya, 1982). These drugs may also alter the pH of urine. The overall effect of the test and the control drug is almost similar in both objective and subjective and parameters but during and after the termination of the treatment, several patients of the control group complained of abdominal discomfort, nausea

and decreased appetite, while in the patients of the test group there were no such complaints. The effect of the test drug is solely cumulative in relieving the symptoms and signs along with the improvement in appetite as well as general well-being.

Table 4: Effect of Drugs on Symptoms & Signs

Sings & symptoms	Test group n = 40				Control group n = 20			
Dysuria Increased frequency Urgency Fever Pain in abdomen Haematuria Nausea/ Vomiting Foul Urine Tenderness	No & % age				No. & % age			
	0day 38 95% 35 87.5 15 37.5% 27 67.5% 18 45% 4 10% 2 5% 5 12.5% 26 65%	7 day 19 47.5% 21 52.5% 12 30% 20 50% 11 27.5% 2 5% 1 2.5% 2 5% 18 45%	14day 12 30% 12 30% 8 22.5% 16 40% 9 22.5% 2 5% 0 0% 1 2.5% 13 32.5%	21 day 6 15% 7 17.5% 5 15% 8 22.5% 5 12.5% 1 2.5% 0 0% 1 2.5% 6 15%	0 day 19 95% 18 90% 6 30% 13 65% 9 45% 1 5% 1 5% 3 15% 12 60%	7 day 9 45% 5 25% 4 20% 7 20% 4 20% 1 5% 1 5% 2 10% 7 20%	14 day 4 20% 3 15% 4 20% 3 15% 2 10% 0 0% 1 5% 1 5% 3 15%	21 day 3 1.5% 3 15% 1 5% 2 10% 1 5% 0 0% 1 5% 0 0% 2 10%

Table 5: Effect of Drugs on Pus Cells and Urine Culture

Investigation	Test Group n = 40		Control Group n = 20	
Pus Cells	Before Treatment	After Treatment	Before Treatment	After Treatment
Present	27 (63.5%)	9 (35%)	14 (70%)	3 (15%)
Absent	13 (32.5%)		6 (30%)	
Total	40 (100%)	9 (35%)	20 (100%)	3 (15%)
X2 = 0.03				
Urine Culture				
Positive	34 (85%)	12 (30%)	18 (90%)	4 (20%)
Negative	6 (15%)		2 (10%)	
Total	40 (100%)	12 (30%)	20 (100%)	4 (20%)
X2 = 0.29				

Table 6: Composition of Test Drugs

Drug	Scientific name	Part used/Form
Safuf Mudir (All ingredients in equal quantities)		
Shora Qalmi	Potassium nitrate	Salt
Jawakhar	*Hordeum vulgare*	Salt
Heel Kalan	*Elitteria cardamomum*	Fruit
Berg-e-turb	*Raphanus sativus*	Leaf
Sharbat Bazuri Motadil (All ingredients equal except Bekh-e-Kasni which is twice)		
Tukhm-e-kasni	*Cichorium intybus*	Seed
Tukhm-e-khira	*Cucumis sativus*	Seed
Tukhm-e-kakri	*Cucumis utilissimus*	Seed
Tukhm-e-kharpaza	*Cucumis melo*	Seed
Bekh-e-badyan	*Foeniculum vulgare*	Root
Bekh-e-kasni	*Cichorium intybus*	Root

Conclusion

It is obvious from the study that the test and the control drugs have similar efficacy in almost all the subjective and the objective parameters. As for data analysis, X^2 test was applied and it was found that there is no significant difference between the test and the control groups regarding the efficacy (Table- 5). The test drugs also showed no apparent adverse effects as evident by laboratory investigations, which were done before and after the trial and showed no remarkable change. Therefore, we can conclude that the test drugs are effective as well as safe when prescribed to the patients of UTIs. But, after all, the exact mechanism of action is not known. Therefore, for any final conclusive data, it is mandatory to study more objectively with the collaborative approach and the involvement of modern pharmacologists and microbiologists.

References

Ahmad S.I., 1980. Introduction to Al-umur al Tabiya, 1st edition, Saini printers, Delhi, pp. 136-42.

Baitar Ibne, 2000. Aljameul mufradat al advia wal aghzia, Urdu translation, Vol. 2, CCRUM, New Delhi, pp. 165-66.

Boon N.A. *et al*., 2006. Davidson's principles and Practice of medicine 20th edition, Elsevier Churchill Livingstone, USA, p. 467.

Chopra R.N. *et al.*, 1958, Glossary of Indian Medicinal Plants, 2nd edition, C.S.I.R., New Delhi, p. 83.

Chugtai T.M., 2000. Nabatat-e-qurani aur jajid science, Zaid book depot private limited, New Delhi, pp. 217-24.

Fauci S.A., Braunwald E., Kasper D.L., et.al 2008. Harrison's Principles of Internal Medicine 17th edition, vol. 2, Mc. Graw Hill International Book Company, p. 1820.

Goldman lee, 2004. CECIL Text book of Medicine, 23rd edition Vol. 2, Saunders publication, pp. 2137-40.

Kabiruddin Hakim Mohd., 2009. Tajuma-e-Kabir (Sharah Asbab), Vol. 3, Idara kitab-ush-shifa, NewDelhi, p.21,44,45.

Kanturi G.H., 1889. Tarjuma Kamil-us- sana'ah, (original author, Ali Ibne Abbas Majusi), Vol. 1&2 Munshi Nawal Kishore, Lucknow, p. 529.

Kirtikar K.R. and Basu B.D., 1981. Indian Medicinal Plants, Vol. 2, 2nd edition, International book distributers, Dehradun, p. 1439.

Khan M.A., 1313H. Muhite-Aazam, Vol. 1, Matab Nizami, Kanpur, p: 6, 176.

Khan N.G., YNM. Khazain-ul-advia, Vol. 4, Idara Kitab-ush-shifa, New Delhi, pp. 260-61, 571, 666, 914-15, 1054, 1102.

Lubhaya R., 1982. Goswami Bayanul Advia, Vol. 1, 2nd edition, Goswami Pharmacy, Delhi, pp. 236-38.

Nadkarni K.M., 1986. Indian Materia Medica, Vol. 2nd edition 2, Bombay Popular Prakashan, p. 91

Razi A.M.B.Z., 2002. Alhavi Fit-Tib, Urdu translation, Vol. 10, CCRUM, New Delhi, pp. 15-32.

Sala A.V., 2003. Indian Medicinal Plants (a compendium of 500 species), Vol. 2, Orient Longman, Chennai, pp. 227-34.

A Clinical Study of the Unani Formulation UNIM-045 for Anti-Vitiligo effect

***Radhey Shyam Verma,**
Pervez Khan,
Mohd. Naseem
and
Latafat Ali Khan

Regional Research Institute of Unani Medicine (CCRUM), Post Box No 70, Aligarh-202002, U.P (India)

Abstract

Leucoderma, a Latin word, meaning "white skin" is caused by the destruction of melanocytes; the cells responsible for skin colour. Out of 23 patients studied, 6 patients showed 40% pigmentation, 8 patients showed 41 to 70 % pigmentation, 8 patients showed 71 to 90 % pigmentation and 1 patient showed complete pigmentation affected on different parts of the body. All the biochemical and haematological parameters were done by the standard methods referred in the text. In biochemical studies a significant reduction on the levels of Serum Total Protein ($P<0.001$) and Serum Albumin ($P<0.01$); however UNIM-045 significantly increase the levels of Serum Globulin ($P<0.01$); and A/G ratio ($P<0.01$) in different follow-up in Bars patients (Table-1). UNIM-045 significantly reduced the levels of Serum Glutamate Pyruvate Transaminase (SGPT) ($P<0.001$) and Serum Glutamate Oxaloacetate Transaminase (SGOT) ($P<0.001$) whereas a significant increases in the levels of Serum Alkaline Phosphatase enzyme, within normal level ($P<0.001$) (Table-2) were observed when compared with pre-treatment to the different follow-up. In haematological studies a significant decrease in the levels of Erythrocyte Sedimentation Rate (ESR) ($P<0.01$), Red Blood Corpuscles (RBC) ($P<0.01$) (Ist and IInd Follow-up) and Total Leucocytes Counts (TLC) ($P<0.05$) (IInd follow-up) (Table-3) were observed, when compared with pre-treatment to different follow-up in bars (vitiligo) patients. Thus test Unani formulation is suggested to have anti-Vitiligo effect (As shown in Fig-1 photographs).

Key Words: Unani Medicine, Bars, Vitiligo

Introduction

Bars (vitiligo) is an idiopathic acquired depigmenting disorder characterized by circumscribed dipigmented macules due to loss of functional melanocytes from the epidermis, the cells responsible for skin color (Suman *et. al.,* 2009). The cause of vitiligo is unknown but research suggests that it may arise from auto-immune (Suman *et.al.,* 2009), genetic (Xue *et. al*., 2005), oxidative stress (Eskandani *et. al*., 2010), neurological (Dutt, 1984), or autocytotoxic (Han & Chun, 2000). The vitiligo is becoming a common social as well as dermatological problem which has affected 1.0 to 4.0% of the world's population and approximately 3.0% of the Indian population (Handa & Dogra, 2003). Vitiligo can develop at any age but several studies report that 50%

*Author for correspondence

of cases appear before the age of 20 (Halder and Nootheti, 2003). As for a possible hereditary link, approximately one third of cases report a family history (Majumder *et. al.*, 1993). The most commonly affected areas of the body are the sun-exposed tops of hands and face and hyper-pigmented areas of the body (Halder *et al.,* 1987). . People affected with vitiligo generally experience depression (Mattoo *et. al.,* 2002), sleep disturbances (Ongenae *et*. *al*., 2006), suicidal attempts (Cotterill & Cunliffe, 1997), and anxiety (Al-Abadie *et. al*., 1994).

Although, currently available modern anti-vitiligo drugs are effective in the treatment of Vitiligo (Bars) but also produce certain adverse side effects and have high cost (Ference & Last, 2009; Kovacs, 1998). Now attention is diverted to herbal and Unani formulations due to their versatile role in the treatment of Bars (Vitiligo) with no or negligible side effects and being cost effective. Keeping in view the above facts, the efficacy of Unani coded drug UNIM-045 was evaluated in the management of Bars (Vitiligo) at Regional Research Institute of Unani Medicine; Aligarh during the period from 2008-2010 and results are presented in this communication.

Materials and methods

Subjects Selection

UNIM-045 capsule and UNIM-045 cream were obtained from Central Council for Research in Unani Medicine, New Delhi. Forty seven patients attending in the out patients department (OPD), Regional Research Institute of Unani Medicine (RRIUM), Aligarh of either sex, age (10-60 yrs) were screened to assess the different biochemical and haematological parameters. Out of forty seven patients, twenty three patients were selected for clinical trial. Criteria for selection of patients were based on inclusion and exclusion criteria. They were informed about the nature and objectives of trial and a written consent was obtained before enrolling them into the trial.

Inclusion Criteria

Patients suffering from Bars (Vitiligo) belonging to both sex and different age group (10-60 years) were selected for study. White patches on surfaces of skin neither elevated nor depressed having no exudation or scaling and no itching with hyperpigmented/ hypopigmented margin was taken as Vitiligo patches without loss of sensitivity. Bars (Vitiligo) cases free from other systemic diseases, skin diseases and intestinal infestation were included in the study.

Exclusion criteria

Pregnant mother and patients with hepato-renal, cardiac and pulmonary malfunction, patients on active vitiligo treatment with other drugs, subjects with other skin diseases such as Leprosy, Pityriasis and albinism, subjects with known allergies, subjects who were unwilling to come for regular follow-up for the entire duration of the study and non-cooperative patients were excluded.

Diet restriction and recommendation

Diet plays an important role according to the Unani System of Medicine. As Unani classics relate Bars as a phlegmatic disorder which is attributed to cold and wet, hence any food articles which produces coolness and moistness in the body qualities were strictly prohibited.

Restricted Food Articles

Articles which produce Balgham (Phlegm) are milk and milk products, lemon and lime, tamarind, orange/ citrus fruits, parsley, custard apple, guava, prunus, cashew nuts, melon, water melon, Chinese dates, sour tomatoes and amla e.t.c. and articles which are supposed to bring changes in blood and make blood impure (Fasad-ud-dam) are egg, fish, beef, brinjal and heavy and light mixed food was restricted.

Recommended Diet

Recommended food articles included Wheat, Indian Millet, Pulses, pure ghee obtained from butter, broad beans, French beans, Spinach, Bitter gourd, Onion, Beet root, Carrot, Chillies, Black pepper, Maize, Figs (fresh and dry), Almond, Walnut, Dates, Mango, Apricots, Grapes, Potatoes, Rice, Papaya, Turnip, Mutton, Bird's flesh. Finally the diet was prescribed according to the patients need.

Collection of blood serum

Blood samples were collected by puncturing the vein at each investigation. 1.0 ml of blood with ethylene diamine tetra acetic acid (EDTA) was used for various haematological parameters and other 2.0-2.5 ml of blood samples were allowed to clot and serum was separated by centrifugation, which was used for various biochemical parameters. Biochemical and haematological investigations were carried out as follows.

Biochemical analysis

Biochemical parameters carried out are as follows. Serum Total Protein, Serum Albumin and Serum Globulin, Serum Glutamate Pyruvate Transaminase (SGPT, E.C. 2.6.1.2) and Serum Glutamate Oxaloacetate Transaminase (SGOT, E.C. 2.6.1.1.), Serum Alkaline Phosphatase enzyme (ALP). The serum total protein is included because some authors had reported that there might be increased auto-antibody formation (Song *et.al*.; 1994) and rise in gamma globulin fraction (Kemp *et. al*.; 2007). Liver function tests were studied for possible side effects. Post-treatment elevated Alkaine Phosphatase enzyme values are within normal limit and were correlated by Chowdhury and Banerjee (1967).

Haematological analysis

Haematological parameters include: Haemoglobin (Hb %), Erythrocyte Sedimentation Rate (ESR), Total Leucocytes Counts (TLC), Red Blood Corpuscles (RBC) and Differential Leucocytes Counts (DLC): Polymorphs, Lymphocyte and Eosinophil Counts. Haemogram is included to see whether there was any change in Hb%, RBC count, TLC, polymorphs, lymphocytes, eosinophil count and ESR. Some author had reported that decrease in ESR (Husain *et. al*., 1991).

Drug, Dose and mode of administration

Compound Unani formulation coded drug UNIM-045 capsule, two capsules each twice daily was given orally with water after meal to the patient.UNIM-045 cream was locally applied on affected area with exposure of early morning sun rays for 2-7 minutes daily.

Duration of treatment and follow-up

Duration of treatment of patients was 12- months. After registration of patients, a pre-treatment (0 days) and follow-up (3-months, 6-months, 9-months and 12-months) observations were made by investigating Serum Glutamate Pyruvate Transaminase (SGPT), Serum Glutamate Oxaloacetate Transaminase (SGOT), Serum Alkaline Phosphatase enzyme (ALP), Serum Total Protein and Serum Albumin, Serum Globulin and A/G ratio were done in biochemical investigations and Haemoglobin (Hb %), Erythrocyte Sedimentation Rate (ESR), Total Leucocytes Counts (TLC), Red Blood Corpuscles (RBC) and Differential Leucocytes Counts (DLC): Polymorphs Lymphocyte and Eosinophil Counts were done in haematological investigations.

Statistical analysis

Data were analyzed statistically by one-way analysis of variance (ANOVA) followed by Dennett's' test. The values were considered significant when the P- value was less than 0.01.

Results and Discussion

Pigmentation response

At the end of treatment with Unani coded drug UNIM-045 (IVrth follow-up or 12 month) 6 (26 %) out of 23 patients showed 40% pigmentation, 8 (35%) patients showed 41 to 70 % pigmentation, 8 (35 %) patients showed 71 to 90 % pigmentation and 1 (4.0 %) patient showed complete pigmentation affected on the different parts of the body in vitiligo patients.

Biochemical Studied

Serum Proteins

UNIM-045 significantly reduced the levels of Serum Total Protein 12.0% ($P<0.001$), 14.0% ($P<0.001$) and 17.0% ($P<0.001$), Serum Albumin 11.0% ($P<0.01$), 10.0% ($P<0.01$), 15.0% ($P<0.01$) and 13.0% ($P<0.05$) (Table-1), when compared with pre-treatment to the different (Ist to IVth) follow-up. A significant increase in the levels of Serum Globulin 16.0% ($P<0.01$), 18.0% ($P<0.001$), 11.0% ($P<0.05$) and 14.0% ($P<0.01$) and A/G ratio 14.0% ($P<0.05$), 32.0% ($P<0.01$) and 24.0% ($P<0.01$) (Table-1) were observed in Ist, IInd and IIIrd follow-up in Bars (Vitiligo) patients. Verma *et. al.,* 2011 had reported similar type of observations in vitiligo patients treated with Unani coded drug UNIM-044. An increase of IgE count was found in 22% of vitiligo patients (Perfetti *et al,* 1991). This could be due to disease condition of patients.

Liver Function Tests

A significant reduction in the level of the Serum Glutamate Pyruvate Transaminase (SGPT) 34.0% ($P<0.001$), 33.0% ($P<0.001$), 32.0% ($P<0.001$) and 31.0% ($P<0.001$) and Serum Glutamate Oxaloacetate Transaminase level (SGOT) 24.0% ($P<0.001$), 20.0% ($P<0.001$), 21.0% ($P<0.001$) and 27.0% ($P<0.001$) were observed, when compared with pre-treatment to the different follow-up (Ist to IVrth) (Table-2). UNIM-045 significantly increased but within normal level of Serum Alkaline Phosphatase enzyme, 39.0% ($P<0.001$), 44.0% ($P<0.001$), 47.0% ($P<0.001$) and 55.0% ($P<0.001$) were observed when

compared with pre-treatment to the different (Ist to IVth) follow-up (Table-2) in bars (vitiligo) patients.

Haematological Studies

In haematological studies UNIM 045 significantly decrease the levels of Erythrocyte Sedimentation Rate (ESR) 28.0% (P<0.01), 33.0% (P<0.01), 18.0% (P<0.05) and 32.0% (P<0.01) and Red blood corpuscles (RBC) 8.0% (P<0.05) and 9.0% (P<0.01) (Ist & IInd follow-up) and Total Leucocytes Counts (TLC) 17.0% (P<0.05) (IInd follow-up) (Table-3) were observed, when compared with pre-treatment to different follow-up in bars (vitiligo) patients. Verma *et. al.,* 2011 had reported similar type of observations in vitiligo patients treated with Unani coded drug UNIM-044. In conclusion: Thus test Unani formulation is suggested to (as shown in photograph fig-1) have anti-vitiligo effect in Vitiligo (Bars) patients. Further studies are warranted.

Table 1: Effect of Unani coded drug UNIM- 045 (Oral and local) on the level of Serum Total Protein, Serum Albumin, Serum Globulin and A / G ratio in Bars (Vitiligo) patients.

Group → Parameter ↓	0th Day (Pre-treatment)	3 -Month (Ist follow-up)	6-Month (IInd follow-up)	9-Month (IIIrd follow-up)	12-Month (IVrth follow-up)
Serum Total Protein (gm/dl)	7.20 ± 0.18	6.85 ±0.15▪	6.33 ±0.16***	6.23 ±0.14***	5.98 ±0.11***
Serum Albumin (gm/dl)	4.05 ± 0.09	3.60 ±0.08**	3.63 ± 0.08**	3.46 ±0.09**	3.51 ±0.08*
Serum Globulin (gm/dl)	3.02 ±0.12	3.49 ±0.14**	3.57 ±0.10***	3.36 ±0.10*	3.43 ±0.11**
A/G Ratio	1.32 ± 0.06	1.50 ±0.08*	1.74 ±0.10**	1.63 ± 0.12**	1.44 ±0.07▪

*P<0.05 significant **P<0.01 significant, ***P<0.001 highly significant and ▪P not being <0.05

Table 2: Effect of Unani coded drug UNIM- 045 (Oral and local) on the levels of SGPT, SGOT and Serum Alkaline Phosphatase in Bars (Vitiligo) patients.

Group Parameter	0th Day (Pre-treatment)	3-Month (Ist follow-up)	6-Months (IInd follow-up)	9-Month (IIIrd follow-up)	12-Months (IVth follow-up)
SGPT (IU/L)	33.58 ± 1.74	22.65 ±0.72***	22.48 ±0.90***	22.72 ±0.97***	23.15 ± 0.50***
SGOT (IU/L)	32.95 ± 1.45	25.14 ±0.91***	26.33 ±1.04***	26.15 ± 1.07***	24.13 ± 0.74***
Serum Alkaline Phosphatase (IU/L)	78.99 ±6.47	109.39 ±6.39***	113.43 ±5.83***	116.12 ±6.57***	122.19 ±4.52***

***P<0.001 highly significant

Table 3: Effect of Unani coded drug UNIM- 045 (Oral and local) on the levels of Haemoglobin (Hb %), Erythrocyte Sedimentation Rate (ESR), Total Leucocytes Counts (TLC), Red Blood Corpuscles (RBC) and Differential Leucocytes Counts (DLC): Polymorphs, Lymphocyte and Eosinophil Counts in Bars (Vitiligo) patients.

Group Parameter	0th Day (Pre-treatment)	3-Month (Ist follow-up)	6- Month (IInd follow-up)	9- Month (IIIrd follow-up)	12-Month (IVrth follow-up)
Haemoglobin (gm %)	12.70 ± 0.25	12.27 ±0.25▪	12.33 ± 0.30*	12.38 ±0.20▪	12.48 ±0.15▪
ESR (mm/hr)	25.87 ± 1.41	18.65 ±0.96 **	17.26 ±1.87 **	21.30 ±2.08*	17.70 ±0.69**
R.B.C. (10 6 /mm3)	4.16 ±0.11	3.85 ±0.10*	3.79 ±0.10**	4.03 ±0.08 ▪	4.10 ±0.08 ▪
T.L.C. (103/mm3)	6.94 ±0.46	6.20 ±0.28▪	5.76 ±0.28*	6.31 ±0.38▪	6.58 ±0.26▪
Polymorphs (%)	62.17 ±1.24	61.48 ±0.98▪	63.22 ±1.54▪	63.13 ±1.06▪	63.35 ±1.21▪
Lymphocyte Counts (%)	34.87 ±1.06	32.48 ±1.47▪	32.78 ±1.13▪	33.70 ±1.10▪	32.70 ±1.10▪
Eosinophil Counts (%)	3.65 ±0.34	4.13 ±0.28▪	4.26 ±0.51▪	3.35 ±0.26▪	4.09 ±0.33▪ *

*P<0.05 Significant, **P<0.01 significant, and ▪P not being <0.05

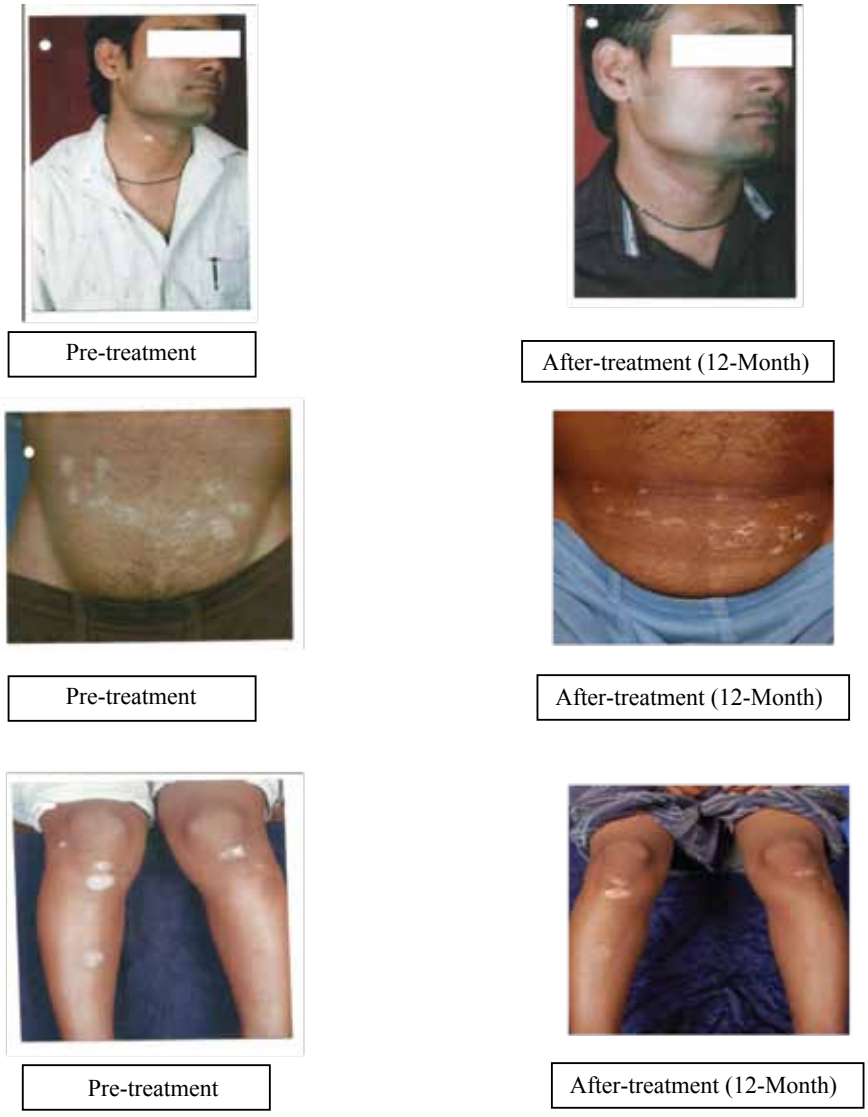


Fig. 1: Photographs showing response to the Unani coded Drug UNIM-045 in Bars (Vitiligo) lesions.

Acknowledgement

We are grateful to Professor Shakir Jamil, Director General, Central Council for Research in Unani Medicine, New Delhi for encouragement and all facilities for the present work. We are thankful to all staff of Biochemistry and Pathology Laboratory and OPD of RRIUM, Aligarh, for investigations.

