3.1.2.3 CLINICAL RESEARCH PROGRAMME

Preclinical Studies

Preclinical safety and pharmacological studies on 13 classical Unani drugs including modified form of one drug were undertaken at the Council’s pharmacological units. During the reporting period, the following studies were undertaken:

Safety evaluation of Khamira-e-Banafsha (KB) at CRIUM, Hyderabad

Sub-chronic oral toxicity study (90-day repeated dose) of Khamira-e-Banafsha (KB) in rats was conducted at CRIUM, Hyderabad as per the OECD Test Guideline 408. Sprague Dawley rats of about 5-6 weeks were randomly divided into two groups (10 male and 10 female in each group). Group-I served as control and was orally administered with distilled water. KB was orally administered at a limit dose of 2,000 mg/kg bw/day to group-II. The animals were periodically observed for clinical sign of toxicity, mortality, morbidity, body weight changes and feed consumption. At the end of the study, haematology, clinical biochemistry, electrolytes, gross pathology, relative organ weight and histological examination were performed.

Treatment with KB showed no significant differences in clinical signs of toxicity, body weight gain, feed consumption, and haematology and biochemistry profile except few changes in total bilirubin, ALP and cholesterol level which were clinically not significant as the values were still in the normal physiological range. No changes were observed in the gross necropsy and relative organ weight of the control and KB treated rats. These observations conclude that
KB is safe up to the tested dose level. Based on the 90-day repeated dose oral toxicity study data, No Observed Adverse Effect Level (NOAEL) of KB may be considered >2000 mg/kg bw in both male and female rats.

**Safety evaluation of Sharbat-e-Deenar (SDR) at CRIUM, Hyderabad**

A 90-day repeated dose oral toxicity study of *Sharbat-e-Deenar* (SDR) was conducted at CRIUM, Hyderabad as per the OECD Test Guideline 408. Sprague Dawley rats of about 5-6 weeks were randomly divided into four groups (10 male and 10 female in each group). Group-I served as control and received distilled water orally. SDR was orally administered at three dose levels i.e., 04, 10 and 20 ml/kg bw/day for 90 days. The animals were periodically observed for clinical signs of toxicity, mortality, morbidity, body weight changes and feed consumption throughout the experiment. At the end of the study, blood samples were collected under isofluorane anaesthesia from retro-orbital plexus. Blood samples were subjected to haematology, clinical biochemistry and electrolytes analysis. All the animals were sacrificed and necropsy was performed. No mortality or morbidity was reported in any group throughout the study. No gross pathological findings were observed between the control and drug treated rats.

**Safety evaluation of Majoon-e-Najah (MN) at CRIUM, Hyderabad**

Chronic toxicity (180-day) study of *Majoon-e-Najah* (MN) was initiated at CRIUM, Hyderabad. Ninety rats of about 5-6 weeks were randomly divided into three groups (15 male and 15 female in each group). Group-I served as control and administered with aqueous suspension of 0.3% carboxymethyl cellulose orally. MN was administered orally at two dose levels viz. 1,000 mg/kg bw/day and 2,000 mg/kg bw/day. The rats were periodically observed for clinical signs of toxicity, mortality, morbidity, change in body weight and feed consumption. No mortality or morbidity was observed and the study continued at the end of the reporting period.

**Safety evaluation of Jawarish-e-Bisbasa (JBS) at CRIUM, Hyderabad**

Sub-chronic toxicity study (90-day repeated dose) of *Jawarish-e-Bisbasa* (JBS) was initiated at CRIUM, Hyderabad as per the OECD Test Guideline 408. Sixty Sprague Dawley rats of about 5-6 weeks were randomly divided into three groups (10 male and 10 female in each group). Group-I served as control and received distilled water orally as vehicle. JBS was administered orally at two dose levels i.e., 1,000 mg/kg bw/day and a limit dose of 2,000 mg/kg bw/day for 90 days. The animals were periodically observed for clinical signs of toxicity, mortality, morbidity, change in body weight and feed consumption. The study continued and no mortality or morbidity was observed during the reporting period.