References

Singh, S., Usha and Pandey, S.S., 2009. Role of immunity in Vitiligo. *Indian J. Allergy Asthma Immunol 23: 67-71.*

Xue-Jun, Z., Jian-Jun, C. and Jiang-Bo, L., 2005.The genetic concept of vitiligo. *J. Dermatol Sci* 39: 137-146.

Eksaadani, M.,Golchai, J., Piooznia, N. Hasannia, S., 2010. Oxidative stress level and tyrosinase activity in vitiligo patients. *Ind. J. Dermatol.* 55: 15-19.

Dutt, A.K., 1984. Neural implications in vitiligo. International Society of Dermatology Conference, Mexico.

Han, S.K., Chun, W.H., 2000. Autocytotoxic hypothesis for the destruction of melanocytes as the cause of vitiligo. In Vitiligo. Ist edition (Eds. by Hann, S.K., Nordlund, J.J. Oxford). Blackwell Scientific Publications, pp. 137-41.

Handa, S. and Dogra, S., 2003. Epidemiology of childhood vitiligo: a study of 625 Patients from North India. *Ped. Dermatol.* 20: 207-210.

Halder, R.M., and Nootheti, P.K., 2003. Ethnic skin disorders cverview. *J. Am. Acad. Dermatol* 46: S143-8.

Majumder, P.P., Nordlund, J.J., Nath, S.K., 1993. Pattern of familial aggregation of vitiligo. *Arch. Dermatol.* 129: 994-998.

Halder RM, Grimes PE, Cowan CA, Enterline JA, Chakrabarti SG, Kenney JA Jr., 1987.Childhood vitiligo. *J. Am. Acad. Dermatol.*16:948-54.

Mattoo, S.K., Handa, S., Kaur, I., Gupta, N., Malhotra, R., 2002. Psychiatric morbidity in vitiligo: prevalence and correlates in India. *J. Eur. Acad. Dermatol Venereol* 16: 573-578.

Ongenae, K., Beelaert, L., Van Geel, N. and Naeyaert, J.M., 2006. Psychosocial effects of vitiligo. *J. Eur. Acad. Dermatol Venereol* 20: 1-8.

Cotterill, J.A. and Cunliffe, W.J., 1997. Suicide in dermatological patients. *Br. J. Dermatol.* 137: 246-250.

Al-Abadie, M.S.K., Kent, G. and Gawkrodger, D.J., 1994. The relationship between stress and the onset and exacerbation of psoriasis and other skin conditions. *Br. J. Dermatol.* 130: 199-203.

Ference, J.D and Last, A.R., 2009. Choosing topical corticosteroids. *Am. Fam. Physican* 79: 135-40.

Kovacs, S.O., 1998. Vitiligo. *J. Am. Acad. Dermatol.* 38: 647-68.

Song, Y.H., Connor, E., Li, Y., Zorovich, B., Balducci, P. and Maclaren, N., 1994. The role of tyrosinasein autoimmune vitiligo. *Lancet* 334: 1049-52.

Kemp,E.H., Gavalas, N.G., Gawkrodger, D.J.,Weetman, A.P.,2007. Autantibody Responses to melanocytes in the depigmenting skin disease vitiligo. *Autoimmune Rev* 6: 138-42.

Chowdury, D and Banerjee, A.K., 1967. Liver function tests in vitiligo: preliminary report. *Bull. Calcutta Sch. Trop. Med.* 15:108-10.

Husain, S.J., Taiyab, M. and Zakiuddin, 1991. Effect of Atrilal on biochemical changes in cases of vitiligo. *Indian Journal of Medicine* 1: 18-28.

Verma, R.S., Abbas, A., Abbas, S., and Khan, L.A., 2011. Efficacy of Unani Coded drug UNIM-044 In Vitiligo (Bars) patients-A clinical Study. *Hippocratic Journal of Unani Medicine* 6(2): 23-31.

Perfetti, L., Cespa, M., Nume, A. and Orecchia, G., 1991. Prevalence of atopy in vitiligo: A preliminary report. *Dermatologica* 182: 218-220.

A Contribution to the Ethnopharmacological Study of the Shivalik Forests of Saharanpur, Uttar Pradesh

[1]*Zaheer Anwar Ali,
Sarfraz Ahmad
and
Latafat Ali Khan

Survey of Medicinal Plants Unit, Regional Research Institute of Unani Medicine (CCRUM), Post Box 70, Aligarh – 202001 (U.P.)

Abstract

This paper deals with the results of an ethnopharmacological survey conducted in the Shivalik forest division Saharanpur of western Uttar Pradesh. Ethnomedicinal uses of 37 plant species belonging to 31 families are described. For each plant species are given the correct botanical and prevalent local names, the part of the plant used, claimed medicinal use(s) and mode of administration. The study has revealed many therapeutic uses which have not been hitherto reported. The potential of traditional medicines and ethnopharmacology in development and discovery of new pharmaceuticals has been highlighted.

Keywords: Ethnopharmacological survey, Folk medicines, Shivalik forests, Saharanpur, Western Uttar Pradesh.

Introduction

Western Uttar Pradesh has vast area, varied flora and diverse cultures. Traditional phytotherapy exists in every cultural area of this region. This is the reason that a lot of information regarding the folk medicinal uses of local plants has been documented from tribal pockets and rural areas across this part of the country (Alam et al., 1987, 1990; Ali, 1999; Ali et al., 2003, 2011a, 2011b; Ali and Singh, 1998; Anis and Iqbal, 1994; Atique et al., 1985a, 1985b, 1985c, 1993; Azam and Hisamuddin, 2009; Khan, 2002; Khan and Khan, 2002, 2003, 2004; Khan et al., 2003a, 2003b; Maheshwari and Singh, 1984; Mittal et al., 2008; Aslam and Masood, 2003; Siddiqui et al., 1989, 2000; Singh and Agarwal, 2008; Singh and Ali, 1989; Singh et al., 1989, 2008, 2009; Singh and Khan,1990; Singh and Rashid, 2003; Tomar, 2007a, 2007b, 2008a, 2008b; Tomar and Singh, 2006a, 2006b). A review of literature revealed that a few fieldworks have also been done on medicinal plants as well as traditional medicines of district Saharanpur as evident by the published reports available for this district (Ahuja, 1965; Dhiman et al., 2006; Husain and Siddiqui, 1987; Khanna and Ramesh, 2000). But, no comprehensive account of folk medicines of Shivalik forest division had previously been reported. Hence, an extensive ethnopharmacological survey was conducted in this part of Uttar Pradesh. In this communication information on various herbal preparations obtained during the fieldwork is presented.

1 Author for correspondence

*Based on the data presented by the first author in National Seminar on "Innovative Trends in Unani Medicine", organized by Regional Research Institute of Unani Medicine, Aligarh, on the eve of its Silver Jubilee Celebrations at Aligarh, 3-4 March 2012.

The study area lies between 30º 0′-30º25′ North latitude and 77º 32′-78º 01′ East longitude in the north of Saharanpur district of western Uttar Pradesh (Fig. 1). It is surrounded by the Kalsi soil conservation forest division (Uttarakhand) in the north, Social forestry division Saharanpur in the south, Rajaji National Park (Uttarakhand) in the east and the river Yamuna in the west which separates it from Karnal and Yamuna Nagar districts of Haryana. The division presents many varieties of features and differs in general appearance than any other portion of Doab land as well as Gangetic Plain as a whole. There are the steep hills of Shivalik chain which appear in a far more marked form in Saharanpur than any other district of Uttar Pradesh while below the hills are to be seen in a modified form the prevailing characteristics of the Bhabar and Tarai regions.

Shivalik forest division has a tropical climate because of the proximity to the Himalayan region. The area receives average rainfalls of about 110 cm. It's Tarai and down hills is rich in forest vegetation which is generally of northern tropical dry deciduous type. Shivalik pine forests with dominance of 'Chir' (*Pinus roxburghii* Sargent) are found on the higher reaches of the hills. The division comprises of three forest ranges namely Barkala, Mohand and Shakumbhari with reserve forests covering an area of 33229.46 hectare. The forest areas surveyed include Mohand, Shahjahanpur, Kaluwala, Khajnawar, Karondi, Khara, Maganpur, Badshahibagh, Khaironwali, Barkala, Shakumbhri, Sahensra Thakur, Kothri, Jasmor located in different forest ranges of the division which are predominantly inhabited by *Vangujjars.* Traditionally, these tribal used to migrate during winter from the hills but now they have been settled here in the Shivalik forests. They have their own dialect and food habits. Their elders still possess good knowledge of medicinal uses of local plants acquired in the course of long experience and close association with the forests.

Methodology

The present investigation was carried out in May and June 2011. In the course of fieldwork a number of villages and tribal settlements were visited and information on ethnomedicinal uses was recorded through interviews with local healers of good reputation and other knowledgeable village elders. Data on common name of the plant, claimed medicinal use(s), part used, other ingredients added (if any), method of drug preparation and mode of administration along with doses and duration of treatment were recorded for each claim. Plant specimens were collected and later identified with the help of related floras (Duthie, 1903-1922; Hooker, 1872-1897, Kanjilal, 1901). In

some cases botanical identify was finally confirmed by matching them in the herbarium of Forest Research Institute, Dehradun (DD). Voucher herbarium specimens of all the species were prepared and deposited in the herbarium of the Survey of Medicinal Plants Unit, Regional Research Institute of Unani Medicine, Aligarh (U.P.), India.

Observations

In the following listing medicinal plants are arranged in alphabetical order by their scientific names. Each entry gives information on botanical name, family (between parentheses), vernacular names, locality, field number and collector's name, followed by popular medicinal use(s) with mode of administration. As far as possible, the probable dosage and duration of these crude drugs are also given.

Achyranthes aspera L. (Amaranthaceae); 'Parkanda', 'Bachitta', 'Chirchita'; Karondi (*ZAA9094*). Fresh leaf juice is applied on cuts and wounds, while leaf paste as poultice, is applied on boils to relieve pain.

Adhatoda zeylanica Medic. (Acanthaceae); 'Kala Bansa'; Kaluwala (*ZAA9061*). Lukewarm aqueous decoction of dried leaves is given two times a day for 3-5 days to treat cough.

Adiantum capillus-veneris L.f. (Adiantaceae); 'Hansraj'; Khaironwali (*ZAA9170*). About 20g of dried fronds are boiled in 100 ml of water. This decoction mixed with powder of few black peppers and little honey is taken two times a day for 30-45 days for asthma.

Aegle marmelos (L.) Corr. (Rutaceae); 'Bel'; Badshahibagh (*ZAA9127*). About 10g of roasted pulp of the ripe fruit are given with milk at bedtime for general weakness. It is also used as an aphrodisiac.

Ageratum conyzoides L. (Asteraceae); 'Jangli Podina'; Barkala (*ZAA9250*). A freshly made paste of the leaves, obtained by crushing, is applied on burns.

Azadirachta indica A. Juss. (Meliaceae); 'Neem'; Mohand (*ZAA9238*). Leaf infusion is given orally on an empty stomach in the morning for treating scabies.

Boerhavia diffusa L. (Nyctaginaceae); 'Santhi'; Karondi (*ZAA9086*). Cooked leaves are eaten in jaundice. Root decoction is administered once daily to prevent kidney and liver from the harmful effects of habitual and excessive consumption of country made liquor.

Bombax ceiba L. (Bombacaceae); 'Simbbal'; Khaironwali (*ZAA9182*). Powder of the stem bark mixed with mustard oil is applied on boil to speed up suppuration and healing.

Butea monosperma (Lam.) Taub. (Fabaceae); 'Dhak'; Badshahibagh (*ZAA 9136*). Aqueous decoction of flowers is given orally for anuria.

Capparis zeylanica L. (Capparaceae); 'Lalbindara'; Khara (*ZAA8956*). Seeds are mixed with fodder and given daily to cow to induce conception.

Cassia fistula L. (Caesalpiniaceae); 'Amaltas', 'Karangal'; Mohand (*ZAA9083*). Fruit pulp mixed with 'gur' (solidified sugarcane juice) and little common salt is given to cattle for worm infestation. This preparation is also used for chronic constipation.

Clausena pentaphylla DC. (Rutaceae); 'Harka'; Badshahibagh (*ZAA8889*). In jaundice, patient is advised to look through large and prominent gland dots of the dried leaf in sunlight.

Cleome viscosa L. (Cleomaceae); 'Jakhiya'; Mohand (*ZAA9241*). Fresh leaf juice is given for worm infestation.

Crataeva adansonii DC. (Capparaceae); 'Bana'; Mohand (*ZAA9073*). Foliage is fed to cattle for bronchitis.

Dendrocalamus strictus (Roxb.) Nees (Poaceae); 'Bans'; Khaironwali (*ZAA9181*). Crushed vegetative buds are squeezed to obtain the juice and given orally to treat anuria.

Diospyros montana Roxb. (Ebenaceae); 'Panchhi'; Shakumbhri (*ZAA9245*). Stem bark paste is applied on bruise.

Drimia indica (Roxb.) Jessop. (Liliaceae); 'Jangli Gantha'; Barkala (*ZAA9248*). Bulb is crushed and boiled in sesame oil. It is cooled and applied locally to treat muscular pain.

Equisetum ramosissimum Desf. (Equisetaceae); 'Jorjori'; Karondi (*ZAA9161*). Fresh juice of aerial parts is applied on burns for healing and to prevent scar.

Euphorbia hirta L. (Euphorbiaceae); 'Dudhi'; Karondi (*ZAA9145*). Leaf paste is given as galactagogue. For treatment of worm infested wounds, 10-15 leaves of the plant are kept in a cotton cloth and tied around horns as well as neck of cattle.

Ficus religiosa L. (Moraceae); 'Pipal'; Maganpur (*ZAA9126*). Paste of vegetative buds is given for colic.

Gmelina arborea Roxb. (Verbenaceae); 'Kumhar'; Maganpur (*ZAA9197*). Leaf paste is applied on boils as poultice.

Hibiscus rosa-sinensis L. (Malvaceae); 'Gulhar'; Badshahibagh (*ZAA9264*). Fresh flowers are taken raw to relieve abdominal pain.

Holarrhena pubescens (Buch.-Ham.) Wall. ex G. Don (Apocynaceae); 'Kokar', 'Inderjo'; Kaluwala (*ZAA9065*). Stem bark decoction is administered orally against flatulence.

Leucas cephalotes (Koen. ex Roth) Spreng. (Lamiaceae); 'Guma'; Khara (*ZAA9260*). Whole plants are chopped and boiled in water; the resulting decoction is given for common fever. However, flower decoction is given to cattle for anuria.

Litsea glutinosa (Lour.) Robinson (Lauraceae); 'Chandna', 'Meda', 'Rehrn'; Karondi (*ZAA9150*). Paste of the stem bark is used as an external application for traumatic pain and inflammation in cases of cattle.

Madhuca longifolia (Koenig) Macbride (Sapotaceae); 'Mahua'; Sahensra (*ZAA9198*). Decoction of stem bark is given orally as abortifacient.

Mallotus philippensis (Lam.) Muell.-Arg. (Euphorbiaceae); 'Reni', 'Rohini', 'Kamila'; Badshahibagh (*ZAA9056*). Crimson red powder which covers the ripe fruits is collected and dried. One teaspoonful of this powder is given with water once a day for 10-15 days to treat scabies.

Moghania lineata (L.) O. Ktze (Fabaceae); 'Salpanni'; Shakumbhri (*ZAA9223*). Leaf decoction is given to treat fever and body ache.

Nyctanthes arbor-tristis L. (Oleaceae); 'Kuri', 'Harsinghar'; Barkala (*ZAA9253*). Leaf decoction is given orally for common cold with fever. It is also claimed to be effective in flatulence.

Prunus persica (L.) Stokes (Rosaceae); 'Aru'; Badshahibagh (*ZAA9206*). One teaspoon of the leaf juice is given at bedtime for few days to treat worm infestation.

Rauvolfia serpentina (L.) Benth. ex Kurz. (Apocynaceae); 'Sarpgandha'; Maganpur (*ZAA9204*). This shrub is planted in the houses and used to treat joint pain. Dried root is ground to make a fine powder; about 10g of this powder are given with water two times a day for 15-21 days consecutively.

Shorea robusta Gaertn.f. (Dipterocarpaceae); 'Sal'; Mohand (*ZAA9057*). Powdered gum-resin (l0g) is given with water three times a day for 5 days to treat diarrhoea.

Solanum virginianum L. (Solanaceae); 'Kathiyali'; Karondi (*ZAA9059*). Finely chopped plants are mixed with fodder and given for one week to treat loss of appetite in cases of domestic animals.

Stephania japonica (Thunb.) Miers (Menispermaceae); 'Jangli Nirbhishi'; Shakumbhari (*ZAA9246*). Leaf juice is given orally for treating urticaria.

Syzygium cumini (L.) Skeels (Myrtaceae); 'Jaman'; Khaironwali (*ZAA9185*). Vegetative buds mixed with 'zeera' (fruits of *Cuminum cyminum* L.), 'heeng' (oleoresin of *Ferula asa-foetida* L.) and 'kala namak' (sodium sulphate mixed with sodium chloride) are pounded. One teaspoon of this preparation is given with curd two times a day for 5 days to treat dysentery.

Vitex negundo L. (Verbenaceae); 'Mahala'; Pelyo (*ZAA9066*). Powdered leaves mixed with 'kala namak' are given to cattle for loss of appetite.

Woodfordia fruticosa (L.) Kuntz. (Lythraceae); 'Dhain', 'Dhawai'; Badshahibagh (*ZAA9113*). Water extraction of the stem bark is prepared till it become viscous. After cooling, it is applied on burns.

Discussion and Conclusion

The present study on Shivalik forest division Saharanpur has led to the documentation of ethnomedicinal uses of 37 plant species. The data are authentic and obtained from local healers who have long been using these plants as folk drugs for treatment of various illnesses and injuries of humans and cattle. These herbal preparations are widely accepted and popular throughout the area. A comparison 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) revealed that majority of these claims are new or imperfectly known. Usages of medicinal plants presented in the listing are based on ancestral knowledge and empiric experience. Therefore, these species deserve scientific screening and evaluation for exploring their therapeutic potential. Such investigations may yield useful leads needed in the search of new biodynamic compounds of potential therapeutic value. As many conventional drugs of today have their origin in Indian traditional medicine and ethnopharmacology (Mukherjee et al., 2007; Patwardhan, 2005). It is, therefore, imperative that herbal materia medica of the tribals from ethnopharmacologically underexplored or unexplored areas of the country should be documented systematically, before this traditional knowledge is lost due to acculturation of indigenous societies by the erosive effect of modernization.

The objectives of ethnopharmacology are to rescue and document the important cultural heritages before these are lost and to investigate as well as evaluate the agents employed. Thus, it plays an immense role in the evaluation of natural products and more particularly the herbal drugs from traditional and folklore resources (Cordell and Colvard, 2005). The aim of present study is to report the information on most commonly used medicinal plants from the Saharanpur Shivaliks and to contribute to the rich heritage of traditional medicine of western Uttar Pradesh.

Fig. 1: Map of Shivalik forest division Saharanpur (U.P), India.

Acknowledgements

We are very grateful to Prof. S. Shakir Jamil, Director General, Central Council for Research in Unani Medicine, New Delhi for providing necessary facilities

for this survey. We should like to thank Mr. M. Umar Khan, Divisional Forest Officer, Shivalik Forest Division Saharanpur for giving us permission to work in this forest division. Throughout the study his forestry staff continuously assisted us in every possible way. We express sincere thanks to all the informants who willingly provided us local names and uses of plants reported herein.

Some Folk Medicinal Plants of the Study Area

Fig. 2: Jangli Gantha (*Drimia indica* (Roxb.) Jessop.)

Fig.-3. *Holarrhena pubescens* (Buch.-Ham.) Wall. ex G. Don (Inderjo)

Fig.-4. *Mallotus philippensis* (Lam.) Muell.-Arg. (Kamela)

Fig.-5. *Madhuca longifolia* (Koenig) Macbride (Mahua)

Fig.-6. *Shorea robusta* Gaertn. f. (Sal)

References

Ahuja, B.S., 1965. Medicinal plants of Saharanpur, Central Council of Ayurvedic Research. Gurukul Kangri Vishwavidyalaya, Haridwar, India.

Alam, M.M. and Anis, M., 1987. Ethnomedicinal uses of plants growing in the Bulandshahr district of Northern India. *J. Ethnopharmacol*. 19: 85-88.

Alam, M.M., Siddiqui, M.B. and Husain, W., 1990. Treatment of diabetes through herbal drugs in rural India. *Fitoterapia* 61: 240-242.

Ali, Z.A. and Singh, V.K., 1998. Folk herbal remedies for treating diarrhoea and dysentery in Uttar Pradesh, India. In: J.N. Govil (Ed.), Current Concepts of Multidiscipline Approach to the Medicinal Plants (Part-2). Today and Tomorrow's Printers and Publishers, New Delhi, pp. 233-240.

Ali, Z.A., 1999. Folk veterinary medicine in Moradabad district (Uttar Pradesh), India. *Fitoterapia* 70: 340-347.

Ali, Z.A., Ahmad, S. and Khan, L.A., 2011a. A contribution to the ethnomedicinal flora of Bijnor district, Uttar Pradesh. *Hippocratic J. Unani Med.* 6(1): 55-61.

Ali, Z.A., Ahmad, S. and Khan, L.A., 2011b. Medicinal plants diversity in the Amangarh forests of Bijnor district, Uttar Pradesh. *Hippocratic J. Unani Med.* 6(1): 95-118.

Ali, Z.A., Khan, A.A. and Singh, V.K., 2003. Folk medicinal plants from Moradabad district (Uttar Pradesh) India. In: V.K. Singh, J.N. Govil, S. Hashmi, G. Singh (Eds.), Recent Progress in Medicinal Plants: Ethnomedicine and Pharmacognosy II, Vol. 7. Studium Press LLC, U.S.A., pp. 15-24.

Anis, M. and Iqbal, M., 1994. Medicinal plant lore of Aligarh, India. *Int. J. Pharmacog.* 32: 59-64.

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, Department of AYUSH, New Delhi.

Aslam, M. and Anwar, M., 2003. Some important aquatic medicinal plants of Tarai Region of North-West Uttar Pradesh, India. In: V.K. Singh, J.N. Govil, S. Hashmi, G. Singh (Eds.), Recent Progress in Medicinal Plants: Ethnomedicinie and Pharmacognosy II, Vol.7. Studium Press LLC, U.S.A., pp. 565-570.

Atique, A., Iqbal, M. and Ghouse, A.K.M., 1985a. Use of *Anona squamosa* and *Piper nigrum* against diabetes. *Fitoterapia* 56: 190-192.

Atique, A., Iqbal, M. and Ghouse, A.K.M., 1985b. Ethnobotanical study of cluster fig (*Ficus racemosa*). *Fitoterapia* 56(4): 236-240.

Atique, A., Iqbal, M. and Ghouse, A.K.M., 1985c. Folk medicinal uses of *Ficus bengalensis* Linn. and *Punica granatum* Linn. in Northern Uttar Pradesdh. *Bull. Med. Ethnobot. Res.* 6: 42-46.

Atique, A., Khair, S. and Iqbal, M., 1993. Traditional herbal contraceptives from North-West Uttar Pradesh. In: J.N. Govil, V.K. Singh and S. Hashmi (Eds.), Glimpses in Plant Research (Vol. X). Medicinal Plants: New Vistas of Research (Part 1). Today and Tomorrow's Printers and Publishers, New Delhi, pp. 41-47.

Azam, T. and Hisamuddin, 2009. A survey of some common medicinal plants of Bulandshahr (U.P.) and their medicinal utilization. *Indian J. Applied & Pure Biol.* 24: 321-323.

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

Cordell, G.A. and Colvard, M.D., 2005. Some thoughts on the future of ethnopharmacology. *J. Ethnopharmacol*. 100: 43-49.

Dhiman, A., Parveen, R., Khurana, S., Sanjay, K. and Bhargava, A.K., 2006. Antipyretic traditional herbal medicinal plants of district Saharanpur, U.P., India. *Plant Archives* 6(2): 706-710.

Duthie, J.F., 1903-1922. Flora of the Upper Gangetic Plain and of the Adjacent Siwalik and Sub-Himalayan Tracts. Vol. I-II (Repr. 1960), BSI, Calcutta.

Hooker, J.D., 1872-1897. The Flora of British India. Vol. I-VII. L Reeva and Co. London.

Husain, W. and Siddiqui, M.B., 1987. Ethnobotanical approach of North-Western U.P. *Acta Botanica Indica* 15: 94-97.

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

Kanjilal, U.N., 1901. Forest flora of the Chakrata, Dehra Dun and Saharanpur Forest Divisions, Uttar Pradesh. Manager Publications, Delhi.

Khan, A.A. and Khan, A.V., 2004. Medico-ethnobotanical uses of *Phyllanthus fraternus* Webst. (Family:Euphorbiaceae) from Western Uttar Pradesh, India. *Journal of Natural Remedies* 4: 73-74.

Khan, A.A., 2002. Folk medicinal plants from Bijnor district (U.P.), India. In: V.K. Singh, J.N. Govil and G. Singh (Eds.), Recent Progress in Medicinal Plants: Ethnomedicine and Pharmacognosy, Vol. 1. Sci Tech. Publishing LLC, USA, pp. 183-188.

Khan, A.V. and Khan, A.A., 2002. A survey of some plants used for termination of pregnancy in part of Western Uttar Pradesh. *Bionotes* 4: 43.

Khan, A.V. and Khan, A.A., 2003. Herbal abortifacients used by folk people of some districts of Western Uttar Pradesh (India). *Journal of Natural Remedies* 3: 41-44.

Khan, A.V., Alam, M.M. and Singh, V.K., 2003b. Ethnomedicinal uses of *Citrullus colocynthis* (L.) Schrad. in rural areas of Aligarh district (Uttar Pradesh) India. In: V.K. Singh, J.N. Govil, S. Hashmi, G. Singh (Eds.), Recent Progress in Medicinal Plants: Ethnomedicine and Pharmacognosy II, Vol. 7. Studium Press LLC, U.S.A., pp. 383-388.

Khan, A.V., Parveen, G., Alam, M.M. and Singh, V.K., 2003a. Ethnomedicinal uses of Neem in rural areas of Uttar Pradesh, India. In: V.K. Singh, J.N. Govil, S. Hashmi, G. Singh (Eds.), Recent Progress in Medicinal Plants: Ethnomedicine and Pharmacognosy II, Vol. 7. Studium Press LLC, U.S.A., pp. 319-326.

Khanna, K.K. and Ramesh, K., 2000. Ethnomedicinal plants used by the Gujjar tribe of Saharanpur district, Uttar Pradesh. *Ethnobotany* 12: 17-22.

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

Maheshwari, J.K. and Singh, J.P., 1984. Contribution to the ethnobotany of Boxa tribe of Bijnor and Pauri Garhwal districts (U.P.). *J. Econ. Tax. Bot.* 5: 251-259.

Mittal, N., Singh, A.K. and Agarwal, G., 2008. Some ethnomedicinal plants used in Agra district of Uttar Pradesh, India. *Plant Archives* 8: 443-445.

Mukherjee, P.K., Rai, S., Kumar, V. and Mukherjee, K., 2007. Plants of Indian origin in drug discovery. *Expert Opin. Drug Disco*. 2(5):633-657.

Nadkarni, A.K., 1954. Indian Materia Medica. Vol. I and II, 3rd Edition. Popular Book Depot, Bombay.

Patwardhan, B., 2005. Ethnopharmacology and drug discovery. *J. Ethnopharmacol*. 100:50-52.

Siddiqui, M.B., Alam, M.M. and Husain, W., 1989. Traditional treatment of skin diseases in Uttar Pradesh, India. *Economic Botany* 43: 480-486.

Siddiqui, T.O., Javed, K. and Alam, M.M., 2000. Folk medicinal claims of western Uttar Pradesh, India. *Hamdard Medicus* 43: 59-60.

Singh, V.K. and Khan, A.M., 1990. Medicinal plants and folklores: A Strategy Towards Conquest of Human Ailments. Today and Tomorrow's Printers and Publishers, New Delhi.

Singh, A., Masih, H. and Singh, S.B., 2008. Survey of medicinal plants of Agra district used in skin diseases. *Advances in plant sciences* 21: 347-349.

Singh, K.P. and Agarwal, R., 2008. Ethnomedicinal studies on cucurbits of Agra district. *J. Econ. Tax. Bot.* 32 (Suppl.): 87-91.

Singh, K.P., Kumar, P. and Bhadauria, S., 2009. An inventory of medicinal plants in Mainpuri district of Uttar Pradesh. *Journal of Medicinal and Aromatic Plant Sciences* 31: 223-227.

Singh, V.K. and Ali, Z.A., 1989. Folk medicines of Aligarh (Uttar Pradesh) India. *Fitoterapia* 60: 483-490.

Singh, V.K. and Rashid, M.A., 2003. Ethnomedicine of North India – A review. In: V.K. Singh, J.N. Govil,, S. Hashmi, G. Singh (Eds.), Recent Progress in Medicinal Plants: Ethnomedicine and Pharmacognosy II, Vol. 7. Studium Press LLC, U.S.A., pp. 127-136.

Singh, V.K., Ali, Z.A., Zaidi, S.T.H. and Husain, W., 1989. Medicinal plants employed by the rural population of Mainpuri forest division, Uttar Pradesh, India. *New Botanist* 26: 137-145.

Tomar, A. and Singh, H., 2006a. Ethno-therapeutics of some medicinal plants from Khatauli block of Muzaffarnagar district (U.P.), India. *Plant Archives* 6: 639-641.

Tomar, A. and Singh, H., 2006b. Ethnomedicinal uses of some weed plants from Baghpat district of U.P., India. *Plant Archives* 6: 691-693.

Tomar, A., 2007a. Some medicinal plants used to cure diarrhoea in Meerut district of Uttar Pradesh, India. *Plant Archives* 7: 365-366.

Tomar, A., 2007b. Use of some medicinal plants by the rural people of Rohta block of Meerut district (U.P.), India. *Plant Archives* 7: 401-402.

Tomar, A., 2008a. Traditional medicinal knowledge about some plants against hydrophobia in Meerut district (U.P.), India. *Plant Archives* 8: 447-448.

Tomar, A., 2008b. Some ethnomedicines for gastric problems from Meerut district of Western Uttar Pradesh, India. *Plant Archives* 8: 489-490.

Watt, G., 1889-1892. A Dictionary of the Economic Products of India. Vol. I-VI (Repri. 1972), Periodical Experts, Delhi.

Pharmaco-Botanical Studies for Quality Assessment of Commercial Samples of Some Herbal Drugs of Root and Rhizome Origin

[1]*Padma Kumar,
[2]Nitin Rai,
3Rajeev Kr. Sharma
and
[2]M.M. Johari

[1]National Medicinal Plants Board, Deptt. of AYUSH, 36 Janpath, New Delhi-110001

[2]Deptt. of Botany M.M.H. (PG) College, Ghaziabad- 201002, India

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

Abstract

Commercial samples of six herbal drugs of root and rhizome origin viz. *Acorus calamus* Linn., *Bergenia ciliata* (Haw.) Sternb., *Gmelina arborea* Roxb., *Nardostachys grandiflora* DC , *Picrorhiza scrophulariflora* Pennel. and *Withania somnifera* (Linn.) Dunal. were evaluated to assess their quality in respect of identity, purity and strength. The samples were resourced from Delhi, Hardwar and Cochin/Trichur markets. Evaluation is based on specific parameters and limits prescribed in Ayurvedic, Unani and Siddha Pharmacopoeia and as well in other literature.

Key-words: Pharmacognostic evaluation, Commercial herbal drugs, Quality assessment.

Introduction

Medicinal plants are used not only to formulate medicines but also for health supplements, natural dyes, perfumery, cosmetics, toiletries etc. The demand for medicinal plants to fetch the need of different stakeholders is growing at a very fast pace. There is a global awareness for the herbal products. But in India, the supply of medicinal plants has not kept pace with the increasing global demand for medicinal plants. India is endowed with a rich wealth of medicinal plants and these plants have made a good contribution to the development of ancient Indian Materia Medica.

About 90% of medicinal plants used by the industries are collected from the wild resources. It is estimated that about 800 species are used in production by the pharmaceutical industry, whereas less than 40 species of plants are under commercial cultivation. Over 70% of the plant collection involves destructive harvesting. This poses a definite threat to the genetic stocks and to the diversity of medicinal plants.

Adulterants/substitutes are being traded/used with at times with full knowledge of the sellers/buyers and are very common in the herb trade especially when the trade is involved. Herbs sold in powdered forms, eg: - the powders of Pterocarpus santalinum (Red Sandal or Lal Chandan) are much more prone to adulteration. The use of some species as substitute of a medicinal plant comes in the picture when the originally recommended plant gets rare and its price rises. In many cases, substitutes have taken over the original plants. In some cases, substitutes have become popular, manufacturers have forgotten about the original plant and they only use substitutes available in the market. It is very much doubtful if such substitution is made after testing or as recommended by any authority.Sometomes different morphological parts of same plant species

* Author for correspondence

is used in place of prescribed part. Use of stem bark in place of roots are not uncommon. At times mere look alike species are used as a substitute, which may not even contain the active ingredients available through the main plants nor the effects of the end product is the same as that obtained from that of original plant (Sharma, 1987 and Rai *et al.*, 2011).

In some cases, pharmacopoeia and formularies permits the use of substitutes in place of original plants thus, giving legitimacy to the substitutes.

Materials and Methods

The root and rhizome herbal drugs under study were collected from natural habitats and authenticated with references to pharmacopoeial standards and other literature. The commercial samples sold under the trade names purported to be prescribed species were drawn from the different market sources (Hardwar, Delhi and Cochin/Trichur).Standard protocols/methods prescribed in pharmacopoeia were followed for pharmacognostical, physico-chemical and phytochemical values prescribed in Ayurvedic, Unani and Siddha Pharmacopoeia of India were taken as standards values (Anonymous, 1986,1998,1999,2007a,b,&2008).

Table 1. Commercial Herbal Drugs studied

No.	Botanical Name	Official Name	Trade Name	Morphological	Official Standards
1.	Acorus calamus Linn.	Vacha	Vach	Rhizome	API-II UPI-II
2.	Bergenia ciliata (Haw.) Sternb.	Pashana-bheda	Pashana-bheda	Rhizome	API-I
3.	Gmelina arborea Roxb.	Gambhari	Gambhari	Root Bark	API-I
4.	Nardostachys grandiflora DC syn.N. jatamansi DC	Jatamansi	Jatamansi	Rhizome	API-I UPI-I SPI-I
5.	Picrorhiza scrophulariflora Pennel. Syn. P. Kurroa auct. non Royle	Katuka	Kutaki	Rhizome	API-II UPI-IV SPI-I
6.	Withania Somnifera (Linn.) Dunal.	Ashvagandha	Asgandh	Roots	API-I UPI-I SPI-I

Observations and Results

All the commercial samples of the drugs were evaluated as per the specifications laid in Pharmacopoeia and other literature. Observation made are given in Table 2 to 7.

Table 2. Pharmacognostical Evaluation of Commercial Crude Drug Samples of *Acorus calamus* Linn.

Sl. No.	Specifications	Official Standards API-II & UPI-II	Samples drawn from the market of		
			Delhi	Hardwar	Cochin / Trichur
A.	Identification (Pharmacognostical)-				
	a. Entire Drug- Organoleptic	Specifications prescribed	Conforms	Conforms	Slightly varies
	b. Entire Drug Microscopic		Conforms	No conformance	No conformance
	c. Powdered drug		Conforms	Conforms	No conformance
B.	Purity & Strength (Physico-Chemical constants)-				
	i. Foreign Matter, %, Not more than	1.0	1.20	0.60	2.90
	ii. Total ash , % , Not more than	7.0	5.80	6.80	6.00
	iii. Acid- insoluble ash, %, not more than	1.0	0.80	0.50	0.95
	iv. Alcohol-soluble extractives, %, not less than	9.0	12.50	15.20	12.00
	v. Water-soluble extractives, %, Not less than	16.0	22.30	19.00	17.50
	vi. Volatile Oil, %, Not less than	2.0	1.8	0.6	0.5
C.	Moisture Content, %	No Specifications prescribed	7.20	5.20	6.50
D.	Major organic groups (Phytochemical)-				
	(i) Alkaloids	No Specifications prescribed	-	-	-
	(ii) Tannins		√	√	√

Sl. No.	Specifications	Official Standards API-II & UPI-II	Samples drawn from the market of		
			Delhi	Hardwar	Cochin / Trichur
	(iii) Glycosides	No Specifications prescribed	-	-	-
	(iv) Sterols		-	-	-
	(v) Volatile Oil		-	-	-
	(vi) Flavonoids		-	-	-
	(vii) Anthraquinone		-	-	-
	(viii) Resins		-	-	-
	(ix) Fixed oil		-	-	-
	(x) Poly phenolic compounds		-	-	-

Table 3. Pharmacognostical Evaluation of Commercial Crude Drug Samples of *Bergenia ciliata* (Haw.) Sternb.

Sl. No.	Specifications	Official Standards API-I	Samples drawn from the market of		
			Delhi	Hardwar	Cochin/Trichur
A.	Identification (Pharmacognostical)-				
	Entire Drug- Organoleptic	Specifications prescribed	Slightly varies	Conforms	Conforms
	Entire Drug Microscopic		No conformance	Conforms	Varies
	Powdered drug		No conformance	Conforms	Varies
B.	Purity & Strength (Physico-Chemical constants)-				
	Foreign Matter, %, Not more than	2.0	1.80	0.90	1.30
	Total ash, %, Not more than	13.0	13.00	8.30	12.20
	Acid- insoluble ash, %, Not more than	0.5	2.20	0.16	2.30
	Alcohol-soluble extractives, %, Not less than	9.0	11.00	14.30	10.20
	Water-soluble extractives, %, Not less than	15.0	13.50	18.20	15.40
C.	Moisture Content, %	No Specifications prescribed	5.50	4.20	6.50

Sl. No.	Specifications	Official Standards API-I	Samples drawn from the market of		
			Delhi	Hardwar	Cochin/Trichur
D.	Major organic groups (Phyto-chemical)-				
	(i) Alkaloids	No Specifications prescribed	-	-	-
	(ii) Tannins		-	-	-
	(iii) Glycosides		-	-	-
	(iv) Sterols		-	-	-
	(v) Volatile Oil		-	-	-
	(vi) Flavonoids		-	-	-
	(vii) Anthraquinone		-	-	-
	(viii) Resins		-	-	-
	(ix) Fixed oil		-	-	-
	(x) Poly phenolic compounds		-	-	-

Table 4. Pharmacognostical Evaluation of Commercial Crude Drug Samples of *Gmelina arborea* Roxb.

Sl. No.	Specifications	Official Standards API-I	Samples drawn from the market of		
			Delhi	Hardwar	Cochin/Trichur
A.	Identification (Pharmacognostical)-				
	Entire Drug- Organoleptic	Specifications prescribed	Conforms	No conformance	Slightly differs
	Entire Drug Microscopic		Conforms	No conformance	No conformance
	Powdered drug		Conforms	No conformance	No conformance
B.	Purity & Strength (Physico-Chemical constants)-				
	Foreign Matter, %, Not more than	2.0	0.90	1.50	1.80
	Total ash, %, Not more than	5.0	4.10	6.30	7.25
	Acid- insoluble ash, %, Not more than	0.3	0.50	2.12	1.20
	Alcohol-soluble extractives, %, Not less than	7.0	9.20	7.40	6.20
	Water-soluble extractives,%, Not less than	20.0	22.20	21.50	19.40

Sl. No.	Specifications	Official Standards API-I	Samples drawn from the market of		
			Delhi	Hardwar	Cochin/Trichur
C.	Moisture Content, %	No Specifications prescribed	5.50	4.80	7.80
D.	Major organic groups (Phyto-chemical)-				
	(i) Alkaloids	No Specifications prescribed	√	√	-
	(ii) Tannins		-	-	-
	(iii) Glycosides		-	-	-
	(iv) Sterols		-	-	-
	(v) Volatile Oil		-	-	-
	((vi) Flavonoids		-	-	-
	(vii) Anthraquinone		-	-	-
	(viii)Resins		-	-	-
	(ix) Fixed oil		-	-	-
	(x) Poly phenolic compounds		-	-	-

Table 5. Pharmacognostical Evaluation of Commercial Crude Drug Samples of *Nardostachys grandiflora* DC

Sl. No.	Specifications	Official Standards API-I, UPI-I, SPI-I	Samples drawn from the market of		
			Delhi	Hardwar	Cochin/Trichur
A.	Identification (Pharmacognostical)-				
	Entire Drug- Organoleptic	No Specifications prescribed	Conforms	Conforms	Conforms
	Entire Drug Microscopic		Varies	Conforms	Slightly varies
	Powdered drug		Varies	Conforms	Conforms
B.	Purity & Strength (Physico-Chemical constants)				
	Foreign Matter, %, Not more than	5.0	6.10	3.80	2.10
	Total ash, %, Not more than	9.0	10.80	5.20	7.50
	Acid- insoluble ash, %, Not more than	5.0	7.20	2.90	3.20
	Alcohol-soluble extractives, %, Not less than	2.0	2.10	9.60	6.00

Sl. No.	Specifications	Official Standards API-I, UPI-I, SPI-I	Samples drawn from the market of		
			Delhi	Hardwar	Cochin/Trichur
	Water-soluble extractives,%, Not less than	5.0	3.60	7.50	12.00
	Volatile oil,% ,Not less than	0.1	0.05	0.07	0.00
C.	Moisture Content, %	No Specifications prescribed	5.40	3.20	6.80
D.	Major organic groups (Phyto-chemical)-				
	(i) Alkaloids	No Specifications prescribed	-	-	-
	(ii) Tannins		-	-	-
	(iii) Glycosides		-	-	-
	(iv) Sterols		-	-	-
	(v) Volatile Oil		-	-	-
	(vi) Essential Oils		√	√	√
	(vii)Flavonoids		-	-	-
	(viii) Anthraquinone		-	-	-
	(ix) Resins		√	√	√
	(x) Fixed oil		-	-	-
	(xi) Poly phenolic compounds		-	-	-

Table 6. Pharmacognostical Evaluation of Commercial Crude Drug Samples of *Picrorhiza scrophulariflora* Pennel.

Sl. No.	Specifications	Official Standards API-I,UPI-I & SPI-I	Samples drawn from the market of		
			Delhi	Hardwar	Cochin/Trichur
A.	Identification (Pharmacognostical)-				
	Entire Drug-Organoleptic	Specifications prescribed	Conforms	Conforms	Conforms
	Entire Drug Microscopic		Conforms	Varies	Varies
	Powdered drug		Conforms	Varies	Varies
B.	Moisture Content, %	No Specifications prescribed	3.80	4.20	3.50

Sl. No.	Specifications	Official Standards API-I,UPI-I & SPI-I	Samples drawn from the market of		
			Delhi	Hardwar	Cochin/Trichur
C.	Purity & Strength (Physico-Chemical constants)-				
	Foreign Matter, %, Not more than	2.0	1.20	1.60	2.10
	Total ash, %, not more than	7.0	6.80	5.20	6.20
	Acid- insoluble ash, %, Not more than	1.0	0.60	0.80	0.95
	Alcohol-soluble extractives, %, Not less than	10.0	10.80	13.60	11.00
	Water-soluble extractives, %, Not less than	20.0	21.00	22.20	20.50
D.	Major organic groups (Phyto-chemical)-				
	(i) Alkaloids	No Specifications prescribed	√	√	√
	(ii) Tannins		-	-	-
	(iii) Glycosides		-	-	-
	(iv) Sterols		-	-	-
	(v) Volatile Oil		-	-	-
	(vi) Flavonoids		-	-	-
	(vii) Anthraquinone		√	-	-
	(viii)Resins		-	-	-
	(ix) Fixed oil		-	-	-
	(x) Poly phenolic compounds		-	-	-

Table 7. Pharmacognostical Evaluation of Commercial Crude Drug Samples of *Withania somnifera (Linn.)* Dunal.

Sl. No.	Specifications	Official Standards API-I, UPI-I & SPI-I	Samples drawn from the market of		
			Delhi	Hardwar	Cochin/Trichur
A.	Identification (Pharmacognostical)-				
	Entire Drug- Organoleptic	Specifications prescribed	Conforms	Conforms	Conforms
	Entire Drug Microscopic		Slightly Varies	Conforms	Conforms
	Powdered drug		Varies	Conforms	Conforms

Sl. No.	Specifications	Official Standards API-I, UPI-I & SPI-I	Samples drawn from the market of		
			Delhi	Hardwar	Cochin/Trichur
B.	Purity & Strength (Physico-Chemical constants)-				
	Foreign Matter, %, Not more than	2.0	0.90	1.80	2.60
	Total ash, %, Not more than	7.0	7.80	3.90	4.20
	Acid- insoluble ash, %, Not more than	1.0	0.90	0.80	0.56
	Alcohol-soluble extractives, %, Not less than	15.0	17.20	18.50	12.50
	Water-soluble extractives,%, Not less than	_	6.10	2.10	3.25
C.	Moisture Content, %	No Specifications prescribed	3.20	2.80	4.50
D.	Major organic groups Major organic groups (Phytochemical)-				
	(i) Alkaloids	No Specifications prescribed	√	√	√
	(ii) Tannins		-	-	-
	(iii) Glycosides		-	-	-
	(iv) Sterols		-	-	-
	(v) Volatile Oil		-	-	-
	(vi) Flavonoids		-	-	-
	(vii) Anthraquinone		-	-	-
	(viii) Resins		-	-	-
	(ix) Fixed oil		-	-	-
	(x) Polyphenolic compounds		-		-

Abbreviation: API-Ayurvedic Pharmacopoeia of India, Part-I, UPI-Unani Pharmacopoeia of India, Part-I, and SPI-Siddha Pharmacopoeia of India, Part-I.

Discussion and Conclusion

Pharmaco-botanicall evaluation of commercial samples of herbal drugs with comparison to genuine and authenticated crude drug sample as well with pharmacopoeial standards revealed the extent of authenticity of commercial samples. Each drug is discussed in discussed in foregoing text below-

Acorus calamus Linn. - Drug consists of dried a rhizome which occurs in simple or rarely with thumb- like branches at nodes, sub-cylindrical to slightly flattened or rarely straight. Light brown with reddish tinge to pinkish externally, buff coloured internally. The dried rhizome is wrinkled longitudinally. Taste is bitter and pungent. Powder is brownish or buff in colour.

Delhi sample conform to the authentic sample. Micro-morphological characteristics of Hardwar and Cochin samples do not conform to the specification. Market sample procured from the markets of Delhi and Cochin varies considerably in appearance. The macroscopica details of both the drug samples are more or less similar whereas microscopically characteristics of Hardwar and Cochin samples do not conform fully with that of the authentic specimen. Powder characteristics of Cochin sample do not conform to the authentic sample. A Physico-Chemical constant also varies from sample to sample. The volatile oil content of samples also varies probably due to the storage conditions. Wide variations exist between certain samples. Alkaloids and Tannins noticed in all the samples.

Bergenia ciliata (Haw.) Sternb. - Authentic drug samples are morphologically rhizomes, cylindrical and bowel shaped with ridges, furrows and distinct root scars, 1.5 to 3 cm long and 1 to 2 cm in diameter, brown in colour with distinct root scars and circular markings, dense and housed with reddish colour. Major phyto- constituents are Tannic and, Gallic acid .Tannins are present in all the three samples.

The drug is available throughout the country. It is a highly controversial drug. Micro morphological characteristics and powdered drug of Delhi sample do not conform to the authentic sample. Similarly, a micro morphological and powder characteristic of Cochin sample varies from the authenticated sample. Foreign matter content varies from 0.90% to 1.8%.Haridwar sample perfectly conforms to the authentic drug sample in all respects. Cochin sample varies in respect of micro morphological and powder characteristics. The Delhi sample not conforms to the authentic drug sample in respect of micro morphological and powder characteristics. However, the foreign matter in all the samples remains within the official limit. The demand of the drug is fairly growing.

Gmelina arborea Roxb. - Root bark is used as the drug which is yellowish in colour when fresh, root greyish brown in colour with fracture somewhat tough and brittle. Powder is greyish brown in colour.It contains alkaloids and lignans.

Delhi sample conforms to the authentic sample, while Cochin and Hardwar samples showed marked variation in macro and micro morphological and powder characteristics. Foreign matter content varies from 0.90% to 1.80%.Commercial

samples of Hardwar and Cochin markets show deviation from the authentic samples. Both the samples do not conform to the authentic sample in respect of macro-morphological, micro-morphological and powder characteristics.

Nardostachys grandiflora DC. –The drug is available as dried rhizome which are which are dark brown in colour covered with reddish brown fibres and internally reddish brown in colour. Powder is light brown in colour. Active chemical constituents are essential oils and resinous matter.

Micro-morphological and powder characteristics of the Delhi sample shows variation to that of authentic sample. Hardwar sample conforms to authentic sample. Foreign matter content is varying from 2.1% to 6.1%.It is an erect perennial herb mostly grows in the alpine zones of Central and Eastern Himalayas. The samples of Delhi showed considerable variation in respect of Micro morphological, powder characteristics and physico-chemical constants with the samples of Cochin and Hardwar. Hardwar samples show perfect correlation with authentic sample. All samples contain essential oil of varying degrees. A fresh sample of Hardwar contains more essential oil than others. Roots of *Selinium vaginatum* C B Clarke and *Cymbopogon schoenanthum* are reported to be used as adulterants (Sharma, 1987).

Picrorhiza scrophulariflora Pennel. – The drug is available as pieces of rhizomes greyish brown in colour straight or slightly curved with longitudinal wrinkles and Powder is grey in colour. Active chemical constituents are alkaloids.

Delhi sample conforms to that of authentic sample. Micro-morphological characteristics and powder characteristics of Hardwar and Cochin sample varies from that of authentic sample. Foreign matter content varies from 1.2% to 2.1%.This trailing herb is found in the alpine Himalayas from Kashmir to Sikkim up to 4300 m.above sea level. Market samples also differ considerably. Roots of *Helleborous niger* are also sold in the market of Cochin as Katu Kutki. The Samples of Cochin market seems to be adulterated. Probably it might be substituted with *Gentiana kurroo*. The micro-morphological characteristics and powder characteristics of Cochin and Hardwar samples varies from Delhi sample. All the samples contain alkaloids.

Withania somnifera (Linn.) Dunal. - Drug is available as cut pieces of un-branched or rarely branched root. Outer surface buff to greyish yellow with longitudinal wrinkles. Powder is creamish brown in colour with fragments of cork cells and non-lignified cells. Active constituents are Alkaloids.

Micro-morphological and powder characteristics of Delhi sample varies to that of the authentic sample. Hardwar and Cochin samples conform to the values of authentic sample. A Physico-chemical characteristic of all the samples

conforms to the values of authentic sample. Foreign matter content varies from 0.90% to 2.60%.The erect branching under-shrub is found throughout the drier parts of India and also under cultivation. All samples shows more or less perfect correlation with authentic sample. However, a micromorphological and powder characteristic of Delhi sample varies from authentic sample. Foreign matter is within the limits of authentic sample in all the three samples.

The study reveals that commercial samples are always subject to quality control for their authenticity to ensure identity, purity and strength as per pharmacopoeial and other quality standards before their use to formulate the medicine. This quality evaluation practice may also ensure the safety and efficacy of medicine up to larger extent.

Acorus calamus Linn.

Bergenia ciliata (Haw.) Sternb

Gmelina arborea Roxb

Nardostachys grandiflora DC

Picrorhiza scrophulariflora Pennel.

Withania somnifera (Linn. Dunal.

Fig. 1: Studied Herbal Drugs of Root and Rhizome Origin

References

Anonymous, 1979. The United States Pharmacopoeia, 20th rev. U.S. Pharmacopoeial Convention Inc., Rockville, U.S.A.