**Safety evaluation of Kushta-e-Faulad at CRIUM, Hyderabad**

Sub-chronic toxicity study (90-day repeated dose) of *Kushta-e-Faulad* (KF) was conducted at CRIUM, Hyderabad as per the OECD Test Guideline 408. Eighty rats of about 5-6 weeks were randomly divided into four groups (10 male and 10 female in each group). KF was administered orally in the form of aqueous suspension in 0.3% CMC at three dose levels i.e., 06, 30 and 60 mg/kg bw/day. The animals were periodically observed for clinical sign of toxicity, mortality, morbidity, change in body weight and feed consumption. At the end, haematology, clinical chemistry, electrolytes, gross pathology, relative organ weight and histological examinations were performed.
The result showed no significant changes in body weight gain, feed consumption and clinical signs of systemic toxicity. Haematological parameters did not reveal any significant differences as compared to the control group except few changes in biochemical parameters which were clinically not significant as the values were still in the normal physiological range. Gross necropsy performed at the termination of the study revealed no alteration in the organs of any KF-treated or control groups. Relative organ weight of the control and KF treated groups were found to be comparable. The study demonstrated no toxicologically significant alteration in physiological parameters, haematology and biochemical profile, hence KF may be considered safe up to the highest tested dose level of 60 mg/kg bw in rats.

**Safety evaluation of Majoon-e-Kundur (MK) at CRIUM, Hyderabad**

Chronic toxicity study of *Majoon-e-Kundur* (MK) was carried out on Sprague Dawley rats of both sexes. Sixty rats were divided into two groups (15 per sex per group). MK was administered at a single limit dose of 2000 mg/kg bw/day orally for 180 days. Thereafter, blood samples were collected for haematological and biochemical analysis and animals were sacrificed and organs were harvested for weight determination, and histopathological evaluation was performed. The animals in MK-treated group did not reveal any abnormal behaviour or clinical signs indicative of systemic toxicity. There was no toxicologically significant alteration in body weight, feed intake, haematological and biochemical parameters, and relative organ weights of the control and MK-treated rats of either sex. There was no toxicologically significant observation with respect to clinical signs of toxicity, haematology, clinical bio-chemistry, organ weight and gross necropsy findings in the MK-treated and control rats. No Observed Adverse Effect Level (NOAEL) of MK may be considered >2000 mg/kg bw in Sprague Dawley rats.

**Safety evaluation of Jawarish-e-Shahi (JS) at CRIUM, Hyderabad**

Chronic oral toxicity of *Jawarish-e-Shahi* (JS) was conducted at CRIUM, Hyderabad. Sixty Sprague Dawley rats were divided into two groups (15 rats of either sex in each group). JS was administered at a limit dose of 2000 mg/kg bw/day orally for 180 days. Thereafter, blood samples were collected for haematological and biochemical analysis; animals were sacrificed and organs were harvested for weight determination and histopathological evaluation was performed. The animals in the JS-treated group did not show any abnormal behaviour or clinical sign indicative of systemic toxicity. There was no toxicologically significant alteration in haematological and biochemical parameters and relative organ weights of control and JS treated rats of either sex. There was no toxicologically significant observation with respect to clinical signs of toxicity, haematology, clinical chemistry, organ weight and gross necropsy findings in the JS treated rats and control animals. No Observed Adverse Effect Level (NOAEL) of JS may be considered >2000 mg/kg bw in Sprague Dawley rats.

**Safety evaluation of Itrifal Ustukhuddus and its modified sugar-free tablet version at CRIUM, Hyderabad**

Sub-chronic oral toxicity (90-day) study was carried out at CRIUM, Hyderabad to understand the comparative toxicity profile of *Itrifal Ustukhuddus* (IU) and its modified sugar-free tablet version (SFIU). The study was carried out on Sprague Dawley rats of both sexes. The animals were divided into six groups (n=10 per sex per group). Classical formulation of IU was
administered at the doses of 1028 and 2000 mg/kg bw/day orally and SFIU was administered at the doses of 357(X), 1070 (3X) and 1783 (5X) mg/kg bw/day orally respectively. After the completion of the treatment, the animals were subjected to rotarod test. Blood samples were collected for haematological and biochemical analysis, animals were sacrificed, subjected to gross necropsy, organ weight was recorded and organs were harvested for histopathological evaluation.