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

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

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

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

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

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

Rai, Nitin, Rajeev Kr. Sharma, Sunil Dutt and V. K. Singh, 2011. Market survey of commercially exploited Unani herbal drugs: Availability, Resources and Quality Assurance. *Hippocreatic Journal of Unani Medicine* 6(4): 97-123.

Sharma, Rajeev Kr., 1987. Pharmacognostic studies leading to standardization for identification and authentication of some commercially exploited roots and rhizomes employed as drug in Ayurveda. D. Phil Thesis. Garhwal University, Srinagar, Garhwal (Uttarakhand)

Pharmacognostical Study of a Unani Herbal Drug 'Parsiaoshan' *(Adiantum venustum* D.Don)

***M.A. Rashid**

Drug Standardisation Research Institute (Unani) CCRUM, PLIM Building, Kamla Nehru Nagar, Ghaziabad-201001 (U.P.), India

Abstract

The unani herbal drug available as 'Parsiaoshan' has been identified as the aerial parts of the plant *Adiantum venustum* D.Don. Apart from being an important drug in the Unani as well as other herbal systems of medicine, the plant has assumed great significance due to recent findings of its anti cancerous, antimicrobial and antiinflammatory activities. In order to provide criteria and to set standards for ascertaining genuineness and quality of the drug, pharmacognostical study has been carried out on the dried sample of the drug. The work describes in detail morphological and anatomical features, study of the powdered drug and its analysis under UV light, qualitative determination of chemical constituents, some physico - chemical parameters and results of thin layer chromatography. The salient features of the drug have been discussed.

Key words: Herbal drug, Parsiaoshan, Pharmacopoeial standardisation, Quality assurance.

Introduction

The drug Parsiaoshan in Unani system is reputed for its antipyretic, demulcent, expectorant, diuretic, emmenagogue, desiccant and resolvent actions. It is used in all types of fevers; in catarrh, coryza and asthma; also useful in anuria, dysuria and amenorrhoea. Its decoction is used to remove dandruff. (Ali, 1979; Khan, 1913; Kirtikar, 1935). Though the drug in Unani system is attributed to the plant *Adiantum capillus-veneris* L. (Anonymous, 1981), it has also been mentioned as *Adiantum venustum* D.Don by some authors (Kirtikar, 1935; Watt, 1889) and in practice, use of various other species of *Adiantum,* particularly *A. venustum* is common. The plant is known as 'Hansraj' and most of the drug available in commerce belongs to this plant (Anonymous, 1985; Watt, 1889). Medicinal properties attributed to this plant have remarkable similarity with those described for the drug 'Parsiaoshan'. The plant has been reported as anodyne in bronchitis; diuretic and emmenagogue; fronds reported to be astringent, aromatic, emetic in large doses, tonic, febrifuge, expectorant and deobstruent; used in the treatment of biliousness, inflammatory diseases of the chest, ophthalmia, hydrophobia, colds and headache; also as hair tonic. (Anonymous, 1985; Gupta, 2004).

The samples of "Parsiaoshan" obtained for the present study have also been identified as the plant *Adiantum venustum* D.Don.

*Author for correspondence

The plant is a graceful fern found very commonly in North-East Himalayas, Kashmir and in Simla at altitudes of 1,350 to 3150m in shaded forest beds; also common in Punjab; having dark glossy stipes; fronds 3-4 pinnate, pinnules obovate-cuneate, striated, 2-3 lobed, finely dentate- serrate; fertile lobes with two, rarely three notches, each notch bearing a rather large sorus at the bottom. (Anonymous, 1985; Kirtikar and Basu, 1935).

Recent studies on the plant *A.venustum* have revealed that it has remarkable anti-inflammatory, anti-microbial and anti-cancerous activities which greatly add to its future therapeutic potential. (Hussain, 2008; Meenakshi, 2008; Devmrari, 2010)

A review of the up to date published works, reported on the subject indicated that no pharmacognostical work on this drug source plant was available. (Anonymous, 1986-2011; 2002; 2003-2005; Farooq, 2005; Gupta and Tanden, 2004; Mitra, 1985).

Material and Methods

Samples of the drug consisting of dried aerial parts were obtained from several separate sources in the market. All were found to be alike and identified, based on the descriptions available, (Anonymous, 1985; Kirtikar, 1935; Watt, 1888) as well as by comparing with live plant available at the Botany department, AMU, Aligarh. Free hand sections were used for microscopic study. The diagrams were sketched using a camera lucida and measurements of cells were done by using a standardized eyepiece micrometer. Method described by Johansen (1940) was followed for maceration of the material. Fluorescence analysis was done according to method described by Kokoski et al. (1958). Physico-chemical parameters were done according to standard methods while extracts of the drug obtained from successive extraction were used for TLC analysis which was performed using pre-coated aluminium plate of silica gel 60 F-254.

Observations

Macroscopic Characteristics

The drug consists of dried fronds having smooth, shining, dark brown, glabrous petioles; 3-4 pinnate (Fig.1). The segments (pinnae) are bright green, shortly petiolulate, glabrous, 6-9 mm long and 3-5 mm broad in the middle. The blade has prominent non reticulate branching venation; not cleft or lobed (Fig.2). The upper margin is rounded, dentate while it is cuneate below. Fertile segments

bear linear, rather large sori, formed by the revolute upper margins of the pinnae (Fig.3). It gives a slight aromatic odour and has no distinguishable taste.

Microscopic Characteristics

Petiole:

A cross section of the petiole shows almost a circular outline with a small notch on one side (Fig.6). The outer most tissue is a single layered epidermis, covered with a smooth thin cuticle and composed of dark coloured thick walled parenchyma; followed by 3-4 seriate layer of sclerenchyma, composed of dark coloured thick walled fibres. This is followed by a fairly large compact zone of cortex, consisting of parenchymatous cells having abundant starch grains and showing little or no inter-cellular spaces (Fig.7). A single stele, enclosed within a layer of endodermis and pericycle occupies the centre (Fig.8). The xylem consisting of tracheids is situated in the centre in the form of a large single band. The metaxylem is in the middle with two opposite protoxylem points, surrounded by phloem, consisting of sieve cells and parenchyma.

The petiole tissue macerated with 20% nitric acid shows an abundance of fibres of varying lengths (Fig.11 A & B) and parenchymatous cells. The xylem consists of quite long tracheids having annular simple pits (Fig.11 C) and spiral thickenings (Fig.11 D).

Measurement of isolated cells (microns)

Tracheids (Length) : 482.00; 940.00; 1012.00

Fibres (Length) : 552.00; 779.00; 1123.00

Table 1: Histo-chemical colour tests

S. No.	Reactions	Observations	Inference
i	Section placed in 10% Aq. FeCl3 + little Na_2CO_3	No Blue green colour	Tannins absent
ii	Section directly placed in a drop of H_2SO_4	No colour	Lipids and Saponins absent
iii	Section placed in a weak iodine solution	Colour appears on small rounded bodies	Starch present
iv	Section placed in 5% Tartaric acid in 95% ethyl alcohol for 2 days, washed and then a solution of iodine added	No colour	Proteins absent

S. No.	Reactions	Observations	Inference
v	Section placed in a drop of 1:2500 resorcinol blue for 15 minutes	No blue colour	Callose absent
vi	Section placed in a drop of Phloroglucinol + a drop of HCl	Violet-red colour appears	Lignin present

Pinna

The upper and lower surfaces are glabrous with scattered anomocytic stomata, present on lower surface only (Fig.5). The stomatal number ranges from 8 to 12 with a mean value of 10. The epidermal cells are much more in length and have wavy outlines (Fig. 4 & 5). A transverse section of pinna shows simple, thin upper and lower epidermal layers with only 2-3 seriate loosely arranged chlorenchyma present in between. Vascular areas show 4-7 xylery elements surrounded by phloem (Fig. 9 & 10).

Macerated leaf tissue shows an abundance of epidermal parenchyma having irregular outlines and chlorenchyma (Fig.12 B & C). Tracheids are much shorter and have simple pits (Fig.12A).

Measurement of isolated cells (microns)

Tracheids (Length) : 94.00; 100.00; 106.00

Epidermal Cells : 12.0 x 79.0; 18.0 x 69.0; 19.0 x 88.0

Chlorenchyma : 31.0 x 63.0; 67.0 x 71.0; 43.0 75.0

Powdered drug

The powder is dark brownish green in colour, homogenous, a bit fluffy in texture. It gives a slight aromatic odour and has no distinguishable taste. The powder after being cleared in chloral hydrate, was observed under microscope which showed mostly fragments of pinnae and petiole; sporangial wall tissue with characteristic transverse thickenings and triangular spore tetrads.

The other studies comprising colour reaction of powder with different reagents, fluorescence analysis, physico-chemical parameters and thin layer chromatography have been provided in respective tables.

Table 2: Reaction of powder on treatment with different reagents

S.No.	Treatment	Observations
i	Powder triturated with water	An emulsion formed.
Ii	Powder shaken with water in a test tube	No frothing occurs.
Iii	Powder treated with 66% H2SO4	Turns dark blackish brown.
Iv	Powder treated with 5% NaOH	Turns dark chocolate brown.
V	Powder treated with 5% FeCl3	Turns dark green.
Vi	Powder pressed between two filter papers for 24 hours	No oil stain appears.

Table 3: Fluorescence analysis of the powdered drug (After Kokoski *et al.*, 1958)

S. No.	Treatment	Observation under	
		Ordinary Light	U.V. light
i	Powder as such	Dark dull Green	Colourless
ii	Powder treated with 1N NaOH in methanol	Dark Brown	Colourless
iii	Powder treated with 1N NaOH in water	Dark Brown	Colourless
iv	Powder treated with 1N HCl	Brown	Colourless
v	Powder treated with 50% HNO3	Dark bright Brown	Colourless
vi	Powder treated with 50% H2SO4	Dark Brown	Colourless
vii	Powder mounted in Nitrocellulose in Amyl acetate	Dark blackish Brown	Colourless
viii	Powder treated with 1N NaOH in methanol, dried and then mounted in Nitrocellulose in Amyl acetate	Dark chocolate brown	Colourless
ix	Powder treated with 1N NaOH in water, dried and then mounted in Nitrocellulose in Amyl acetate	Dark Brown	Colourless
x	Powder treated with 1N HCl, dried and then mounted in Nitrocellulose in Amyl acetate	Dark Brown	colourless

Note: Reactions (ii) to (vi) observed immediately after treatment, within one minute while reactions (vii) to (x) are observed after being allowed to dry.

Table 4: Physico chemical studies

1	Chemical Constituents (Qualitative)	Organic: Inorganic: Heavy Metals:	Carbohydrates, Glycosides, Phenolics, Steroids / Terpenes and Resins. Aluminium, Calcium, Iron, Magnesium, Potassium and sodium Mercury, Lead, Cadmium and Arsenic not detected.
2	Ash Values (%)	Total Ash Acid insoluble (10% HCl) Water soluble	7.60 - 8.20 4.20 - 4.60 0.50 - 0.70
3	Loss on drying at 105oC(%)		7.00 - 8.00
4	Solid Contents (%)		74.00 - 76.00
5	Successive extractives values (%)	Petroleum Ether (60-80o): Chloroform: Acetone: Alcohol: Water:	4.40 - 4.60 3.00 - 3.40 4.50 - 4.80 9.00 - 9.50 14.00 - 14.60

Table 5: Thin Layer Chromatography

Extract	Solvent System	Treatment	No. of Spots	Rf Values
Petroleum Ether (60-80o) Absolute Alcohol	Petroleum Ether(40-60o): Solvent Ether (4:1) Toluene: Ethyl formate: Formic Acid (5:4:1)	Exposed to Iodine Vapours Spraying with 2% H2SO4 in Ethanol & heating the plate for about ten minutes at 105oc in an oven	8 5	0.96 0.90 0.71 0.62 0.55 0.49 0.42 0.28 0.63 0.58 0.56 0.50 0.07

Conclusion

The study has provided a detailed description of the drug based on morphological and anatomical features along with some important physico-

Chemical characteristics. As a result, certain specific key characters have been worked out on the basis of which, the drug samples can be checked for genuineness and quality. Distinguishing morphological features include dark, shining, smooth stipe; 3-4 pinnate frond; rounded, deltoid-cuneate, dentate segments having prominent free, forking veins; fertile segments having sub marginal sori and inrolled upper margins. Internally the stipe shows a sclerenchymatous hypodermis and stele with a band of xylery tissue having opposite protoxylem. The macerated tissue shows long tracheids while triangular spore tetrads are present in the powder. Apart from these prominent structural features, other details worked out under macro-microscopic studies, fluorescence analysis, physico-chemical studies and thin layer chromatography constitute definite specifications for the drug.

Fig. 1: Habitat of *Adiantum venustum* D.Don.

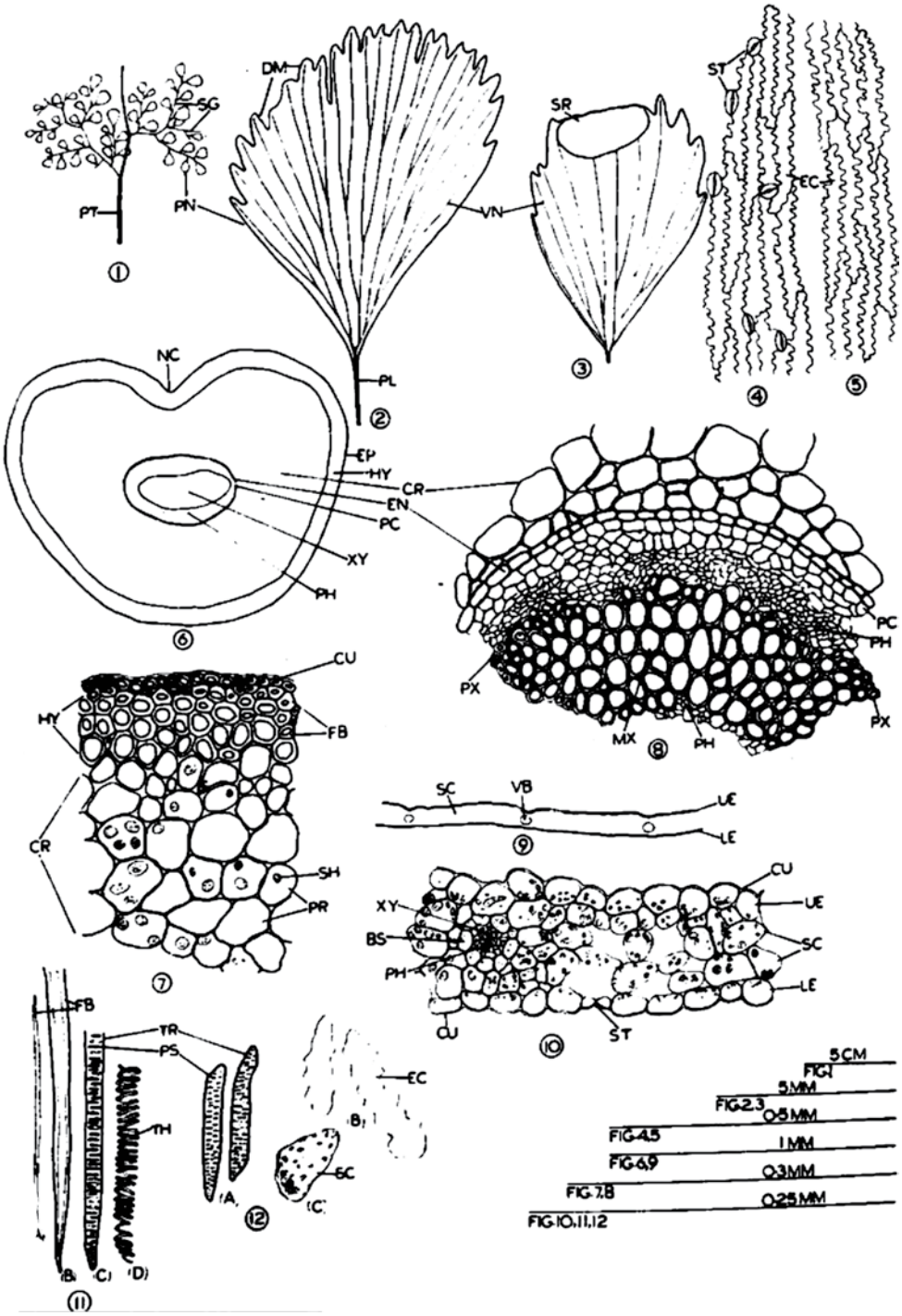


Fig. 2: Adiantum Venustum Don: Pharmacognostic details

Explanation of Figures

1. The Frond
2. A pinna

3. Pinna with sorus
4. Pinna: Upper surface view
5. Pinna: Lower surface view
6. Petiole: Transverse section (Diagrammatic)
7. Petiole: Transverse section showing Hypodermis & Cortex
8. Petiole: Transverse section showing Stele
9. Pinna: Transverse section (Diagrammatic)
10. Pinna: Transverse section showing cellular details
11. Macerates (Rachis): Fibre under low magnification (A); Fibre under high magnification (B); Portion of Tracheid (C); Spiral thickenings (D)
12. Macerates (Pinna): Tracheids (A); Epidermal Cells (B); Chlorenchyma (C).

Abbreviations

BS = Bundle sheath; CR = Cortex; CU = Cuticle; DM = Dentate margin;

EC = Epidermal cells; EN = Endodermis; EP = Epidermis; FB = Fibre;

HY = Hypodermis; LE = Lower Epidermis; MX = Metaxylem; NC = Notch;

PC = Pericycle; PH = Phloem; PL = Petiolule; PN= Pinna;

PR = Parenchyma; PS = Pits; PT = Petiole; PX = Protoxylem;

SC = Spongy Chlorenchyma; SG = Segments; SH = Starch grains;

SR = Sorus; ST = Stomata; TH = Thickening; TR = Tracheids;

UE = Upper Epidermis; VB = Vascular bundle; VN = Veins; XY = Xylem.

Acknowledgement

The author is thankful to the Director General, Central Council for Research in Unani Medicine, New Delhi, for all the facilities and constant encouragement.

References

Ali, S.S., 1979. Unani Adviya Mufarrada. National Council for Promotion of Urdu, New Delhi; pp. 98-9.

Anonymous, 1981. National Formulary of Unani medicine, Ministry of Health & Family Welfare, Dept. Of AYUSH, New Delhi, Part –1, p.270.

Anonymous, 1985. The wealth of India, PID, CSIR, New Delhi, Vol. 1, pp. 81-82.

Anonymous, 2002. India Herbal Pharmacopoeia. India Drug Manufacturer`s Association, Mumbai.

Anonymous, 1986-2011. Medicinal and Aromatic Plants Abstracts. NISCAIR, CSIR, New Delhi.

Anonymous, 2003-2005. Quality Standards of Indian Medicinal Plants, ICMR, New Delhi, Vol. 1-6.

Chopra, R.N., Nayar, S.L. and Chopra, I.C., 1956. Glossary of Indian Medicinal plants. CSIR, New Delhi, p.7.

Farooq, S., 2005. Medicinal plants: Field and Laboratory Manual. International Book Distributors, Dehradun.

Gupta, A. K. and Tandan, N. (Eds.), 2004. Reviews on Indian Medicinal Plants. Indian Council of Medical Research, New Delhi. Vol. 1, pp. 291-93.

Hussain M.M., Muthuprasanna P, Srinivasarao T, Velraj M, Shanmugapandian P, Suriaprabha K., 2008. Analgesic and anti inflammatory activity of *Adiantum venustum. Res Rev Biosci.* 2: 102-104.

Johansen, D.A., 1940. Plant Microtechnique. Tata McGraw Hill Publishing Co. Ltd., New Delhi.

Khan, Najmul Ghani, 1913. Khaza-inul Adviya, Munshi Naval Kishore Press, Lucknow. Vol. III, pp. 916-18.

Kirtikar, K. R. and Basu, B. D., 1935. Indian Medicinal Plants. Periodical Experts, Delhi, (Reprint ed. 1975), Vol. IV, pp. 2737-39.

Kokoski,C.J., Kokoski,R.J. and Slama,F.J., 1958. Fluorescence of powdered vegetable drugs under ultra violet radiation. Sci. edi . *J. Am. Pharm. Association*, p. 47.

Meenakshi Singh, Neha Singh, P.B. Khare, A.K.S. Rawat, 2008. Antimicrobial activity of some important *Adiantum* species used traditionally in indigenous systems of medicine. *Journal of Ethnopharmacology* 115(2) : 327-329.

Mitra, R., 1985. Bibliography on Pharmacognosy of Medicinal plants: Economic Botany Information Service, NBRI, Lucknow, p. 170.

Watt, G., 1989. A Dictionary of the Economic Products of India. Periodical Experts, Delhi, (Reprint ed. 1972), pp. 110-14.

Physico-chemical and Phyto-chemical Standardization of 'Kanghi booti' (*Abutilon indicum* Linn.)

***Abdullah, S.H. Afaq, Abdul Latif and Abdur Rauf**

Department of Ilmul Advia, A.K. Tibbiya College, Aligarh Muslim University, Aligarh – 202002 (U.P.), India

Abstract

butilon indicum Linn. (Family: Malvaceae), commonly known as 'Kanghi booti' is a perennial herb, distributed throughout tropical India and Siri Lanka. The herb is used widely in many ailments such as fever, gonorrhoea, meningitis, chronic cough, diarrhoea and diseases of thorax. It is also used for eye wash. As per ethno-medical literatures the drug is reported as antiflatulant, antihelminthic, anti-inflammatory, demulcent and diuretic.

It is interesting to note that being an important plant, it is lesser known and except the positive antimicrobial activity on gram positive and gram negative bacteria, no works are reported in the literature. Therefore, an effort has been made to carry out the physicochemical and phytochemical studies of plant to find out the possible active constituent. The plant was collected directly from premises of Aligarh Muslim University Aligarh, in the month of December 2008. The successive extraction, soluble matter in aqueous and alcohol, ash values, loss on drying, moisture content, pH values, qualitative and quantitative analysis of organic constituents were estimated. The percentage of alkaloid (1.54%), nitrogen (0.02%), fatty matter (0.70%), phenols (0.27%), flavonoid (5.60%), sterols/terpenes (0.17%), proteins (1.02%), carbohydrate (1.04%) and crude fibre (2.75%) are reported. With the help of descending paper chromatography, amino acids and sugars were also identified and quantified.

Key words: Kanghi booti, Physicochemical and Phytochemical standardization, *Abutilon indicum* Linn.

Introduction

The drug consists of whole plant of *Abutilon indicum* Linn. (Family: Malvaceae), is reported in Unani System of Medicine to cure many ailments. As mentioned by Dymock *et al* (1890) another species of *Abutilon* is reported by Ibn-e-Sina (Avicena), grows at hilly areas, its fruits resemble to 'pumpkin' and the leaves are similar to the leaves of coriander. This species was confirmed as *Abutilon avicenna* Gartn. by Dymock *et al.* (1890). Ibn-e-Sina described it as wound healer. 'Kanghi booti' is written in various Arabic and Persian works under the name of "Masht-el-ghoul" and "Dieshar" respectively and mentioned that its bark is diuretic. Mostly the leaves of the plant are used for medicinal purposes but to get more beneficial effects the seeds and roots of the herb can also be used along with leaves and stem (Ghani, 1921).

*Author for correspondence

Abutilon is a large genus with record of 120 species (Anonymous, 1948; Kirtikar & Basu, 1995). It is distributed throughout tropical India and Sri Lanka. Leaves are cordate nearly entire or irregularly toothed covered on both surfaces with closely-felted white down with few or no hairs intermingled; sepals ovate; carpals 15-20 longer them the calyx, glabrescent, truncate or shortly awns, spreading; stipules deflexed, peduncles longer than the petioles jointed near the top; flowers yellow, 2.5 cm diameter, opening in the evening. (Hooker, 1875)

The drug is reported by various scholars as Antiflatulant, antihelminthic, antiinflammatory, antipyretic, aphrodisiac, astringent, analgesic, demulcent, styptic, diuretic, laxative and resolvent. It is useful in asthma, burning micturition, meningitis, chronic cough, diarrhea, diseases of thorax and also used for washing eye. It is used in gonorrhoea, haematuria, haemoptysis, inflamed gums, jaundice, leprosy, menorrhagia, bleeding pile and diseases of bile. The juice of leaves is beneficial in rabies, syphilis, stone in bladder and toothache. The fumigation of its seed is useful in ano rectal fistula and scariasis and ulcer (Khan, 1859; Khan, 1896; Ghani, 1921; Ghulam, 1923; Khan, 1937; Daljeet, 1974; Lubhaya, 1984; Anonymous, 2006; Munshi, 2007).

No work has been reported except the positive antimicrobial activity on gram positive and gram negative bacteria (Abdullah *et al*., 2010). Keeping in view the medicinal importance of this plant in Indian System of Medicine, a physico-chemical and phytochemical study of 'Kanghi booti' was carried out.

Materials and Method

The drug sample of "Kanghi" was collected from the premises of Aligarh Muslim University, Aligarh in the month of December 2008. With the help of available literatures 'Kanghi booti' was identified and confirmed as *Abutilon indicum* Linn. (Family: Malvaceae), the specimen deposited in the museum of the Department of Ilmul Advia (Voucher No.SC 0115/09). The whole plant of 'Kanghi booti' was air dried and ground to get coarse powder and then subjected to physicochemical and phytochemical studies. Ash values (total ash, acid insoluble ash and water soluble ash) and loss on drying were determined and estimated using the methods recommended in Indian Pharmacopoeia (Anonymous, 1996). The moisture content was determined by Toluene distillation method. The extractive values in petroleum ether (60-80^{o}c), diethyl ether, benzene, chloroform, ethyl alcohol and water were successively estimated using Soxhlet's Apparatus. The pH value of 1% and 10% aqueous solution was also measured. The water soluble and ethanol soluble matter were determined. The percentage of alkaloid, nitrogen, fatty matter, phenols, flavonoid,

sterols/terpenes, proteins, carbohydrate and crude fiber were determined quantitatively. The alkaloid fraction was separated (Paech and Tracey, *et al*, 1955) and the TLC of this fraction was made. The phenol, flavonoids and amino acid were separated using method of Paech and Tracey (1955), Sharma *et al*. (1991) and Tandon *et al*. (1970) respectively. The TLC of phenol and flavonoids fraction were made. The colour emitted by the powder, with various treatments under day light as well as Ultra Violet light (short and long wave length) was observed. Thin layer Chromatography (TLC) profile of the extracts in different solvents were determined using pre-coated silica gel (60 F254) aluminum plates (layer thickness 0.25mm), Descending paper chromatography for identification and quantification of Amino acids (Gowenlock, 1988) and sugars (Afaq *et al*., 1994) were also made.

Observation and Results

(a) Phytochemical Studies

The drug contains alkaloids, carbohydrates, flavonoids, glycoside, tannin, phenols, proteins, starch, saponin, sterols/terpenes, amino acids and resin.

The percentage of total alkaloids, flavonoids, phenols, nitrogen, fatty matter, sterols/terpenes, proteins and carbohydrates that were determined are depicted in table 1.

Table 1: Quantitative Estimation of chemical constituents

S.No.	Chemical constituent	Percentage (w/w)*1.54±0.05
1	Total Alkaloid	1.54 ± 0.05
2	Total Flavonoid	5.60 ± 0.05
3	Phenol	0.02 ± 0.05
4	Nitrogen	0.27 ± 0.05
5	Fatty matter	0.70 ± 0.05
6	Sterol/Terpenes	0.71 ± 0.05
7	Protein	1.02 ± 0.05
8	Carbohydrates	1.04 ± 0.05

*Note: Values are average of three experiments.

(b) Fluorescence Analysis of the Drug

The fluorescence analysis of the powder of *Abutilon indicum* Linn., was carried out after treatment with different reagents and chemicals the powder was observed under Day Light and U.V. Light and the colours emitted are recorded in table 2.

Table 2: Fluorescence Analysis of powdered drug of *'Kanghi booti'* chemical reagent

S. No.	Powdered drug	Day light	UV short	UV long
1	Powdered drug + Con. HNO_3	Orange	Green	Green
2	Powdered drug +Con. HCL	Green	Green	Black
3	Powdered drug + Con. H_2SO_4	Black	Black	Black
4	Powdered drug + 2% Iodine Sol.	Brown	Dark green	Black
5	Powdered drug + Acetic acid	Dark green	Green	Green
6	Powdered drug + 10% NaOH sol.	Green	Dark green	Black
7	Powdered drug + Acetic acid + H_2SO_4	Black	Black	Black
8	Powdered drug +10%NaHO + few drop of $CUSO_4$ sol.	Green	Dark green	Black
	Powdered drug +10%NaHO +Few drop of Lead acetate	Green	Green	Black
10	Powdered drug +Acetic acid+5%FeCl + H_2SO_4	Black	Dark green	Black
11	Powdered drug +5% FeCl	Green	Dark green	Black
12	Powdered drug +1NHCl	Straw water	Green	Black
13	Powdered drug +2NHCl	Light green	Green	Black
14	Powdered drug +1N H_2SO_4	Straw	Green	Black
15	Powdered drug +2N H_2SO_4	Light green	Green	Black

(c) Thin Layer Chromatographic

TLC profile of different extracts, extracted using soxhlet apparatus was studied and the Rf Values of spots visualized after treatment of various reagents were measured. The colours of the spots were also noted. The details are given in table 3 (Fig No.1-5).

(d) TLC of Alkaloid fraction (Fig. 6)

The alkaloid fraction was separated from chloroform extract and the TLC of that fraction was made using Pre-coated aluminum plates (silica gel (60 F 254), Thickness 0.25 mm).

Table 3: TLC evaluation of Successive extracts of '*Kanghi booti*'

Extract	Spraying reagent	Mobile phase	No. of spots	Rf Values & colour
1.Petroleum Ether	Day light Iodine Vapour Vaniline Sulphuric acid UV Long UV Short	Petroleum Ether: Di-ethyl Ether (1:1½)	11 09 08 05 07	0.17 (Y), 022 (Y), 0.26 (Lg), 0.3 (Lf), 0.34 (Lg), 0.37 (Dg), 0.46 (G), 0.47 (Y), 0.52 (Dg), 0.65 (Dg), 0.71 (Lg). 0.26 (Lg), 0.31 (Lg), 0.38 (Dg), 0.47 (Ly), 0.52 (Dg), 0.59 (Dy), 0.65 (Dg), 0.70 (Ly), 0.82(Dy). 0.05 (P), 0.10 (P), 0.38 (Lg), 0.55 (Dp), 0.62 (P), 0.68 (Dp), 0.82 (Lp), 0.97 (Dp). 0.22 (P), 0.32 (P), 0.38 (P), 0.53 (Dp), 0.67 (P). 0.22 (Y), 0.38 (Y), 0.47 (Ly), 0.52 (Y), 0.65 (Y), 0.71 (Ly), 0.77 (B).
2. Diethyl Ether extract	Day light Iodine Vapour Vaniline Sulphuric acid UV Long UV Short Day light Iodine Vapour UV Short	Petroleum Ether: Di-ethyl Ether (1½:1)	10 09 13 08 07 05 04 05	0.7 (G), 0.11 (Dg), 0.14 (Lp), 0.35 (Dy), 0.46 (Lg), 0.52 (Lg), 0.59 (Ly), 0.66 (Gy), 0.74 (G), 0.83 Dg). 0.05 (G), 0.11 (Dg), 0.42 (Dy), 0.52 (Yg), 0.59 (Yg), 0.59 (Yg), 0.66 (G), 0.74 (G), 0.83 (Dg), 0.91 (Y). 0.05 (G), 0.11 (G), 0.16 (P), 0.28 (Lg), 0.38 (Lg), 0.45 (Lg), 0.54 (Lp), 0.61 (G), 0.61), 0.67 (Dg), 0.73 (P), 0.77 (G), 0.84 (Dg), 0.94 (Gp). 0.07 (P), 0.12 (Dp), 036 (P), 0.54 (Dp), 0.60 (P), 0.66 (P), 0.74 (P), 0.84 (Dp). 0.07 (Y), 0.12 (Y), 0.39 (Y), 0.60 (Y), 0.66 (Dy), 0.74 (Lg), 0.84 (Dg). 0.08 (Y), 0.19 (G), 0.30 (Y), 0.39 (G), 0.52 (Dg). 0.19 (G), 0.30 (Y), 0.39 (G), 0.52 Dg). 0.08 (Y), 0.19 (Y), 0.39 (Y), 0.52 Dy).
3.Chloroform extract	Day light Iodine Vapour	Petroleum Ether: Di-ethyl Ether (1:1)	08 08	0.12 (G), 0.22 (G), 0.38 (Lg), 0.54 (G), 0.68 (Y), 0.72 (Y), 0.78 (G), 0.83 (Dg). 0.12 (G), 0.22 (G), 0.38 (Lg), 0.54(G), 0.68 (Y), 0.72 (Y), 0.78 (G), 0.83(Dg).
4.Benzene extract	Vanillin Sulphuric acid UV Short		07 08	0.06 (P), 0.12 (P), 0.22 (G), 0.65 (G), 0.69 (G), 0.74 (G), 0.77 (P). 0.06 (Y), 0.12 (Y), 0.22 (Y), 0.51 (Y), 0.66 (Y), 0.71 (Dy), 0.80 (Dy).
5.Alcoholic extract	Day light Iodine Vapour UV Long UV Short	Chloroform: Methnol (1:¼)	05 05 01 03	0.40 (G), 0.44 (Dg), 0.49 (Y), 0.58 (Lg), 0.60 (Dg). 0.40 (G), 0.44 (Dg), 0.49 (Y), 0.58 (Y), 0.60 (Dg). 0.61 (P). 0.44 (Y), 0.49 (Y), 0.60 (Dy).

Note: G = green, Dg = dark green, Y = yellow, Dy = dark yellow, Lg = light green, Gy = greenish yellow Gp=grayish purple,

P = purple, Lp = light purple, Dp = dark purple

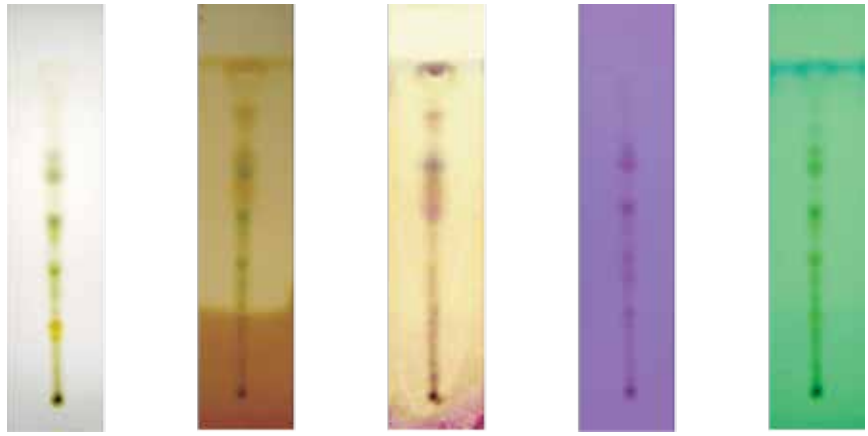


Fig. 1: TLC of Petroleum ether extract of *Abutilon indicum* Linn.

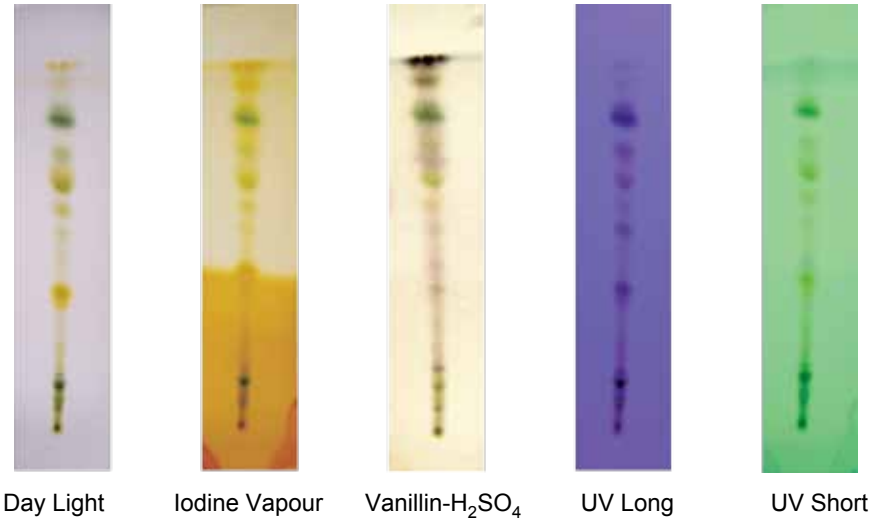


Fig. 2: TLC of Diethyl Ether extract of *Abutilon indicum* Linn.

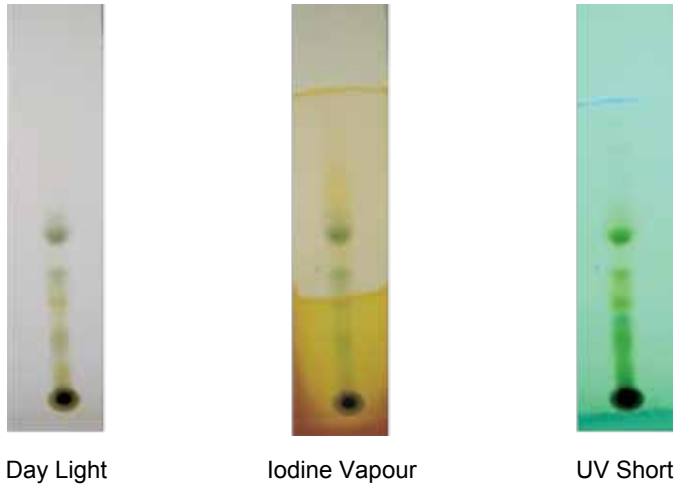


Fig. 3: TLC of Chloroform extract of *Abutilon indicum* Linn.

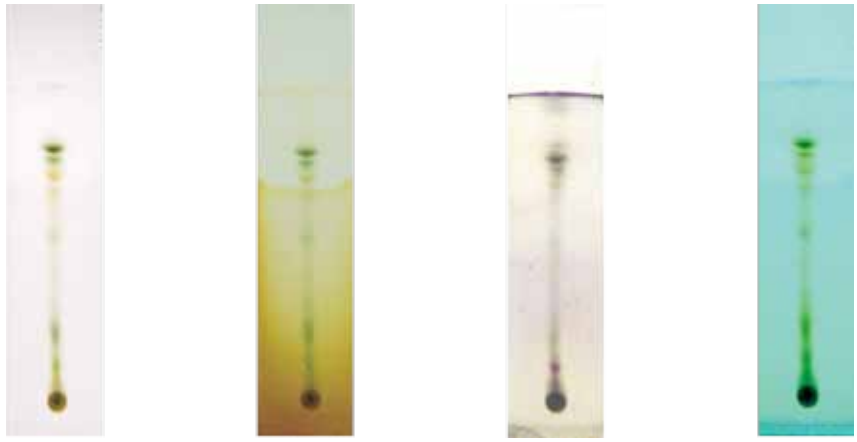


Fig. 4: TLC of Benzene extract of *Abutilon indicum* Linn.

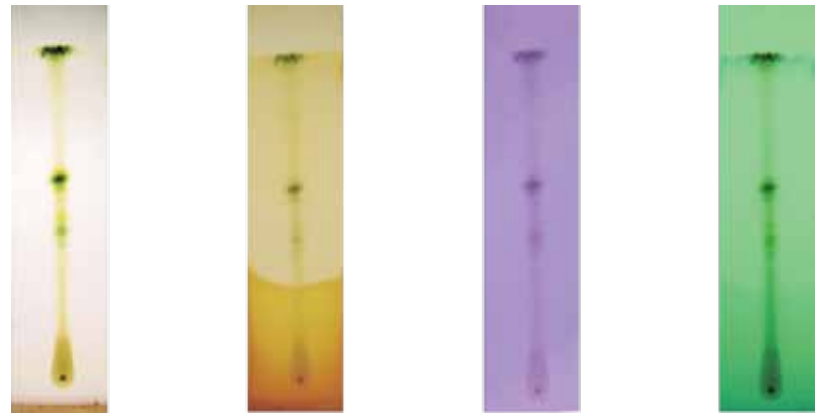


Fig. 5: TLC of Alcohol extract of *Abutilon indicum* Linn.

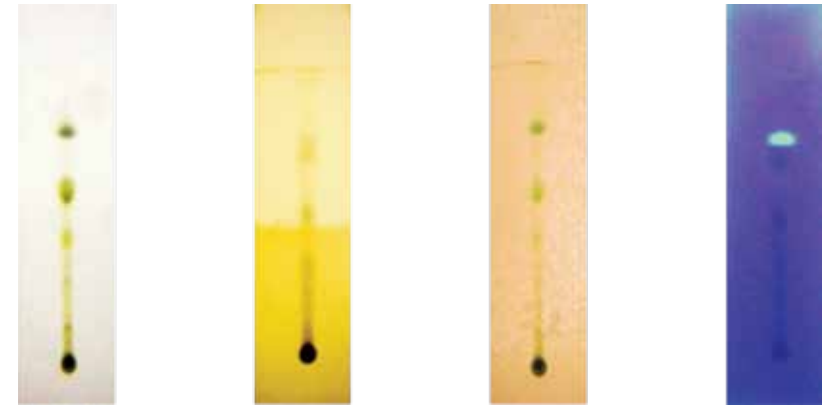


Fig. 6: TLC of Chloroform extract for alkaloid determination of *Abutilon indicum* Linn.

The Mobile Phase was Petroleum ether: Di-ethyl ether (1:1). In daylight 5 spots (Rf: 0.14, 0.30, 0.44, 0.62, 0.83) were clearly visible and in Iodine vapor 2 spots, (Rf: 0.48, 0.71) were visible. Using Vanillin Sulphuric acid as spraying reagent 5 spots (Rf: 0.14, 0.30, 0.44, 0.62, 0.83) was very clear, whereas under UV (long wavelength), 1 spot (Rf: 0.79) was visible.

(e) TLC of Flavonoides fraction (Fig. 7)

The TLC of flavonoid fraction on Pre-coated aluminum plates (silica gel (60 F 254), Thickness 0.25 mm) was made using Toluene, Ethyl acetate and Formic acid (50:40:10) as mobile phase. After spraying the plate with Polyethylene glycol, 3 spots (Rf: 0.45, 0.48, 0.76) appears, shows that three type of flavonoids are present in the plant.

5% Ferric chloride

Fig. 7: TLC of Ethanolic extract of *Abutilon indicum* Linn., for phenols determination

(f) TLC of Phenols fraction (Fig. 8)

The TLC of phenol fraction on Pre-coated aluminum plates, silica gel 60 F 254, (Thickness 0.25 mm) were made using Toluene and Ethyl acetate (8:2) as mobile phase. After spraying the plate with 5% Ferric chloride: 3 spots, (Rf: 0.26, 0.44, 0.49) appears indicate the presence of at least three phenolic compounds.

(g) Descending Paper chromatography for Amino acids:

Using Whatman filter paper (No.1). The amino acid fractions were subjected to decending paper chromatography. The mobile plate was the organic layer of n-Butanol, Acetic acid and Water, (6:2:2). The paper was sprayed with Ninhydrine solution (1% in acetone). Eight (8) amino acid were identified and

the percentage composition calculated using Torhniwal Densitometer and given in table no. 4.

Polytheleneglycol

Fig. 8: TLC of 85% and 50% methanol extract of *Abutilon indicum* Linn., for Flavonoid determination.

Table 4: Amino Acids and Sugars of 'Kanghi booti'.

Name	Percentage Composition
Amino Acids	
Cystine	4.50
Histidine	6.33
Serine	22.50
Alanine	10.60
Histidine hydrochloride	5.40
Tryptophan	6.40
Proline	8.60
Phenyl alanine	35.50
Sugars	
Glucose	50
Fructose	50

(h) Descending Paper chromatography for Sugars:

Using Whatman filter paper (No. 1). The alcoholic extract was subjected to descending paper chromatography. The n-Butanol, Acetic acid and Water

(4:1:5) organic layer, was selected as mobile phase. The paper was sprayed with Aniline phthalate solution. Two sugar spots identified. The percentage compositions are given in table no. 4.

Discussion

The present study is an attempt to ascertain the pharmacopoeial standards for the standardization of 'Kanghi booti'. The quality, identity, purity and strength of the powder has been undertaken as a tool to bring out several features like ash standards, solubility in alcohol and water, successive extractive values, and qualitative screening of physicochemicals, total alkaloids, total flavonoids, phenol, nitrogen, fatty matter, sterol/terpenes, protein, carbohydrates, amino acids and sugars. All these parameters could be incorporated as standards in Unani Pharmacopoeia. Characterization of an herbal drug is essential for the quality control to check the presence of adulterants as a single drug remedy or its polyherbal Unani formulation.

Acknowledgement

The authors are thankful to the Chairman of the Department of Ilmul Advia, Ajmal Khan Tibbiya College & Hospital, Aligarh Muslim University, Aligarh (UP), for providing necessary research facilities and encouragement.

References

Abdullah, S.H. Afaq, Abdul Latif and Asad Ullah Khan, 2010. Antimicrobial activity of *Abutilon indicum* (Linn) SW. (Kanghi booti) Extracts. *Hippocratic Journal of Unani Medicine* 5 (1): 139-146.

Afaq, S.H., Tajuddin and Siddiqui, M.M.H., 1994. Standardization of Herbal Drugs. Publication Division, AMU, Aligarh, pp. 44, 70, 145

Anonymous, 1948. Wealth of India "Raw Materials", CSIR, New Delhi, pp.3, 24.

Anonymous, 1996. Indian Pharmacopoeia, 4th Edn. Vol.2, Controller of publication, Govt. of India, p. 7.

Anonymous, 2006. Medicinal plants in Folklores of Southern India-Part II, Central Council for Research in Unani Medicine, Ministry of Health and Family welfare, Deptt. of AYUSH, Govt. of India, New Delhi, pp.31, 36, 37

Dymock Willium, 1890. Pharmacographica India. Bombay Education Society's Press, Byculla, India, Vol-1, pp.60-61.

Daljeet Singh, 1974. Unani Drveyagurnadarsh, Vol-II, Ayurvedic and Tibbi Academy, Lucknow, pp. 95, 298

Ghulam Nabi, 1923. Jadeed Booti, Khad-ut-Taleem. Barqui Press, Lahore, pp. 27, 94

Ghani, Hakim Najmul, 1921. Khazainul Adviya, Idara Kitab-ul-Shifa, Darya Ganj, New Delhi, pp. 597, 1074.

Gowenlock, A.H., 1988. Practical Clinical Biochemistry. Heinmann Medical Books, London, pp. 375-77

Hakim. M.A.H., 2002. Bustanul Mufridat Jadid, Idara Kitabul Shefa, 2075. Kucha Chelan Darya Ganj, New Delhi, p.142, 263.

Hooker, J.D., 1875. The Flora of British India, Henrieta Street, Convent Garden London, Vol.I, p.326.

Kirtikar, K.R. and Basu, B.D., 1995. Indian Medicinal Plants, Valley Offset Printers and Publishers Dehradun, India, Vol.I, pp.314-316.

Khan, H. S., 1859. Talif-e-Sharifi, Darussalam, Delhi, pp.88, 89.

Khan R.A., 1937. Tazkartul Hind maroof-ba- Yadgar Razae, pp. 86-87

Khan, M.A., 1896. Moheet-e-Azam, Nazami Press, Kanpur, Vol-III, pp.76-77.

Lubhaya, H.R., 1984. Gosowami Bayanul Advia Part ii. Naumani Press, Lahore, pp.161-162

Munshi, G., 2007. Makhzan-e-Mufridat-wa-Murakkabat Maroof ba Khawasul Advia, Department of AYUSH, CCRUM, pp.112, 191

Paech, M. and Tracey, M.V., 1955. Modern Methods of Plant Analysis, Springer Verlag, Berlin, Vol. 7, pp. 290-319.

Sherma, J. and Fried, B., 1991. Hand Book of TLC (IIIrd ed.), Marcel Dekker, Inc., New York., Basel, pp. 701-703.

Tandon, S.P., Tiwari, K.P. and Saxena, V.K., 1970. Proc. Nat. Acad. Sci., India, 40: 217-221 (Cited from Yajnik, R.S. and Andhiwal, C.K., 1979, Amino Acids in the Tubers of *Ruellia tuberose* L., *Geobios* : 62-64).

Physico-chemical and Phyto-chemical Evaluation of 'Shahtra' (*Fumaria officinalis* Linn.) – An important Unani drug

***Abdul Latif, Sumbul Rehman, S.H. Afaq and Nazish Siddiqui**

Department of Ilmul Advia,
A.K. Tibbiya College,
Aligarh Muslim University,
Aligarh-202002, U.P

Abstract

The entire dried plant of *Fumaria officinalis* Linn. commonly known as Shahtra is used as a important medicinal drug of herbal origin in Unani system of Medicine. The plant possesses many medicinal properties and it is an important component of some marketed herbal formulations. There are various other species of *Fumaria* that are sometime used in place of *F.officinalis* . So phytochemical and physico-chemical studies on the whole plant of *F.officinales* has been undertaken for its pharmacopoeial standardization in order to lay down standards for the quality control, genuinity and purity.

The main aspects included in the study are organoleptic characters, physico-chemical constants, qualitative determination of organic chemical constituents, thin layer chromatographic profile and IR spectral study of the drug.

Key Words: Standardization, *Fumaria officinalis*, Physico-chemical and Phytochemical, IR spectrum.

Introduction

Fumaria officinalis Linn. (Fumariaceae) known as Common Fumitory, Shahtra in Persian or Pitpapra in Hindi (Ainslie, 1826; Chopra, 1958; Evans and Trease, 2009) is a perennial herb which has been used in the traditional medicine since a long time in various health ailments. There are seventeen wild species belonging to this genus in Turkey. Practically all the species are known by the name of Fumitory. Two species are widespread in India *F.officinalis* and *F.parviflora. F.officinalis* occur as a pale green, much branched annual herb up to 2 ft. high, with leaves divided into narrow segments (Anonymous, 1956).

Fumaria species have been used in traditional medicine as an infusion prepared from the stem and the leaves are used in various health ailments (Chopra, 1958). Examples include the treatment of skin rashes and other skin diseases like pyoderma and folliculitis. In addition the herb has been used for conjunctivitis, hypertension, as a diuretic, for hepatoprotection, as a laxative, digestive tonic, for sclerosis of the liver and as a vermifuge. The main medicinal use of fumitory, however, is in eruptive skin diseases taken internally as an infusion (Anonymous, 1956, Karim, 1880, Ghani, 1921, Baitar, 1991). The biological activity of *Fumaria* is mostly associated with the presence of isoquinoline alkaloids in the plant (Anonymous, 1956). In the last few years,

*Author for correspondence

a large number of scientific reports have described the properties of *Fumaria*. The plant has also been evaluated pharmacologically and shown to possess antihelminthic, antipyretic and hypoglycemic properties (Erdogan, 2009; Wasu and Muley, 2009; Hentschel *et al*., 1995; Brinkhaus *et al*., 2005).

Ethno-medicinal Uses:

Traditionally, whole herb of *F.officinalis*, which also features in a number of commercial Indian preparations is used for liver disorders (Evans and Trease, 2009), for digestive problems, certain metabolic disease, to purify blood (Hakeem, 1343H). It is extremely useful in syphilis, scrofula, leprotic affections (Ainslie, 1826), used as diuretic, tonic, diaphoretic, alterative, blood purifier (Ainslie, 1826; Chopra, 1958; Hakeem, 1343H, Nadkarni, 2000).

A review of literature reveals that *F.officinalis* has been in use in treating various health ailments including ‘‘colicky pain affecting the gallbladder and billiary system, together with the gastrointestinal tract’’ (Heidari, 2004). Various pharmacological studies have been done like its use in Irritable Bowel Syndrome (Brinkhaus, 2005). Brine shrimp Lethality Bio assay done (Krishnaraju, 2005).