The animals in groups treated with IU and SFIU did not show any abnormal behaviour or clinical sign indicative of systemic toxicity. No toxicologically significant alteration was observed in haematological and biochemical parameters and relative organ weights of the control and IU or SFIU treated rats of either sex. No changes in neuromuscular coordination were observed in rotarod test. Further, no adverse finding was observed in gross necropsy and histopathology. Both SFIU and IU were found to be safe in Sprague Dawley rats and No Observed Adverse Effect Level (NOAEL) of SFIU and IU in Sprague Dawley rats may be considered >1783 mg/kg bw and >2000 mg/kg bw respectively.

Safety evaluation of Habb-e-Kabid Naushadri at RRIUM, Aligarh

Sub-chronic oral toxicity of aqueous suspension of Habb-e-Kabid Naushadri was conducted at RRIUM Aligarh. Albino rats of either sex weighing 100-150 gm were randomly divided into four groups of 10 animals (5 male and 5 female) in each. Group-I served as control which received distilled water orally for 90 days, while group-II, group-III and group-IV animals orally received aqueous suspension of Habb-e-Kabid Naushadri at the doses of 103mg/kg bw, 514mg/kg bw and 1027mg/kg bw per day respectively. The animals were observed for general behaviour changes in skin and fur, mucous membrane, tremors, convulsion, salivation, etc. On the 91st day, blood of all the four groups of animals was collected and analyzed for haematological and biochemical parameters. No statistically significant changes were observed in haematological and biochemical parameters. No change was observed in gross behaviour and no mortality reported. Hence, these results suggest that the drug is safe for oral administration at the dose level, of 103mg/kg, 514mg/kg and 1027mg/kg bw.

Safety evaluation of Habb-e-Hindi Zeeqi at RRIUM, Aligarh

Sub-chronic oral toxicity of aqueous suspension of Habb-e-Hindi Zeeqi was conducted at RRIUM, Aligarh. Albino rats of both sexes weighing 100-150g were devided into four groups of 10 animals (5 male and 5 female) each. Group-I served as control which received distilled water orally for 90 days, while group-II, group-III and group-IV animals received aqueous suspension of Habb-e-Hindi Zeeqi in the doses of 26mg/kg bw, 128mg/kg bw and 257mg/kg bw per day respectively. The animals were observed for general behaviour changes in skin and fur, mucous membrane, tremors, convulsion, salivation, etc. On the 91st day, blood of all of the three groups of animals was collected and analyzed for haematological and biochemical parameters. No statistically significant changes were observed in haematological and biochemical parameters. No change was observed in gross behaviour and no mortality reported. There were no changes in organ weight in both male and female rats as compared to the control group. Hence, these results suggest that the drug is safe for oral administration at the dose levels of 26 mg/kg, 128 mg/kg and 257mg/kg bw.
Safety evaluation of Habb-e-Tinkar at RRIUM, Srinagar

Sub-acute oral toxicity (28-day repeated dose) study of Habb-e-Tinkar was conducted at the dose level of 1000 mg/kg bw in both male and female Wistar rats. The animals were randomly divided into four groups. Group-I and group-II being the male and female controls were orally given distilled water (vehicle) for 28 days. Group-III and group-IV being the drug treated male and female rats were orally administered Habb-e-Tinkar at the dose of 1000 mg/kg bw per day.

The cage side observation of rats was carried out for any behavioural and neurological changes for next 24 hours after the administration of the drug. The physiological parameters such as body weight change, water consumption and feed consumption were recorded on weekly basis. The rats were sacrificed after 28 days of daily oral drug administration.

Blood was collected from dorsal vena cava after opening the abdomen for haematological and biochemical analysis. The rats were dissected, organs were collected and observed for any macroscopic as well as morphological changes and the individual organ weight was also recorded.

There were no significant changes in body weight, feed and water consumption, gross behavior and their haematological and biochemical parameters as compared with the respective male and female control groups. The result of the study shows that the drug is safe for oral administration at the tested dose level.