The biological activity of *Fumaria* is mostly associated with the presence of isoquinoline alkaloids in the plant (Anonymous, 1956). In the last few years, a large number of scientific reports have been described the properties of *Fumaria*.

Thus keeping in mind the medicinal importance of the drug various physico-chemical and phytochemical studies on the whole plant of *F.officinalis* were carried out for its standardization, in order to lay down standards for its purity, quality control and quality assurance.

Chemical Constituents

Phytochemical investigation revealed the presence of several alkaloids such as adlumidiceine, copticine, fumariline, perfumine, protopine fumaric acid (considered at one time as a treatment of psoriasis), fumaranine, fumaritine, paprafumicin and paprarine (Erdogan, 2009) and other biologically active compounds like isoquinolone alkaloid including fumaricine, sanguinarine (Evans and Trease, 2009).

It is a major source of fumaric acid (isomer with malic acid), alkaloids (including fumarine and protopine), tannic acid, mucilage, resin. It contains pentatriacontane (0.5%), an alkaloid principle identical with protopine (0.13%),

tannins, phlobaphenes and sugars. Potassium salts predominate among the ash constituents and diuretic property is attributed to their presence (Anonymous, 1956). Cryptopine (0.31%) is a major constituent in total alkaloids (1.25%) from aerial parts of Turkish plant. Phytochemical investigations revealed the presence of several alkaloids such as adlumidiceine, copticine, fumariline, perfumine, protopine, fumaranine, fumaritine, paprafumicin and paprarine (Ainslie, 1826; Anonymous, 1987; Rastogi and Mehrotra, 1998).

Material and Method

Collection of plant material: The whole plant of *F. officinalis* was collected from Dawakhana Tibbiya College, AMU, Aligarh and identified in the Pharmacognosy Section of Department of Ilmul Advia, AMU, Aligarh. Voucher specimens were preserved in the herbarium of Medicinal Plant Lab in the Department of Ilmul Advia, F/O Unani Medicine, Aligarh Muslim University, Aligarh (V.No-SC-0118/09-F).

Chemical parameters: First the organoleptic characters were identified. The dried powder of the whole plant of *F. officinalis* was used for chemical analysis. Various physico-chemical studies like total ash, acid insoluble ash, water soluble ash, sulphated ash, alcohol and water soluble matter, moisture content, successive extractive values using soxhlet extraction method, bulk density and pH studies were carried out as per guidelines of WHO (Anonymous, 1998) and Govt. of India (Anonymous, 2008). Qualitative analysis of the drug was conducted to identify the organic chemical constituents present in the drug (Overtone, 1963; Harborne, 1973).

Besides this, IR spectral study was also done. For IR spectroscopy the alcoholic extract of the drug was obtained by refluxing powdered drug (5.0 gm) with absolute alcohol (50 ml) for 5 hours and removing the solvent under reduced pressure. Then IR spectrum of alcoholic extract was determined in KBr pellets with Perkin Elmer 1600 FTIR spectrometer.

The thin layer chromatographic analysis was conducted (Stahl, 1969; Harborne, 1973) on precoated silica gel $60F_{254}$ TLC plates. The plates were visualized in Day light, Iodine vapour, in short UV and Long UV. They were also derivatised using vanillin-sulphuric acid and heated at 105^{o}C.

Observations

A. *Organoleptic characters:* The powder of the whole plant was light green, without any characteristic odour, slightly bitter in taste. Summarized in Table-1.

Table 1: Organoleptic Characters of *Fumaria officinalis* Linn.

S.No.	Organoleptic parameters	Observations
1.	Colour	Light Green
2.	Smell	Odourless
3.	Taste	Slightly bitter

B. *Physico-chemical constants:* The analytical values of different physico-chemical constants were determined and are depicted in Table-2.

Table-2: Physico-chemical Constants

S.No.	Parameters	Analytical values (%)*
1.	Ash values	
	a) Total ash (w/w)	10.46
	b) Acid Insoluble ash (w/w)	2.82
	c) Water soluble ash (w/w)	7.72
	d) Sulphated ash	15.25
2.	Moisture content (v/w)	5.92
3.	Solubility	
4.	Alcoholic soluble matter (w/w)	2.18
5.	Water soluble matter (w/w)	5.38
6.	Successive extractives	
	a) Petroleum ether (60-800C)	4.52
	b) Di-ethyl ether	2.55
	c) Chloroform	1.11
	d) Absolute alcohol	14.66
	e) Distilled water	24.10
	Bulk density	0.37
	Loss in weight on drying at 1050C (%)	12.35
7.	pH- values	
	1% Aqueous solution	6.74
	10% Aqueous solution	6.92
8.	Total Alkaloid Content (%)	0.13

*Values are average of three experiments.

C. *Qualitative analysis of organic chemical constituents of drug:* The phytochemicals present in the drug were identified on the basis of different chemical tests given for various plant constituents, results have been summarized in Table-3.

Table 3: Qualitative Analysis of Phytochemicals

S.No.	Chemical Constituent	Tests/Reagents	Inference
1.	Alkaloids	Dragendorff's reagent	+
		Wagner's reagent	+
		Mayer's reagent +	
2.	Carbohydrates	Molisch Test	+
		Fehling's Test	+
		Benedict Test +	
3.	Flavonoids	Mg ribbon and dil.Hcl	–
4.	Glycosides	NaOH Test	+
5.	Tannins / Phenols	Ferric Chloride test	+
		Liebermann's test	+
		Lead Acetate test +	
6.	Proteins	Xanthoproteic test	+
		Biuret test	+
7.	Starch	Iodine Test	–
8.	Saponins	Frothing with NaHCO3	+
9.	Steroids / Terpenes	Salkowski Reaction	+
10.	Amino acids	Ninhydrin Solution	+

Indications: ' ' Absence and '+' Presence of constituents

D. *IR spectral study of the drug*: IR spectrum of the alcoholic extract of the drug Shahtra was recorded and major characteristic bands were noted, which are given in Table-4.

Table 4: IR Spectral Details of Alcoholic Extract of Drug

IR , υ (cm^{-1})	3383, 2926, 2858,1733,1634, 1523, 1395, 1065, 541,409

E. *Thin layer chromatographic profile:* Thin layer chromatographic analysis of alcoholic extract was carried out using different solvent systems and visualizing agents and R_f values were calculated to standardize the drug for its identity and purity. The results obtained are given in Table-5.

Table 5: TLC Profile of Alcoholic Extract of Shahtra

Extract	Solvent System	Visualizing agent	No. of Spots	R_f values
Alcohol	Chloroform: Methanol (10 : 1) Toulene: Ethyl acetate: Formic acid (5:4:1)	Day light	4	0.21,0.26,0.38,0.62
		Iodine Vapour	7	0.21,0.26,0.38,0.62,0.69,0.73, 0.76
		UV Short	4	0.21,0.26,0.38,0.62
		UV Long	4	0.21,0.38,0.62,0.69
		Day light	4	0.28,0.79,0.83,0.97
		Iodine Vapour	5	0.28,0.38,0.79,0.83,0.97
		Vanilline-H_2SO_4	8	0.07 (Br.Gr),0.15(L.Gr.), 0.22(L.Gr.),0.29(Y),0.39(L.Y), 0.46(L.P),0.85(Gr.P.),0.97(Br.)
		UV Short	4	0.28,0.79,0.83,0.97
		UV Long	2	0.25(Flouroscent green),0.97

G: Green; Y: Yellow; Br.: Brown; P: Purple; L: Light; D: Dark

Discussion

With the tremendous increase in the global use of medicinal plants, several concerns regarding the efficacy and safety of the herbal medicines have also been raised. Hence it has become necessary to standardize the efficacy and safety measures so as to ensure supply of medicinal plant materials with good quality. As the basic source of the raw materials (herbal drugs) for the pharmaceutical companies of indigenous origin comes from various forest zones, lands and plains. The bulk of raw materials (root, leaves, rhizomes, bark, flowers, fruits, exudates and seeds) are collected annually from these wild sources and a small amount comes from cultivation. Unskilled persons are usually the collectors of the drugs from the land. So, the genuinity and authenticity of the drug collected, always remains a big question mark. There are more chances of possible adulteration. Therefore standardization of the drug is of prime importance before discovering any biological activity. Correct identification and quality assurance of the raw material is, therefore an essential step to ensure reproducible quality of herbal medicine, which contributes to its safety and efficacy.

The standardization is a prerequisite in quality control of any drug used for the welfare of human kind. However in making any assay, allowance must be

given to experimental error, which is about 5%, and for error due to natural variations due to difference of variety and of habitat (Wallis, 1985).

If herbal remedy is effective quality assurance is needed to ensure that the product has expected effects. Quality implies certification in respect of authentification, standardization, composition, stability and safety. It also ensures that the herbal product is free from adulterants and contaminants.

In view of the above, the present standardization study has brought out many diagnostic characters of herbal drug *Fumaria officinalis* (Shahtra) concerning organoleptic, physico- chemical and phytochemical aspects on the basis of which the drug can be identified from its possible adulterants and other wasteful matter present in the commercial sample.

Physico-chemical parameters like ash values, extractive values, moisture content, soluble matter etc. gives indication of quality of drug. If adulteration is caused by siliceous matter, then ash content changes, if drug is improperly stored, the moisture content may change. Estimation of the moisture content present in the drug is an important parameter that not only gives an idea regarding the adulteration but also satisfy the basic consideration that accurate scientific works where the drug is to be sold is within guaranteed assay.

In the same manner idea of the pH values of the aqueous extract of the drug helps in knowing the drug receptor site interactions. It also affects the stability and therapeutic activity (through drug absorption) of the drug.

Phytochemical screening is helpful to know the chemical constituents present in the drug. Generally Infra Red (IR) spectroscopy is used for the determination of different functional groups present in a compound IR spectrum has a region known as finger print region (3383-1733 cm^{-1}) characteristic of a particular compound. This region can be compared with the finger prints of other species of the same genus, which differ from species. To check the purity of the drug, the IR spectrum of the commercial sample may be compared with the authentic sample. If characteristic bands are similar the test drug would be genuine. So, major bands in the alcoholic extract of the drug were recorded and reported (Table-4), which will be helpful in confirming the identity and purity of the drug.

Thin layer chromatography is one of the important parameter used for detecting the adulteration and judging the quality of the drug. The R_f values were calculated using different visualizing agents (Table-5). If the drug is adulterated there might be appearance of the other compounds present in adulterant, in turn may increase the number of spots. On the other hand the exhausted or deteriorated drugs may lose the component and the number of

spots appeared might be less.

This study assumes great significance as it will provide a key of diagnostic characters which serves as an important tool in laying down the standards for quality assurance.

References

1. Ainslie, W, 1826. Materia Medica. Vol 1. Longman, Rees, Orme, Brown and Green, Printed at Javed Press, pp. 138-39.
2. Anonymous, 1956. The Wealth of India “Raw Materials”. Vol.4. CSIR, New Delhi, p.68.
3. Anonymous, 1998. Quality control methods for medicinal plant materials. World Health Organization, Geneva, pp. 25 -28.
4. Anonymous, 2008. Quality control manual for Ayurveda, Siddha and Unani medicine. Govt. of India, Dept. of AYUSH, New Delhi, pp. 21 – 29.
5. Bhattacharya, S.K., R. Lal, A.K. Sanyal, B. Dasgupta and P.K. Das, 1970. Preliminary pharmacological studies on the total tertiary alkaloids of *Fumaria parviflora* Lam. (parpataka). *Journal of Research in Indian Medicine* (4) 2: 152-159.
6. Brinkhaus B. et al., 2005. Herbal medicine with curcuma and fumitory in the treatment of irritable bowel syndrome: A randomized, placebo-controlled, double-blind clinical trial. *Scandinavian Journal of Gastroenterology*. 40 (8):936 – 943.
7. Chopra R.N., Nayar S.K. and Chopra I.C., 1956. Glossary of Indian Medicinal plants. CSIR, New Delhi, p. 241.
8. Erdoğan T.F., 2009. Brine Shrimp Lethality Bioassay of *Fumaria Densiflora* DC. and *Fumaria officinalis* L. Extracts. *Hacettepe University Journal of the Faculty of Pharmacy* 28 (2):125-132.
9. Evans W.C. and Trease, 2009. Pharmacognosy. 15th edition, Elsevier publications, Delhi, p. 417.
10. Ghani, Hakim Najmul, 1921. Khazainul Adviya. Idara Kitab-ul-Shifa, Darya Ganj, New Delhi, pp. 94-95.
11. Gilani A.H, Bashir S., Janbaz K.H and Khan A., 2005. Pharmacological basis for the use of *Fumaria indica* in constipation and diarrhea. *Journal of Ethanopharmacology* 96 (3):585–589.
12. Hakim, M.A., 1343H. Bustan-ul-Mufridat. Idare-Taraqqee, Urdu publication, Lucknow, p. 215.

13. Harborne, J. B., 1973. Phytochemical methods. Chapman and Hall, London, p. 70.
14. Hentschel C, Dressler S, Hahn E.G., 1995. *Fumaria officinalis* (fumitory)-clinical applications. *Fortschr Med.* 10 (113) : 291-292.
15. Heidari M.R., Mandgary A. and Enayati M., 2004. Antinociceptive effects and toxicity of *Fumaria parviflora* lam. in mice and rats. DARU. 12(4):136 – 140.
16. Ibn-e-Baitar, 1291H. Al-jamiul Mufridat-al-advia-wal-Aghzia (Urdu translation., 1999). Central Council for Research in Unani Medicine, New Delhi, pp. 108-109.
17. Karim N, 1880. Tarjuma Makhzanul Advia. Matba Munshi Nawal Kishore, Lucknow, p. 681.
18. Krishnaraju V.A., Rao T.V.N, Sundararaju D., Vanisree M., Tsay H.S., and Gottumukkala V. Subbaraju G.V., 2005. Assessment of Bioactivity of Indian Medicinal Plants Using Brine Shrimp (*Artemia salina*) Lethality Assay. *International Journal of Applied Science and Engineering* 3(2): 125 – 134.
19. Nadkarni K.M., 2000. Indian Materia Medica, Vol. 1. Bombay Popular Prakashan, pp. 560-61.
20. Overtone, K.H., 1963. Isolation, Purification and preliminary observation in elucidation of structures by physical and chemical methods. Bentley Interscience Pub., New York, p. 34.
21. Sener B., 1994. Recent results in the search for bioactive compounds from Turkish medicinal plants. *Pure & Appl. Chem.* 66 (10/11): 2295 – 2298.
22. Stahl, 1969. Thin Layer Chromatography: A laboratory handbook. (student edition). Springer Verlag, Berlin.
23. Wallis T.E., 1985. Text book of Pharmacognosy. CBS Publishers, *Delhi, pp. 547, 564.*
24. Wasu S.J and Muley B.P., 2009. Antioxidant Activity of *Fumaria officinalis* Linn. and its Study on Ethanol induced Immuno suppression.*Research J. of Pharm. and Tech*.2 (2):405 – 408.

Development of Standard Operating Procedures and Quality Control Standards of Roughan-a-Amla and Roughan-e-Surkh : Unani Oil Preparations

***Rashid H. Zuberi and Shamima Hashmi**

Regional Research Institute of Unani Medicine (CCRUM), P.O. Box 70, Aligarh-202002, U.P., India

Abstract

The analytical standards of two highly medicinal and frequently used oil preparations viz. Roughan-e-Amla and Roughan-e-Surkh have been established in order to maintain their quality, safety and efficacy while taken for a commercial preparation. The standardization is based on the pharmacopoeial parameters such as organoleptic features, physico-chemical validation, thin layer chromatography, estimation of microbial load, pesticide residue, aflatoxins and heavy metals of both these compound drugs. Accordingly, their standard operating procedure (SOP) are also developed.

Key words: SOP, Physico-chemical validation, Thin layer chromatography

Introduction

Both Roughan-e-Amla and Roughan-e-Surkh are important polyherbal Unani formulations classified under the category of "Roughaniyat" in NFUM-I (Anonymous, 2006). Therapeutically both these oil preparations are used externally to relieve a variety of human ailments. As Roughan-e-Amla consisting of four herbal ingredients, is used frequently as a hair tonic (Muqawwi-e-Shar), for blackening of hair (Musawwid-e-Shar) and more often to control the falling of hair (Intesar-e-Shar) while Roughan-e-surkh being highly antiinflammatory (Mohalil-e-Waram) is prescribed generally to relieve Rheumatism (Waj-ul-mafasil), sciatica (Irqun-nisa) and Gout (Niqras) according to Arzani (1880), Kabiruddin (1967), Sina (1994), Anonymous (2006) and many others.

A review of literature revealed that a large number of unani formulations have already been standardized and their SOPs also developed accordingly. Some of such studies on Unani formulations such as sufoof, Majoon, Habbs and Sunoon are reported by various workers viz., Aminuddin and Siddiqui (2007), Bagul *et al*. (2006), Goel *et al*. (2007), Hashmi and Zuberi (2010), Khan *et al*. (2010), Negi *et al*. (2009, 2010), Ramaswamy *et al*. (2009), Sajwan *et al*. (2010), Siddiqui *et al*. (1991), Zuberi and Tajuddin (2008) and many others. However, no such work appears to be taken up on any of these two oil preparations thus far. It was therefore considered essential to take up the investigation of two oil preparations in order to develop certain standards for the commercial producers.

*Author for correspondence

Materials and Methods

In order to develop SOP and the pharmacopoeial standard, sufficient quantity of all the raw ingredients of Roughan-e-Amla and Roughan-e-surkh were procured from three different sources i.e. one form Dawakhana Tibbiya College, AMU Aligarh and the other two from authorized local druggists. The botanical identity of all these raw ingredients were established with the help of parameters as described in API, UPI and IP (1966). Foreign matter if any in the raw ingredients was removed and dried further. Three batches of both these formulations were prepared in pharmacognosy lab of RRIUM, Aligarh, following the ingredient ratio and methodology given in NFUM-I (2006) as described below in Table 1 and 2 respectively.

Table 1: Formulation Composition of Roughan-e-Amla

S.No.	Unani Name	Botanical Name	Part used	Quantity
1.	Aab-e-Amla Taza	Emblica officinalis Gaertn	Amla water	1 lit
2.	Berg-e-Moorad	Myrtus communis L.	Leaf	125 g
3.	Berg-e-Hina	Lawsonia inermis L.	Leaf	125 g
4.	Roughan-e-Kunjad	Sesamum indicum L.	Seed oil	3.75 lit.

Table 2: Formulation Composition of Roughan-e-surkh

S.No.	Unani Name	Botanical Name	Part used	Quantity
1.	Majeeth	Rubia cordifolia L.	Stem	200 g
2.	Saleekha	Cinammomum cassia L.	Bark	80 g
3.	Kaiphal	Myrica nagi Buch	Stem bark	80 g
4.	Charela	Parmelia perlata Ach	Lichen	80 g
5.	Saad kufi	Cyperus rotundus L.	Rhizome	80 g
6.	Waj-e-Turki	Acorus calomus L.	Rhizome	80 g
7.	Qaranful	Syzygium aromaticum L.	Flowerbud	80 g
8.	Narakachoor	Zingiber zerumbet (L.)Sm	Rhizome	80 g
9.	Roughan-e-Sarshaf	Brassica campestris L.	Mustard oil	150 g
10.	Roughan-e-kunjad	Sesamum indicum L.	Sesame oil	150 g
11.	Aab-e-Aahak	Water	–	QS

The physico-chemical estimations which include parameters such as Acid, Iodine, Peroxide and the saponification value and also the thin layer chromatographic analysis of the two oil preparations have been carried out

as per WHO guidelines (Anonymous, 1998). Determination of microbial load, pesticide residue, Aflatoxins and the heavy metals on the other hand done following Anonymous (2000).

Observations and Result

Based on the preparation of three batches of each, Roughan-e-Amla and Roughan-e-Surkh their standard operating procedures (SOP) have been developed as described below -

SOP of Roughan-e-Amla

In order to get required quantity of Aab-e-Amla taza sufficient green, fresh, healthy Amla fruits were taken and the pulp separated from the seed. It was grinded and then squeezed through a muslin cloth to get the Aab-e-Amla taza. The other two ingredients already being soaked overnight in water was boiled for half an hour. After cooling it was smashed again and filtered through a muslin cloth. The decoction thus obtained was mixed with Aab-e-Amla taza, Roughan-e-kunjad in the same proportion was then added to the above decoction and boiled continuously for several hours till all water evaporates from the preparation. After slight cooling, the viscous portion was decanted in another container and filtered finally before packing.

SOP of Roughan-e-Surkh

The required quantity of all the eight herbal ingredients were first of all grinded coarsely (Neem kafta) one by one in the ratio as per NFUM-I and then soaked together overnight in Aab-e-Amla, already prepared earlier in sufficient quantity. Next day, the soaked drugs were boiled till only half of the water left in it. After slight cooling, it was smashed slowly and then filtered through a double fold of Muslin cloth. The extract thus obtained was heated again until reduced to half. A mixture of Roughan-e-sarshaf and Roughan-e-kunjad in 1:1 ratio was then added to the condensed extract and boiled again for several hours till water evaporates completely and finally the viscous portion decanted carefully and filtered finally to ensure its' transparency.

After the preparation of three batches, the organoleptic examination of both the drugs was conducted and the features recorded below in Table 3.

Table 3

Organoleptic feature	Name of drug	
	Roughan-e-Amla	Roughan-e-Surkh
Appearance	Viscous liquid	Viscous liquid
Colour	Light brown	Bright red
Taste	Not specific	Not specific
Odour	Agreeable	Agreeable

Physico-chemical Study

The physico-chemical estimation of two oil preparations which includes the parameters such as determination of acid value, iodine value, saponification value, ester value, refractive index and weight per ml have been recorded in Tables 4 & 5 and the test for presence of various adulterant oils in Table 6 accordingly.

Thin Layer Chromatography (TLC)

TLC of the petroleum ether (60-80^{o}) extract of both Roughan-e-Amla and Roughan-e-Surkh was developed on precoated Aluminium plates (silica gel 60 F_{254}) using Toluene-Ethyl acetate-Formic acid (9:1:1) as mobile phase, and the chromatogram were viewed under visible light as well as under the UV (365 nm).

Further on spraying the plate with vanilline-H_2SO_4 regent and heating at 110^{o}C till optimum spot development. The number of spots, the Rf values and the colour zones observed for the two oil preparations are recorded in Table 7 & 8 and their chromatograms presented in Plate-3.

The observations about the determination of microbial load and pesticide residue are shown in Table 9 and the estimation of Aflatoxins and heavy metals in Table 10.

Conclusion

Based on the present study of two highly medicinal oil preparations of the unani system of medicine, a number of physico-chemical standards of both Roughan-e-Amla and Roughan-e-Surkh have been established besides their standard operating procedures (SOPs).

Sad-kufi

Majeeth

Charela

Saleekha

Narkchur

Wajturki

Plate 1. Ingredients of Roughan-e-Surkh and Roughan-e-Amla

Kaifal

Qaranful

Amla

Berg-e-Hina

Berg-e-Moorad

Plate 2. Ingredients of Roughan-e-Surkh and Roughan-e-Amla

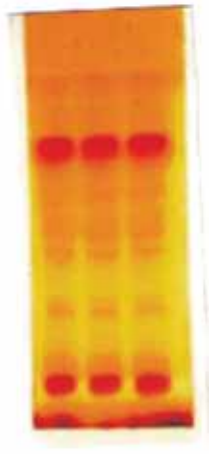
Under UV 365 nm after spraying with VSA

Under UV 365 nm

Under UV 365 nm After spraying with VSA and heating at under 110oC

After spraying with VSA and heating at 110oC

After spraying with 10% Eth. H2SO4 reagent



Under iodine vapours

Under UV 365 nm and heating at 110oC

After spraying with VSA and heating with 110oC

After spraying with 10% Eth. H2SO4

Plate-3. TLC profile of Roughan-e-Surkh and Roughan-e-Amla

All the three batches of these two oil preparations when qualitatively analysed for the presence of any adulterant oil, it was found totally lacking. The petroleum ether extractive of Roughan-e-surkh was found to be 100%, while Roughan-e-Amla was found not less than 98.72%. The saponification value on the other hand ranging from 166.33 – 169.94 and 189.37 – 193.44 in Roughan-e-surkh and Roughan-e-Amla respectively is also an indication that all three samples of drugs under study are uniform.