Safety evaluation of Habb-e-Suranjan at RRIUM, Srinagar

Sub-chronic oral toxicity (90–day repeated dose) study of Habb-e-Suranjan was conducted at the dose level of 2440mg /kg bw in both male and female Wistar rats. The animals were randomly divided into four groups. Group-I and group-II being the male and female controls were orally given distilled water (vehicle) for 90 days. Group-III and group-IV being the drug treated male and female rats were orally administered Habb-e-Suranjan at the dose of 2440mg /kg bw per day.

The rats were observed carefully for any behavioural and neurological changes for next 24 hours after the administration of the drug and twice daily thereafter till the completion of the experiment. The physiological parameters such as body weight change, water consumption and feed consumption were recorded on weekly basis. On the 91st day after overnight fasting, blood was collected from dorsal vena cava after opening the abdomen for haematological and biochemical parameters. The rats were dissected, organs were collected and observed for any macroscopic and morphological changes, individual organ weight was recorded, and tissue was collected for histopathological examination.

There were no significant changes in body weight, feed and water consumption, gross behavior and their haematological and biochemical parameters as compared with the respective male and female control groups. The result of the study shows that the drug Habb-e-Suranjan is safe for oral administration at the tested dose level.
Effect of co-administration of Unani pharmacopoeial formulations (UPF) Qurs Tabasheer Sartani (QTS) and Arq Hara Bhara (AHB) with anti tuberculosis (CAT-I) drugs in adult Wistar Albino rats at RRIUM, Srinagar

The anti tubercular therapy (ATT) study was conducted to determine the hepatoprotective effect of two Unani pharmacopoeial formulations – Qurs Tabasheer Sartani and Arq Hara Bhara against the known anti tubercular therapy (ATT) in Albino Wistar rats. The study was conducted for 14 days, 60 days and 180 days respectively. In each study, the rats were randomly divided into four groups (sex ratio 50%). Group-I served as the control received RO water only while Group-II received only UPF. Group-III received only CAT-I and group-IV received CAT-I and UPF in combination. The body weight of rats was recorded after every two days and the feed and water consumption was recorded alternately throughout the study. The calculation for dosage of drugs was carried out as per the newly recorded body weight. The data pertaining to body weight, feed consumption, water consumption and oral dosing of all the groups were recorded on Data Recording Sheets (DRS’s).

Tissues of 60 and 180 days ATT study were fixed in 10% formalin followed by tissue processing which was carried out on automatic tissue processor. Tissue blocks were prepared and labelled. Finally, all the tissue blocks as well as fixed wet tissues were sent to RRIUM, Chennai on their request.

Clinical Studies

The Clinical Research Programme of the Council deals with the methods of diagnosis and treatment of diseases and aims at critical appraisal of the theory of pathogenesis, symptomatology, clinical methods of diagnosis, principles and methods of treatment, and the drug and diet therapies peculiar to Unani Medicine. Under this programme, clinical studies on different diseases were undertaken with a view to develop safe and effective Unani treatments. Besides, clinical validation of safety and efficacy of Unani pharmacopoeial formulations was conducted. Clinical validation of Unani pharmacopoeial fast-acting drugs was also undertaken in different diseases.

This programme continued at the following centres:

- Central Research Institute of Unani Medicine (CRIUM), Hyderabad
- Central Research Institute of Unani Medicine (CRIUM), Lucknow
- Regional Research Institute of Unani Medicine (RRIUM), Chennai
- Regional Research Institute of Unani Medicine (RRIUM), Bhadrak
- Regional Research Institute of Unani Medicine (RRIUM), Patna
- Regional Research Institute of Unani Medicine (RRIUM), Aligarh
- Regional Research Institute of Unani Medicine (RRIUM), Mumbai
- Regional Research Institute of Unani Medicine (RRIUM), Srinagar
- Regional Research Institute of Unani Medicine (RRIUM), Kolkata
### CENTRE-WISE ALLOCATION OF DISEASES FOR CLINICAL STUDIES ON SAFETY AND EFFICACY OF UNANI DRUGS