Table 4: Physico-chemical Standards of Roughan-e-Amla

S.No.	Parameters	Sample I	Sample II	Sample III	Limit
1.	Acid value	2.47 2.42 2.51	2.82 2.77 2.88	2.37 2.32 2.35	Not more than 2.88
2.	Iodine value	112.28 112.31 112.23	116.23 116.42 116.29	114.45 114.41 114.33	Range 112.28 – 116.42
3.	Saponification value	190.88 190.82 190.78	193.38 193.44 193.33	189.44 189.46 189.37	Range 189.37 – 193.44
4.	Unsaponifiable matter (%, w/v)	1.78 1.74 1.71	2.17 2.22 2.14	1.57 1.52 1.62	Not more than 2.22
5.	Ester value	188.41 188.40 188.27	190.56 190.68 190.45	187.07 187.14 18702	Range 187.02 – 190.68
6.	Refractive index	1.4663 1.4661 1.4662	1.4732 1.4734 1.4731	1.4660 1.4662 1.4658	Range 1.4658 – 1.4734
7.	Weight per ml	0.9419 0.9421 0.9418	0.9632 0.9634 0.9633	0.9423 0.9424 0.9422	Range 0.9418 – 0.9634
8.	Petroleum Ether (60-80oC) extractive (%, v/w)	98.47 98.39 98.32	98.66 98.72 98.69	97.84 97.88 97.81	Not less than 98.72

Table 5: Physico-chemical Standards of Roghan-e-Surkh

S.No.	Parameters	Sample I	Sample II	Sample III	Limit
1.	Petroleum ether (60-80o) extractive (%)	100.00	100.00	100.00	Not less than 100.00

S.No.	Parameters	Sample I	Sample II	Sample III	Limit
2.	Acid value	1.87 1.82 1.90	1.72 1.78 1.83	1.45 1.49 1.38	Not more than 1.90
3.	Iodine value	103.18 103.23 103.11	101.88 101.32 101.60	104.16 104.07 104.02	Range 101-32-104.16
4.	Peroxide value	8.51 8.45 8.58	8.49 8.60 8.52	7.24 7.32 7.38	Not more than 8.60
5.	Unsaponifiable matter (%)	4.12 4.19 4.24	4.22 4.28 4.13	4.08 4.13 4.21	Not more than 4.28
6.	Weight per ml (g)	0.882 0.884 0.884	0.872 0.873 0.872	0.867 0.866 0.867	0.866-0.884
7.	Saponification value	167.92 168.66 168.98	168.86 169.23 169.94	166.33 166.65 166.44	Range 166.33-169.94
8.	Ester value	166.84 166.05 167.08	167.14 167.45 168.11	164.88 165.16 165.06	Range 165.05-168.11
9.	Refractive index	1.4872 1.484 1.4869	1.4837 1.4835 1.4832	1.4773 1.4772 1.4775	

Table 6: Qualitative tests for presence of various oil

Name of Formulation	Qualitative Tests			
	Arachis oil	Cotton seed oil	Sesame oil	Mineral oil
Roughan-e-Amla Sample-I Sample-II Sample-III	 -ive -ive -ive	 -ive -ive -ive	 +ive -ive +ive	 -ive -ive -ive
Roughan-e-Surkh Sample-I Sample-II Sample-III	 -ive -ive -ive	 -ive -ive -ive	 +ive _ive +ive	 -ive -ive -ive

Table 7: TLC Profile of Roughan-e-Amla and Roughan-e-Surkh with their Rf values

No.	Extracts	Solvent system	Detection	Rf values and their colour zones			
				No. of spots	Raughan-e-Surkh	No. of spots	Raughan-e-Amla
1.	Petroleum Ether (60-80oc)	Toluene-Ethylacetate-Formic Acid (9:1:1)	Visible light	4	0.06 (fade brown), 0.16 (light pinkish brown), 0.43 (light yellow), 0.56 (light pinkish yellow)	2	0.10 (grayish green), 0.17 (light brown)
2.	Petroleum Ether (60-80o)	Toluene-Ethyl acetate-formic acid (9:1:1)	UV (365 nm)	8	0.13 (pinkish brown), 0.15 (light blue), 0.35 (orange brown), 0.38 (light blue), 0.43 (light orange yellow), 0.58 (light yellowish green), 0.70 (light orange blue), 0.92 (orange brown)	3	0.07 (dark brown), 0.58 (fade orange red), 0.69 (light blue)
3.	Petroleum Ether (60-80o)	Toluene-Ethyl acetate-formic acid (9:1:1)	Vanilline-H2SO4 reagent	7	0.16 (reddish brown), 0.39 (orange yellow), 0.61 (light blue), 0.72 (fade brown), 0.81 (orange brown), 0.87 (light blue), 0.97 (orange yellow)	5	0.11 (brown), 0.27 (dark brown), 0.62 (dull red), 0.65 (light reddish brown), 0.70 (light blue)

Table 8: TLC Profile of Roughan-e-Amla and Roughan-e-Surkh with their Rf values

No.	Extracts	Solvent system	Detection	Rf values and their colour zones			
				No. of spots	Raughan-e-Surkh	No. of spots	Raughan-e-Amla
1.	Methanol	Petroleum Ether (60-80O)-Diethyl ether- Ethyl acetate-formic acid (4:4:1)	UV (365 m)	7	0.05, 0.19 (dull brown), 0.35 (fade gray), 0.39 (gray), 0.82 (light green), 0.85 (light brown), 0.98 (light orange brown)	3	0.07 (Light pink), 0.42 (light gray), 0.94 (dull pinkish brown)

No.	Extracts	Solvent system	Detection	Rf values and their colour zones			
				No. of spots	Raughan-e-Surkh	No. of spots	Raughan-e-Amla
2.	Methanol	Petroleum Ether (60-80O)-Diethyl ether- Ethyl acetate-formic acid (4:4:1)	Vanilline-H2SO4 reagent	5	0.16 (light pink), 0.53 (pink), 0.67 (light violet brown), 0.77 (light orange red), 0.98 (violet pink)	2	0.10 (grayish green), 0.66 (pinkish brown)
3.	Methanol	Petroleum Ether (60-80O)-Diethyl ether- Ethyl acetate-formic acid (4:4:1)	I2 vapours	6	0.12 (light brown), 0.48 (fade brown), 0.62 (dark brown), 0.68 (light brown), 0.73, 0.81 (fade brown)	5	0.06 (brown), 0.44 (fade green), 0.51 (light brown), 0.88, 91 (fade brown)

Table 9: Determination of Microbial load and Pesticide residue of two drugs

Parameters studied	Roughan-e-Amla	Roughan-e-Surkh	WHO Limit
A. Microbial load			
Total Bacterial load	1x102	16x102	Not more than 105/g
Salmonella spp.	Nil	Nil	Absent
Escherichia coli	Nil	Nil	Absent
Total fungal count	1x10	1x102	Not more than 103/g
B. Pesticide residue			
DDT	Nil	Nil	Nil
Endosulfan	Nil	Nil	Nil

Table 10: Determination of Aflatoxins and Heavy metals of two drugs

Parameters studied	Roughan-e-Amla	Roughan-e-Surkh	WHO Limit
A. Alfatoxins			
B1	Nil	0.0018	Not more than 0.50 ppm
B2	Nil	Nil	Not more than 0.10 ppm
G1	Nil	Nil	Not more than 0.50 ppm
G2	Nil	Nil	Not more than 0.10 ppm

Parameters studied	Roughan-e-Amla	Roughan-e-Surkh	WHO Limit
B. Heavy metals			
Arsenic	Nil	Nil	Not more than 3 ppm
Cadmium	Nil	Nil	Not more than 0.3 ppm
Lead	Nil	Nil	Not more than 10 ppm
Mercury	Nil	Nil	Not more than 1 ppm

Further, both the oil preparations are almost totally devoid of any microbial load, pesticide residue, Aflatoxin and heavy metals except found very much within the permissible limit in a few samples.

Acknowledgement

The authors are highly thankful to Prof. S. Shakir Jamil, Director General, CCRUM, New Delhi for providing necessary facilities and encouragement during the period of research.

References

Aminuddin and Siddiqui, M.K., 2007. Microscopic examination of Jawarish Podina – A polyherbal formulation in Unani system of medicine. *Hippocratic Journal of Unani Medicine* 2(2): 113-120.

Anonymous, 1966. Indian Pharmacopoeia, Manager of Publications, Delhi, p. 293.

Anonymous, 1989-2007. The Ayurvedic Pharmacopoeia of India, Part I, Vols. I-VI, Ministry of Health & Family Welfare, Government of India, New Delhi.

Anonymous, 2007-2009. The Unani Pharmacopoeia of India, Part I, vols. I-VI, Ministry of Health & Family Welfare, Govt. of India, New Delhi.

Anonymous, 1998. Quality control methods for medicinal plant materials, WHO, Geneva, p. 25-28.

Anonymous, 2000. Official methods of analysis of the Association of official analytical chemists (AoAC), 17th Ed. Arlington USA, p. 38-60.

Anonymous, 2006. National Formulatory of Unani Medicine, part I, Ministry Health and Family Welfare, Govt. of India, New Delhi, p. 189, 200.

Arzani, M.A., 1880. Qarabadeen Qadri, CCRUM, Repr. Ed. 2009, New Delhi, p. 501.

Bagul, M.S., Pathak, S.B., Ravishankar, M.N. and Rajani, M., 2006. Phytochemical standardization of Sharbat-e-Aijaz, Proc. Of Natl. workshop on Institute-Industry interaction on research in Unani Medicine, Narasi Publication House, Delhi, p. 131-138.

Goel, S., Ahmad, R. and Khan, M.S.Y., 2007. Microscopical examination of compound formulation – Majoon-e-Ispand Sokhtani. *Proc. Of Int. Conf. on Unani Drugs*, 8-11 Feb. 2005, CCRUM New Delhi, p. 817-819.

Hashmi, S. and Zuberi, R.H., 2010. Botanicl and physic-chemical standardization of sufoof-e-Bers – a polyherbal unani drug of repute. *Hippocratic Journal of Unani Medicine* 5(3): 131-139.

Kabiruddin, 1967. Bayaz-e-Kabir, vol. II, Hikimat Book Depot, Hyderabad Repr. Ed. p. 85.

Khan, N.A., Muzaffar, M., Qsim, J.A., Nasiruddin, M. and Haque, M.M., 2010. Physico-chemical and phytochemical studies on Majoon-e-Baladur. *Hippocratic Journal of Unani Medicine* 5(3): 15-19.

Negi, K., Singh, V.K. and Siddiqui, M.K., 2009. Ingredients identity in Itrifal-e-Kishnizi – a polyherbal formulation of Unani System of medicine, *Hippocratic Journal of Unani Medicine* 4(1): 55-65.

Negi, K., Sajwan, K. and Khan, M.S.Y., 2010. Standardization of Habb-e-Man-e-Hamad – A Unani contraceptive, *Hippocratic Journal of Unani Medicine* 5(3): 31-38.

Ramaswamy, D., Meena, R.P., Khan, S.A., Arfeen, S., Mageshwari, S. and Sultana, G., 2009. Chemical standardization of Majoon-e-Rewnd chini – A Unani formulation, *Hippocratic Journal of Unani Medicine* 4(3): 59-67.

Sajwan, S., Sajwan, K., Asim,. S.M. and Agarwal, U.C., 2011. Standardization of Polyherbal unani formulation – Jawarish Kamooni. *Hippocratic Journal of Unani Medicine* 6(4): 1-9.

Siddiqui, S.H., Zaidi, S.T.H., Khan, G. and Sharma, H.P., 1991. Standardization of Itrifal-e-Zamani and some of its constituents. *Ind. Jour. Unani Med*. 1: 37-42.

Sina, B.A., 1994. Mujarribat-e-Bu Ali Sina, Almoor raj Tohfatul Aashqeen. Aijaz Publ. House, New Delhi, p. 200.

Zuberi, R.H. and Tajuddin, 2008. Physico-chemical and phytochemical evaluation of Sunoon-e-Tambaku, *Hippocratic Journal of Unani Medicine* 3(4): 53-61.

Studies on Quality Evaluation of Some Commercial Herbal Drugs and Spices

[1]*Nitin Rai, [2]Rajeev Kr. Sharma, [3]Lalit Tiwari and [1]A.K. Verma

1. Department of Botany, M.M.H. (PG) College, Ghaziabad-201002

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

3. Homoeopathic Pharmacopoeial Laboratory, PLIM Campus, Ghaziabad-201002, India.

Abstract

Commercial samples of ten herbal drugs and spices of fruit and seed origin viz. *Capsicum frutescens* L., *Coriandrum sativum* L., *Cuminum cyminum* L., *Emblica officinalis* Gaertn., *Foeniculum vulgare* Mill., *Piper longum* L., *Piper nigrum* L., *Syzygium cumini* L. (Skeels.), *Terminalia chebula* Retz. and *Trigonella foenum-graecum* L. were evaluated to assess their quality in respect of identity, purity and strength. The samples were resourced from Delhi, Hardwar and Ghaziabad markets. Evaluation is based on specific parameters and limits developed by standardising authentic samples of drugs and spices.

Key-words: Pharmacognostic evaluations, commercial herbal drugs, quality assessment.

Introduction

Herbal drugs are also used as an ingredient of health supplements, spices, natural dyes, perfumery, cosmetics, toiletries etc. The herbal drug also leads to potential synthetic drugs. *Commiphora mukul* **Engl.** (hypolipidaemic), *Centella asiatica* (L.) Urb. (nootropic), *Boswellia serrata* Triana & Planch. (anti-inflammatory), *Trichopus zeylanicus* Gaerten (adaptogen); *Withania somnifera* Dunal. (anti stress), *Pterocarpus marsupium* Roxb. (diabetes mellitus), *Albizia lebbeck* (L.) Benth. (bronchial asthma), *Trigonella foenum-graecum* (diabetes mellitus) are some of the potential medicinal plants species with proven pharmacological studies. The commercial demand of herbal drugs to fetch the need of different sectors is growing at a very fast pace. There is a global awareness for the use of herbal products. But in India, the supply of raw material has not kept pace with the increasing global demand for herbal drugs. Indian herbal market is endowed with vast range of medicinal plants and these plants have made a good contribution to the development of herbal based industries.

Herbal drugs used by the industries are collected from the wild resources. It is estimated that about 800 species are used in production by the pharmaceutical industry, whereas less than 40 species of plants are resourced through commercial cultivation. Over 70% of the plant collection involves destructive harvesting. This poses a definite threat to the genetic stocks and to the diversity of medicinal plants. Adulterants/substitutes are being traded/ used with at times with full knowledge of the sellers/buyers and are very common in the herb trade especially when the trade is involved. Herbs sold

*Author for correspondence

in powdered forms, eg:- the powders of *Pterocarpus santalinum* (Red Sandal or Lal Chandan) are much more prone to adulteration. The use of some species as substitute of a medicinal plant comes in the picture when the originally recommended plant gets rare and its price rises. In many cases, substitutes have taken over the original plants. In some cases, substitutes have become popular, manufacturers have forgotten about the original plant and they only use substitutes available in the market. It is very much doubtful if such substitution is made after testing or as recommended by any authority. Sometimes different morphological parts of same plant species is used in place of prescribed part. Use of stem bark in place of roots are not uncommon. At times mere look alike species are used as a substitute, which may not even contain the active ingredients available through the main plants nor the effects of the end product is the same as that obtained from that of original plant (Sharma, 1987; Rai *et al*., 2011 and Padmakumar *et al*., 2012).

Materials and Methods

The fruit and seed herbal drugs under study were collected from natural habitats and authenticated with references to pharmacopoeial standards and other literature. The commercial samples sold under the trade names purported to be prescribed species were drawn from the different market sources (Delhi, Hardwar and Ghaziabad). Standard protocols/methods prescribed in pharmacopoeia were followed for pharmacognostical, physico-chemical and phytochemical parameters prescribed in Ayurvedic, Unani and Siddha Pharmacopoeia of India. Standards limits in respect of each parameter were obtained by conducting these tests on pre-authenticated material of these drugs (Anonymous, 1986, 1998, 1999, 2007a, b, & 2008).

Table 1: Commercial Herbal Drugs under study

S. No.	Botanical name	Trade name	Morphological part	Utility patterns
1.	Capsicum frutescens L.	Lal mirch	Fruit	Drug and Spice
2.	Coriandrum sativum L.	Dhaniya	Fruit	Drug and Spice
3.	Cuminum cyminum L.	Jeera	Fruit	Drug and Spice
4.	Emblica officinalis Gaertn.	Awala	Fruit	Drug
5.	Foeniculum vulgare Mill.	Sauf	Fruit	Drug and Spice
6.	Piper longum L.	Pipali	Fruit	Drug and Spice
7.	Piper nigrum L.	Kali mirch	Fruit	Drug and Spice
8.	Syzygium cumini (L.) Skeels.	Jamun	Seed	Drug

S. No.	Botanical name	Trade name	Morphological part	Utility patterns
9.	Terminalia chebula Retz.	Harad	Fruit pericarp	Drug
10.	Trigonella foenum-graecum L.	Methi	Seed	Drug and Spice

Observations and Results

All the commercial samples of the drugs collected from Delhi, Haridwar and Ghaziabad were evaluated as per the parameters of quality specifications viz. pharmacognostical characteristics (Identification), histo-chemical tests, major organic groups of chemical compounds (phytoconstituents), physico-chemical constants, UV-Spectrophotometric study and HPTLC fingerprinting prescribed in various Pharmacopoeias and other literature for herbal drugs. (Table 2 to 11). The qualitative and quantitative values in respect of quality specification were predetermined on authenticated herbal drugs comparable with pharmacopoeial standards (Rai, 2012).

Table 2. Quality Evaluation of Commercial Drug Samples of *Capsicum frutescens* L.

Sl. No.	Quality Specifications	Standard Limits	Samples drawn from the market of		
			Delhi	Haridwar	Ghaziabad
A.	Pharmacognostical Characteristics (Identification)				
	• Organoleptic	Descriptive	Conform	Conform	Conform
	• Micro-morphological	Descriptive	Conform	Conform	Conform
B.	Histo-chemical Tests	Descriptive	Conform	Conform	Conform
C.	Major organic groups of chemical compounds (Phyto-constituents)				
	Alkaloid	+	+	+	+
	Anthraquinone	+	+	+	+
	Coumarin	+	+	+	+
	Flavonoid	+	+	+	+
	Glycoside	+	+	+	+
	Protein	+	+	+	+
	Resin	+	+	+	+
	Saponin	+	+	+	+
	Steroid	+	+	+	+
	Tannin	–	–	–	–

Sl. No.	Quality Specifications	Standard Limits	Samples drawn from the market of		
			Delhi	Haridwar	Ghaziabad
D.	Physico-Chemical constants				
	Foreign Matter, %, w/w	2.0	0.7	0.5	1.0
	Moisture content, % w/w, Not more than	6.0	5.0	6.7	7.0
	pH	7.2	7.1	7.0	6.9
	Total Ash, % w/w , Not more than	14.5	13.0	13.6	14.2
	Acid insoluble ash, % w/w, Not more than	2.5	2.1	2.4	2.3
	Alcohol soluble extractive % w/w, Not less than	15.6	15.8	16.6	16.2
	Water soluble extractive % w/w, Not less than	33.0	31.0	35.0	32.0
	Essential Oil , % v/w, Not less than	–	–	–	–
E	UV-Spectrophotometric study	2 absorption peaks	2 absorption peaks	2 absorption peaks	2 absorption peaks
F	HPTLC Fingerprinting after derivatization	5 spots	5 spots	4 spots	6spots

Table 3. Quality Evaluation of Commercial Drug Samples of *Coriandrum sativum* L.

Sl. No.	Quality Specifications	Standard Limits	Samples drawn from the market of		
			Delhi	Haridwar	Ghaziabad
A.	Pharmacognostical Characteristics (Identification)				
	• Organoleptic	Descriptive	Conform	Conform	Conform
	• Micro-morphological	Descriptive	Conform	Conform	Conform
B.	Histo-chemical Tests	Descriptive	Conform	Conform	Conform
C.	Major organic groups of chemical compounds (Phyto-constituents)				
	Alkaloid	–	–	–	–
	Anthraquinone	+	+	+	+

Sl. No.	Quality Specifications	Standard Limits	Samples drawn from the market of		
			Delhi	Haridwar	Ghaziabad
	Coumarin	+	+	+	+
	Flavonoid	+	+	+	+
	Glycoside	+	+	+	+
	Protein	+	+	+	+
	Resin	+	+	+	+
	Saponin	+	+	+	+
	Steroid	+	+	+	+
	Tannin	+	+	+	+
D.	Physico-Chemical constants				
	Foreign Matter, %, w/w	2.0	2.3	1.7	0.5
	Moisture content, % w/w, Not more than	10.0	8.0	12.2	9.6
	pH	7.3	7.1	7.1	7.0
	Total Ash, % w/w , Not more than	2.5	3.0	2.2	2.1
	Acid insoluble ash, % w/w, Not more than	2.0	2.5	2.2	2.2
	Alcohol soluble extractive % w/w, Not less than	10.0	12.0	12.6	11.7
	Water soluble extractive % w/w, Not less than	20.0	18.9	21.4	21.6
	Essential Oil , % v/w, Not less than	0.25	0.10	0.12	0.10
E	UV-Spectrophotometric study	3 absorption peaks	3 absorption peaks	3 absorption peaks	3 absorption peaks
F	HPTLC Fingerprinting after derivatization	6 spots	5 spots	6 spots	6 spots

Table 4. Quality Evaluation of Commercial Drug Samples of *Cuminum cyminum* L.

Sl. No.	Quality Specifications	Standard Limits	Samples drawn from the market of		
			Delhi	Haridwar	Ghaziabad
A.	Pharmacognostical Characteristics (Identification)				
	• Organoleptic	Descriptive	Conform	Conform	Conform
	• Micro-morphological	Descriptive	Conform	Conform	Conform

Sl. No.	Quality Specifications	Standard Limits	Samples drawn from the market of		
			Delhi	Haridwar	Ghaziabad
B.	Histo-chemical Tests	Descriptive	Conform	Conform	Conform
C.	Major organic groups of chemical compounds (Phyto-constituents)				
	Alkaloid	–	–	–	–
	Anthraquinone	–	–	–	–
	Coumarin	+	+	+	+
	Flavonoid	+	+	+	+
	Glycoside	+	+	+	+
	Protein	+	+	+	+
	Resin	–	–	–	–
	Saponin	–	–	–	–
	Steroid	–	–	–	–
	Tannin	+	+	+	+
D.	Physico-Chemical constants				
	Foreign Matter, %, w/w	2.0	2.2	1.9	1.7
	Moisture content, % w/w, Not more than	8.0	9.0	7.5	7.9
	pH	7.3	7.2	6.9	7.3
	Total Ash, % w/w , Not more than	7.5	8.0	7.2	6.9
	Acid insoluble ash, % w/w, Not more than	1.0	1.3	0.9	1.2
	Alcohol soluble extractive % w/w, Not less than	6.5	5.0	4.6	6.2
	Water soluble extractive % w/w, Not less than	13.0	12.1	13.6	13.9
	Essential Oil , % v/w, Not less than	–	–	–	–
E	UV-Spectrophotometric study	3 absorption peaks	3 absorption peaks	3 absorption peaks	3 absorption peaks
F	HPTLC Fingerprinting after derivatization	9 spots	9 spots	9 spots	9 spots

Table 5. Quality Evaluation of Commercial Drug Samples of *Emblica officinalis* Gaertn.

Sl. No.	Quality Specifications	Standard Limits	Samples drawn from the market of		
			Delhi	Haridwar	Ghaziabad
A.	Pharmacognostical Characteristics (Identification)				
	• Organoleptic	Descriptive	Conform	Conform	Conform
	• Micro-morphological	Descriptive	Conform	Conform	Conform
B.	Histo-chemical Tests	Descriptive	Conform	Conform	Conform
C.	Major organic groups of chemical compounds (Phyto-constituents)				
	Alkaloid	+	+	+	+
	Anthraquinone	–	–	–	–
	Coumarin	–	–	–	–
	Flavonoid	+	+	+	+
	Glycoside	+	+	+	+
	Protein	–	–	–	–
	Resin	–	–	–	–
	Saponin	–	–	–	–
	Steroid	–	–	–	–
	Tannin	+	+	+	+
D.	Physico-Chemical constants				
	Foreign Matter, %, w/w	2.0	1.0	1.2	1.6
	Moisture content, % w/w, Not more than	10.0	9.7	9.6	11.0
	pH	6.4	6.5	6.8	6.9
	Total Ash, % w/w, Not more than	6.5	5.0	6.2	6.4
	Acid insoluble ash, % w/w, Not more than	2.0	1.7	1.9	2.1
	Alcohol soluble extractive % w/w, Not less than	3.0	3.6	4.0	3.2
	Water soluble extractive % w/w, Not less than	45.0	41.2	36.0	38.7
	Essential Oil , % v/w, Not less than	–	–	–	–
E	UV-Spectrophotometric study	3 absorption peaks	3 absorption peaks	3 absorption peaks	3 absorption peaks
F	HPTLC Fingerprinting after derivatization	2spots	2 spots	2 spots	2 spots

Table 6. Quality Evaluation of Commercial Drug Samples of *Foeniculum vulgare* Mill.

Sl. No.	Quality Specifications	Standard Limits	Samples drawn from the market of		
			Delhi	Haridwar	Ghaziabad
A.	Pharmacognostical Characteristics (Identification)				
	• Organoleptic	Descriptive	Conform	Conform	Conform
	• Micro-morphological	Descriptive	Conform	Conform	Conform
B.	Histo-chemical Tests	Descriptive	Conform	Conform	Conform
C.	Major organic groups of chemical compounds (Phyto-constituents)				
	Alkaloid	+	+	+	+
	Anthraquinone	+	+	+	+
	Coumarin	+	+	+	+
	Flavonoid	+	+	+	+
	Glycoside	+	+	+	+
	Protein	+	+	+	+
	Resin	+	+	+	+
	Saponin	+	+	+	+
	Steroid	+	+	+	+
	Tannin	+	+	+	+
D.	Physico-Chemical constants				
	Foreign Matter, %, w/w	2.0	1.7	2.1	1.5
	Moisture content, % w/w, Not more than	11.0	9.2	8.6	10.3
	pH	7.2	7.0	7.1	7.1
	Total Ash, % w/w , Not more than	12.5	10.7	11.1	9.0
	Acid insoluble ash, % w/w, Not more than	15.5	12.2	10.7	6.4
	Alcohol soluble extractive % w/w, Not less than	3.0	3.6	3.2	3.9
	Water soluble extractive % w/w, Not less than	00.5	00.6	0.8	1.1
	Essential Oil , % v/w, Not less than	1.0	0.7	0.6	0.9
E	UV-Spectrophotometric study	4 absorption peaks	4 absorption peaks	4 absorption peaks	4 absorption peaks
F	HPTLC Fingerprinting after derivatization	4 spots	4 spots	4 spots	4 spots

Table 7. Quality Evaluation of Commercial Drug Samples of *Piper longum* L.

Sl. No.	Quality Specifications	Standard Limits	Samples drawn from the market of		
			Delhi	Haridwar	Ghaziabad
A.	Pharmacognostical Characteristics (Identification)				
	• Organoleptic	Descriptive	Conform	Conform	Conform
	• Micro-morphological	Descriptive	Conform	Conform	Conform
B.	Histo-chemical Tests	Descriptive	Conform	Conform	Conform
C.	Major organic groups of chemical compounds (Phyto-constituents)				
	Alkaloid	+	+	+	+
	Anthraquinone	–	–	–	–
	Coumarin	+	+	+	+
	Flavonoid	–	–	–	–
	Glycoside	–	–	–	–
	Protein	+	+	+	+
	Resin	+	+	+	+
	Saponin	–	–	–	–
	Steroid	–	–	–	–
	Tannin	+	+	+	+
D.	Physico-Chemical constants				
	Foreign Matter, %, w/w	2.0	0.5	0.7	0.6
	Moisture content, % w/w, Not more than	11.0	12.2	9.7	7.2
	pH	6.9	7.0	7.1	7.0
	Total Ash, % w/w , Not more than	5.0	5.1	4.9	3.7
	Acid insoluble ash, % w/w, Not more than	0.50	0.46	0.51	0.48
	Alcohol soluble extractive % w/w, Not less than	10.5	12.2	10.9	11.4
	Water soluble extractive % w/w, Not less than	23.50	24.7	25.0	27.2
	Essential Oil , % v/w, Not less than	–	–	–	–
E	UV-Spectrophotometric study	3 absorption peaks	3 absorption peaks	3 absorption peaks	3 absorption peaks
F	HPTLC Fingerprinting after derivatization	6 spots	6 spots	6 spots	6 spots

Table 8. Quality Evaluation of Commercial Drug Samples of *Piper nigrum* L.

Sl. No.	Quality Specifications	Standard Limits	Samples drawn from the market of		
			Delhi	Haridwar	Ghaziabad
A.	Pharmacognostical Characteristics (Identification)				
	• Organoleptic	Descriptive	Conform	Conform	Conform
	• Micro-morphological	Descriptive	Conform	Conform	Conform
B.	Histo-chemical Tests	Descriptive	Conform	Conform	Conform
C.	Major organic groups of chemical compounds (Phyto-constituents)				
	Alkaloid	+	+	+	+
	Anthraquinone	+	+	+	+
	Coumarin	+	+	+	+
	Flavonoid	–	–	–	–
	Glycoside	–	–	–	–
	Protein	+	+	+	+
	Resin	+	+	+	+
	Saponin	–	–	–	–
	Steroid	–	–	–	–
	Tannin	+	+	+	+
D.	Physico-Chemical constants				
	Foreign Matter, %, w/w	2.0	2.3	1.7	1.8
	Moisture content, % w/w, Not more than	6.0	6.3	5.0	4.2
	pH	6.7	6.9	6.6	7.1
	Total Ash, % w/w , Not more than	5.5	3.2	4.7	4.9
	Acid insoluble ash, % w/w, Not more than	0.5	0.2	0.7	0.6
	Alcohol soluble extractive % w/w, Not less than	6.0	5.7	6.9	7.2
	Water soluble extractive % w/w, Not less than	6.0	.2	5.7	7.7
	Essential Oil , % v/w, Not less than	–	–	–	–
E	UV-Spectrophotometric study	2 absorption peaks	2 absorption peaks	2 absorption peaks	2 absorption peaks
F	HPTLC Fingerprinting after derivatization	5 spots	5 spots	5 spots	5 spots

Table 9. Quality Evaluation of Commercial Drug Samples of *Syzygium cumini* (L.) Skeels.

Sl. No.	Quality Specifications	Standard Limits	Samples drawn from the market of		
			Delhi	Haridwar	Ghaziabad
A.	Pharmacognostical Characteristics (Identification)				
	• Organoleptic	Descriptive	Conform	Conform	Conform
	• Micro-morphological	Descriptive	Conform	Conform	Conform
B.	Histo-chemical Tests	Descriptive	Conform	Conform	Conform
C.	Major organic groups of chemical compounds (Phyto-constituents)				
	Alkaloid	–	–	–	–
	Anthraquinone	+	+	+	+
	Coumarin	+	+	+	+
	Flavonoid	+	+	+	+
	Glycoside	+	+	+	+
	Protein	+	+	+	+
	Resin	+	+	+	+
	Saponin	+	+	+	+
	Steroid	–	–	–	–
	Tannin	–	–	–	–
D.	Physico-Chemical constants				
	Foreign Matter, %, w/w	2.0	0.5	1.0	0.9
	Moisture content, % w/w, Not more than	15.0	13.6	12.2	10.0
	pH	7.1	7.0	7.1	7.1
	Total Ash, % w/w , Not more than	5.0	4.8	4.6	5.2
	Acid insoluble ash, % w/w, Not more than	1.0	0.9	0.6	1.1
	Alcohol soluble extractive % w/w, Not less than	5.0	6.2	6.6	6.1
	Water soluble extractive % w/w, Not less than	12.0	13.3	14.4	15.7
	Essential Oil , % v/w, Not less than	–	–	–	–
E	UV-Spectrophotometric study	3 absorption peaks	3 absorption peaks	3 absorption peaks	3 absorption peaks
F	HPTLC Fingerprinting after derivatization	4 spots	4 spots	4 spots	4 spots

Table 10. Quality Evaluation of Commercial Drug Samples of *Terminalia chebula* Retz.

Sl. No.	Quality Specifications	Standard Limits	Samples drawn from the market of		
			Delhi	Haridwar	Ghaziabad
A.	Pharmacognostical Characteristics (Identification)				
	• Organoleptic	Descriptive	Conform	Conform	Conform
	• Micro-morphological	Descriptive	Conform	Conform	Conform
B.	Histo-chemical Tests	Descriptive	Conform	Conform	Conform
C.	Major organic groups of chemical compounds (Phyto-constituents)				
	Alkaloid	–	–	–	–
	Anthraquinone	–	–	–	–
	Coumarin	+	+	+	+
	Flavonoid	+	+	+	+
	Glycoside	+	+	+	+
	Protein	–	–	–	–
	Resin	+	+	+	+
	Saponin	–	–	–	–
	Steroid	–	–	–	–
	Tannin	+	+	+	+
D.	Physico-Chemical constants				
	Foreign Matter, %, w/w	2.0	1.1	0.9	1.3
	Moisture content, % w/w, Not more than	12.0	11.6	9.2	10.7
	pH	7.2	7.0	6.9	7.2
	Total Ash, % w/w , Not more than	5.0	4.9	4.7	5.1
	Acid insoluble ash, % w/w, Not more than	1.0	0.7	0.9	0.9
	Alcohol soluble extractive % w/w, Not less than	5.0	6.7	5.9	6.2
	Water soluble extractive % w/w, Not less than	12.0	14.0	13.2	15.0
	Essential Oil , % v/w, Not less than	–	–	–	–
E	UV-Spectrophotometric study	3 absorption peaks	3 absorption peaks	3 absorption peaks	3 absorption peaks
F	HPTLC Fingerprinting after derivatization	6 spots	6 spots	6 spots	6 spots

Table 11. Quality Evaluation of Commercial Drug Samples of Trigonella *foenum-graecum* L.

Sl. No.	Quality Specifications	Standard Limits	Samples drawn from the market of		
			Delhi	Haridwar	Ghaziabad
A.	Pharmacognostical Characteristics (Identification)				
	• Organoleptic	Descriptive	Conform	Conform	Conform
	• Micro-morphological	Descriptive	Conform	Conform	Conform
B.	Histo-chemical Tests	Descriptive	Conform	Conform	Conform
C.	Major organic groups of chemical compounds (Phyto-constituents)				
	Alkaloid	+	+	+	+
	Anthraquinone	–	–	–	–
	Coumarin	+	+	+	+
	Flavonoid	+	+	+	+
	Glycoside	+	+	+	+
	Protein	–	–	–	–
	Resin	–	–	–	–
	Saponin	+	+	+	+
	Steroid	+	+	+	+
	Tannin	+	+	+	+
D.	Physico-Chemical constants				
	Foreign Matter, %, w/w	2.0	2.7	2.2	1.7
	Moisture content, % w/w, Not more than	10.0	6.2	8.1	7.2
	pH	7.3	7.1	7.1	7.3
	Total Ash, % w/w , Not more than	6.5	5.0	6.9	6.3
	Acid insoluble ash, % w/w, Not more than	0.6	0.2	0.6	0.3
	Alcohol soluble extractive % w/w, Not less than	6.0	7.2	8.2	6.7
	Water soluble extractive % w/w, Not less than	30.0	34.3	29.7	32.0
	Essential Oil , % v/w, Not less than	–	–	–	–
E	UV-Spectrophotometric study	4 absorption peaks	4 absorption peaks	4 absorption peaks	4 absorption peaks
F	HPTLC Fingerprinting after derivatization	6 spots	6 spots	6 spots	6 spots

Table 12. Commercial Samples of Herbal Drugs and Spices not Conforming the Quality Specifications

S. No.	Quality Specifications	Commercial drug samples from Delhi (D), Haridwar (H) and Ghaziabad (G)									
		Cf	Cs	Cc	Eo	Fv	Pl	Pn	Sc	Tc	Tf
A.	Pharmacognostical Characteristics (Identification)										
	Organoleptic	-	-	-	-	-	-	-	-	-	-
	Micro-morphological	-	-	-	-	-	-	-	-	-	-
B.	Histo-chemical Tests	-	-	-	-	-	-	-	-	-	-
C.	Major organic groups of chemical compounds (Phyto-constituents)										
	Alkaloid	-	-	-	-	-	-	-	-	-	-
	Anthraquinone	-	-	-	-	-	-	-	-	-	-
	Coumarin	-	-	-	-	-	-	-	-	-	-
	Flavonoid	-	-	-	-	-	-	-	-	-	-
	Glycoside	-	-	-	-	-	-	-	-	-	-
	Protein	-	-	-	-	-	-	-	-	-	-
	Resin	-	-	-	-	-	-	-	-	-	-
	Saponin	-	-	-	-	-	-	-	-	-	-
	Steroid	-	-	-	-	-	-	-	-	-	-
	Tannin	-	-	-	-	-	-	-	-	-	-
D.	Physico-Chemical constants										
	Foreign Matter, %, w/w	-	D	D	-	H	-	D	-	-	D
	Moisture content, % w/w, Not more than	H, G	H	D	G	-	D	D	-	-	-
	pH	-	-	-	-	-	-	-	-	-	-
	Total Ash, % w/w , Not more than	-	D	D	-	-	D	-	G	G	-
	Acid insoluble ash, % w/w, Not more than	-	D, H, G	D, G	G	-	H	-	G	-	-
	Alcohol soluble extractive % w/w, Not less than	-	-	-	H	-	-	D	-	-	-
	Water soluble extractive % w/w, Not less than	D, G	D	H, G	-	-	-	H	-	-	H
	Essential Oil , % v/w, Not less than	-	D, H, G	-	-	D, H, G	-	-	-	-	-
E.	UV-Spectrophotometric study	-	-	-	-	-	-	-	-	-	-
F.	HPTLC Fingerprinting after derivatization	G	D	-	-	-	-	-	-	-	-

Abbreviations: Cf: *Capsicum frutescens* L., Cs: *Coriandrum sativum* L., Cc: *Cuminum cyminum* L., Eo: *Emblica officinalis* Gaertn., Fv: *Foeniculum vulgare* Mill., Pl: *Piper longum* L., Pn: *Piper nigrum* L., Sc: *Syzygium cumini* L. (Skeels.), Tc: *Terminalia chebula* Retz. and Tf: *Trigonella foenum-graecum* L.

Discussion and Conclusion

Pharmaco-botanical evaluation of commercial samples of herbal drugs with comparison to genuine and authenticated crude drug samples reveal the extent of authenticity and quality of commercial samples. Each drug is discussed in the table 12. All the commercial samples do not conform the requirement of physico-chemical constants. Physico-chemical constants (foreign matter, moisture content, pH, total Ash, acid insoluble ash, alcohol soluble, water soluble, and essential oil) reveal the status of samples in respect of purity (physical contamination) and strength (extractive values, indicating the availability of phyto-constituents in a drug).

The present study reveals that commercial samples are always subject to quality control for their authenticity to ensure identity, purity and strength as per pharmacopoeial and other quality standards before their use to formulate the medicine. This quality evaluation practice may also ensure the safety and efficacy of medicine up to larger extent. Although all the herbal drugs are common in use but the analytical values in respect of quality parameters varies. The cause of non-conformance to identity is not to use genuine and prescribed plant species whereas difference in physico-chemical and phyto-chemical parameters leads to conclusion poor harvesting and storage practices adopted in commercial stock of drugs by collectors and traders. The code of 'Good Collection and Storage Practices' must be followed to ensure the availability of quality drug material in commerce.

References

Anonymous, 1979. The United States Pharmacopoeia, 20th rev. U.S. Pharmacopoeial Convention Inc., Rockville, U.S.A.

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

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

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

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

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

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

Padamkumar, Nitin Rai, Rejeev Kr. Sharma and M. M. Joshi, 2012. Pharmaco-botanical studies quality assessment of commercial samples of some herbal drugs of root and rhizome origin. *Hippocratic J Unani Medicine* (in press).

Rai, Nitin, 2012. Quality Control Studies on Certain Powdered Herbal Drugs of Fruit and Stem, Origin. (unpublished work).

Rai, Nitin, Rajeev Kr. Sharma, Sunil Dutt and V. K. Singh, 2011. Market survey of commercially exploited Unani herbal drugs: availability, resources and quality assurance. *Hippocratic J Unani Medicine*, 6(4): 97-123.

Sharma, Rajeev Kr., 1987. Pharmacognostic studies leading to standardization for identification and authentication of some commercially exploited roots and rhizomes employed as drug in Ayurveda. D. Phil Thesis. Garhwal University, Srinagar-Garhwal.

Standardization of a Unani Poly- Herbal Formulation 'Habb-e-Irq-un-Nisa'

[1]Sonali Sajwan, [1]Kunal Sajwan, [2]R. K. Negi, [1]Mustehasan, [2]Rajneesh Kumar, [3]Nitin Rai, and [2]Rajeev Kr. Sharma

1. Drug Standardization Research Institute (Unani), CCRUM, PLIM Building, Kamla Nehru Nagar, Ghaziabad, U.P., India, 201002

2. Pharmacopoeial Laboratory for Indian Medicine, Kamla Nehru Nagar, Ghaziabad, U. P.

3. Dept. of Botany, M.M.H. College, Ghaziabad, U.P.

Introduction

Hubb (pills) are small round and uniformly shaped medicinal preparations in Unani system of medicine. Habb-e-Irq-un-Nisa is a poly-herbal Unani formulation listed under the category of Habb in National formulary of unani medicine, Part- III (Anonymous, 2001). The ingredients prescribed for this formulation are: Sibr (*Aloe barbadensis* Linn.), Post-e-Halela Zard (*Terminalia chebula* Retz*)*, Suranjan Shreen (*Colchicum autmnale S*tev*)*. The formulation has many therapeutic actions in Unani System of Medicine such as Irq-un-Nisa (Sciatica), Niqras (Gout), Waj-ul- Mafasil (Asthralgia). Previous standardization work on various Habb preparations was carried out on Habb- e- Shifa (Rashid *et al*., 2007), Habb- e- Narmushk (Negi *et al*., 2010), pharmacopoeial monographs on Habb- e- Aftimoon, Habb- e- Anjeer, Habb- e- Ashkhaar, Habb- e- Baogola, Habb- e- Beesh were published by (Anonymous, 2009; 2010).

Material and Methods

Ingredients of the formulation were collected from the market of Delhi and identified with the help of pharmacopoeial standards (Anonymous, 2007) and finally compared with reference standard samples kept in Pharmacopoeial Laboratory of Indian system of medicine. The compound formulation was prepared in the laboratory following standard operating procedure prescribed in the formulary (Anonymous, 2001).

Formulation/Composition: Habb-e-Irq-un-Nisa has following ingredients in the composition (Anonymous, 2001).

Table 1: Composition of Formulation Habb-e-Irq-un-Nisa

S. No.	Unani Name	Botanical Name	Part used	Quantity
1.	Sibr	Aloe baradensis Linn.	Leaf extract	35 g
2.	Post-e-Halela Zard	Terminalia chebula Retz.	Pericarp	35 g
3.	Suranjan Shreen	Colchicum autmnale stev	Corm	35 g

Method of Preparation: The formulation was prepared as per methodology given in official formulary (Anonymous, 2006).

Powder microscopy, physico- chemical and chromatographic studies of the ingredients and formulation were carried out according to the standard methods given in Anonymous (2007).

Observations

A. Pharmacognostical Studies

a. Ingredients

(i) Suranjan Shirin (*Colchicum autmnale* Stev) Part used- Corm

Macroscopy: Form-conical rounded on one side flattened on the other with a groove in the middle running throughout the length of corm; colour –yellowish white; Surface- Smooth; fracture- short, odourless and bitter taste (Fig. 1B).

Powder Microscopy: Starch grains simple and compound type, compound grains-usually have three rarely have four components, which were separated are curved on one side and angular on the others. They have a conspicuous stellate hilum, the simple grains are rounded; fragments of epidermis with thin, reddish brown walls; tracheae few with spiral or scleriform markings.

(ii) Sibr (*Aloe barbadensis* Linn): Part used- Leaf extract.

Macroscopy: Irregular masses, black brown colour surface dull, opaque, fracture irregular, characteristic odour, taste bitter and unpleasant (Fig- 1A).

Powder Microscopy: (Mounted in lactophenol) Powder coarse, dark brown with characteristic odour and bitter taste. It shows transparent shinning irregular crystalline bodies.

(iii) Post- e- Halela (*Terminalia chebula* Retz)**:** Part used- Pericarp.

Macroscopy: Broken pieces of yellowish brown fruit, glabrous, wrinkled, fracture brittle with agreeable odour and astringent taste (Fig. 1C).

Powder Microscopy: Groups of sclerieds lignified, pitted; Fibers in groups, thick walled lignified; pitted trechieds; Rossette of crystals.

b. Macroscopic/Organoleptic characteristics of formulation:

Small coffee brown colour,solid round pills having sweet but slightly bitter taste with aromatic smell.

c. Microscopic examination of compound Formulation

Microscopic examination of the powdered drug shows fragments of transparent, shining, irregular crystalline bodies of (Sibr) (Fig.2A).

Powdered drug shows starch grains which are simple, oval to round with stellate hilum of (Suranjan) (Fig. 2C).

Some elongated fibres thick walled, lignified with distinct simple pits of (Halela zard) (Fig. 2B).

B. Physico-Chemical Analysis

1. Physico- chemical analysis of compound formulation:

Table-2

Chemical Parameters	Value
Alcohol soluble matter, %, w/w	9.30
Water soluble matter, %, w/w	30.20
pH value, 1% solution	4.99
pH value, 10% solution	4.67
Loss on drying, %, w/w	8.56

C. Thin Layer Chromatography

Five g powdered drug was extracted in 60 ml of absolute alcohol under reflux on water bath for 10 min. Filtered and concentrated the filtrate up to 4 ml. The extract obtained was applied on a pre-coated silica gel plate and developed in Ethyl acetate: Methanol: Water (100: 13.5: 10) system in developing chamber. The plate was dried and sprayed with Anisaldehyde- Sulphuric acid reagent and again the plate was dried and kept in an oven for heating at 105^0 c for 10 minutes, Fig-3R_f values of the observed spots are tabulated in:

Table 3: TLC Data on ingredients and formulation

Ingredients / Formulation	Rf VALUE
Suranjan	0.13, 0.24, 0.51, 0.62
Sibr	0.15, 0.43, 0.51, 0.72
Post-e-Halela	0.10, 0.39, 0.64, 0.72
Habe-e-Irqunisha	0.13, 0.37, 0.51, 0.64, 0.72

Conclusion

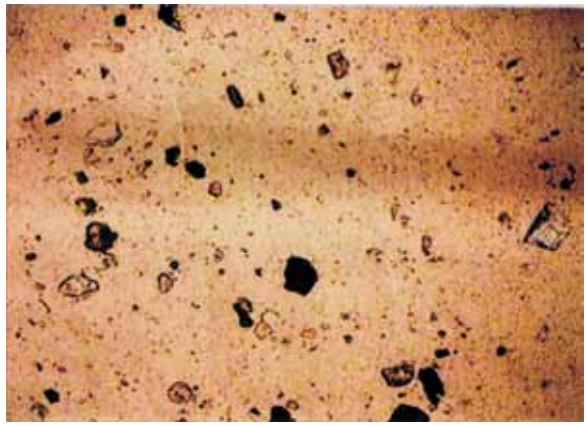
Authentification of ingredients by Macroscopy, Microscopy (Fig. 1, 2), along with physico- chemical parameter (Table 2) followed by HPTLC Profile (Fig-3, Table No. 3) demonstrates the genuineness and purity of Hab- e- Irqunisha, that may helping ensuring the quality of other indigenous medicine as well.

A. Sibr (Aloe barbadensis)

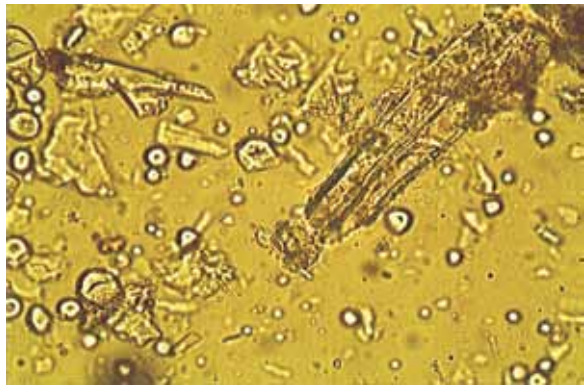
B. Suranjan (Colchicum luteum)

C. Post-e-Halela zard (Terminalia chebula)

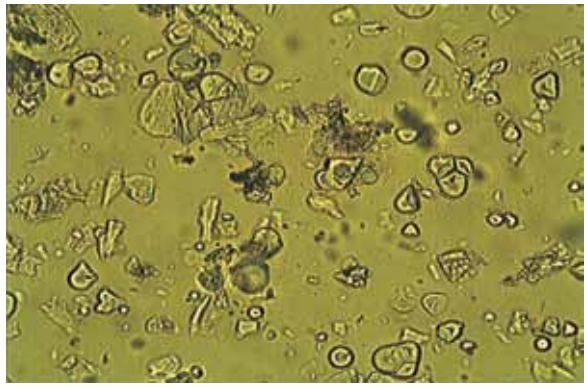
Fig.1: Ingredients of Habb-e-Irqunisha



A. Habb Irquinisha shows Crystals of Sibr x40

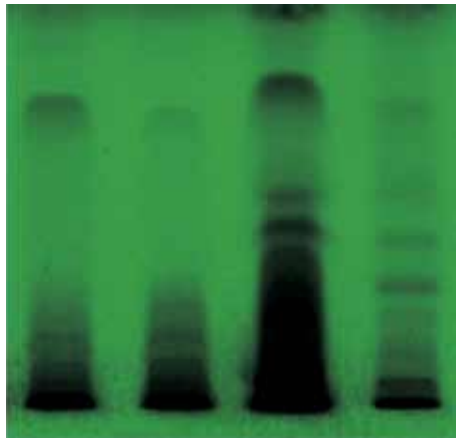


B. Habb Irquinisha shows Fibers of Halela Zard x40



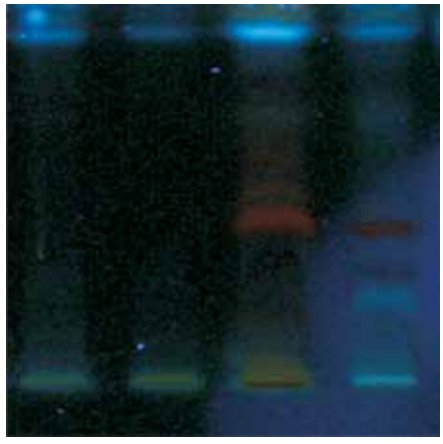
C. Habb Irquinisha shows starch grains of Suranjanx40

Fig.2 Microscopic Examination of Habb-e-Irqunisha



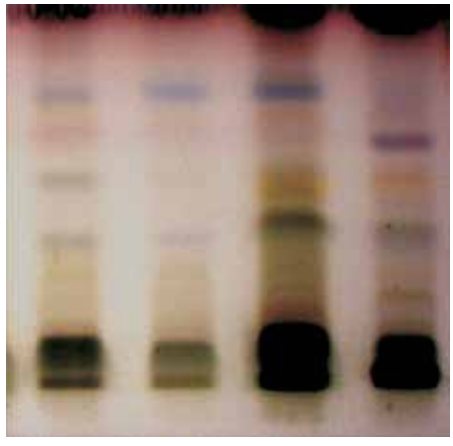
1 2 3 4

A. U. V. 254 n.m.



1 2 3 4

B. U.V. 366 n.m.



1 2 3 4

C. After derivatization

1-Habb-e-Irqunisha, 2-Halela Siyah, 3-Sibr, 4-Suranjan Shirin
Solvent System: Ethyl acetate: Methanol: Water (100:13.5:10)
Spray reagent: Anisaldehye- sulphuric acid.

Fig-3: HPTLC Profile of Habb-e-Irqunisha

Acknowledgement

The authors are highly thankful to Prof. Syed Shakir Jamil, Director-General CCRUM, New Delhi for providing necessary research facilities and Dr. G. P. Garg, Hony. Project Director, D.S.R.I. (Unani), CCRUM, Ghaziabad for continuous encouragement.

References

Anonymous, 2001. The National Formulary of Unani Medicine, *Part-III,* Ministry of Health and family Welfare, Govt. of India, New Delhi, pp. 17,149

Anonymous, 2007. Unani Pharmacopoeia of India, Part-1, Vol-1, Ministry of Health and family Welfare, Govt of India, New Delhi, pp. 102-138

Anonymous, 2009. Unani Pharmacopoeia of India, Part-2, Vol-1, Ministry of Health and family Welfare, Govt of India, New Delhi, pp. 26, 29, 32.

Anonymous, 2010. Unani Pharmacopoeia of India, Part-2, Vol-2, Ministry of Health and family Welfare, Govt of India, New Delhi, pp. 23, 34.

Kirtikar, K.R. and Basu, B. D., 1998. Indian Medicinal Plants, Vol.- IV, Mahendra Pal Singh book Depot, Dehradun, pp. 2504, 2524.

Negi, K., and Khan, M. S. Y. 2010. Ingredient Identification in Habb-e-Narmushk – Quality Control Strategies. *Hippocratic Journal of Unani Medicine* **5** (1): 61-68.

Rashid, H., Zuberi, M., Afzal, T., Iqbal, A., Qasmi, M. A., and Arfin, S., 2007. Physicochemical Standarization and Phytochemical Evaluation of a Unani drug Habb-e-Shifa. *Unimed Kulliyat* **3** (1): 18- 21.

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 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.