<table>
<thead>
<tr>
<th>Centre</th>
<th>Diseases</th>
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</thead>
<tbody>
<tr>
<td>Central Research Institute of Unani Medicine (CRIUM), Hyderabad</td>
<td>Barați (Vitiligo), Dhayâbêöûs Sukkarê Qism-i Thäñi (Diabetes Mellitus Type-II), Ōaghô al-Dam Qawé Lâzîmê (Essential Hypertension), Nazla Mûzmin (Chronic Rhinosinusitis), Kathra Shaïûm al-Dam (Hyperlipidaemia), Dâ’ al-Ñadaf (Psoriasis), Nisyân (Annesia), Ôu’f al-Dimâgh (Cerebrasthenia), Ùâñä al-Kulya (Nephrolithiasis), Khafaqân (Palpitation), Taiâujur al-Mañûfîl (Osteoarthritis), Kathra al-Ôamth (Heavy Menstrual Bleeding), Ôêq al-Nafas (Bronchial Asthma), Litha Dûmiya (Bleeding Gums)</td>
</tr>
<tr>
<td>Central Research Institute of Unani Medicine (CRIUM), Lucknow</td>
<td>Dhayâbêöûs Sukkarê Qism-i Thäñi (Diabetes Mellitus Type-II), Siman Mûfriö (Obesity), Barați (Vitiligo), Sîî’ al-Qinya (Anaemia), Dêđân al-Am ‘ã’ (Helminthiasis), Sîî’ al-Haôm (Dyspepsia), Sayalân al-Raûûm (Leucorrhoea), Niqris (Gout), Nisyân (Amnesia), Khafaqân (Palpitation), Nazla Mûzmin (Chronic Rhinosinusitis), Ôêq al-Nafas (Bronchial Asthma), Sur’a al-Inzäl (Premature Ejaculation), Nazla (Common Cold), Ôu’f al-Dimâgh (Cerebrasthenia)</td>
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<td>Regional Research Institute of Unani Medicine (RRIUM), Chennai</td>
<td>Nazla (Common Cold), Ňudâ’ (Headache), Dhayâbêöûs Sukkarê Qism-i Thäñi (Diabetes Mellitus Type-II), Qulâ’ (Stomatitis), Waja’ al-Asnûn (Toothache), Niqris (Gout), Ùâñä al-Kulya (Nephrolithiasis), Sharâ Mûzmin (Chronic Urticaria), Kalaf (Melasma), Waram al-Ûalaq (Pharyngitis), Bawäsér ‘Amiya (Non Bleeding Piles), Khushûna al-Ûalaq (Sore Throat), Ôu’f al-Ishtihâ’ (Anorexia)</td>
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<tr>
<td>Centre</td>
<td>Diseases</td>
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<td>Regional Research Institute of Unani Medicine (RRIUM), Bhadrap</td>
<td>Dā’ al-Fél (Lymphatic Filariasis), Jarab (Scabies), Buthūr al-Jīlī (Macules / Pustules), Waja’ al-Asnān (Toothache), Únānā al-Kūlā (Nephrolithiasis), Sharā Muzmin (Chronic Urticaria), Waram al-Ūlaq (Pharyngitis), Bawāsér Dāmīya (Bleeding Piles), Öu’f al-Ishtihā’ (Anorexia), Dēdān al-Am‘ā’ (Intestinal Worms), Qulā’ (Stomatitis), Khushūnā al-Ūlaq (Sore Throat), Zāu’r (Dysentery), Waja’ al-Mafānīl (Rheumatoid Arthritis)</td>
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<tr>
<td>Regional Research Institute of Unani Medicine (RRIUM), Patna</td>
<td>Dā’ al-Fél (Lymphatic Filariasis), Waja’ al-Mafānīl (Rheumatoid Arthritis), Sayalān al-Rā‘īm (Leucorrhoea), Qulā’ (Stomatitis) Waja’ al-Asnān (Toothache), Waram al-Ūlaq (Pharyngitis), Sharā Muzmin (Chronic Urticaria), Jarab (Scabies), Öu’f al-Ishtihā’ (Anorexia), Nazla (Common Cold), Khafaqān (Palpitation), Óeq al-Nafās (Bronchial Asthma), Sū’ al-Qinya (Anemia)</td>
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<td>Regional Research Institute of Unani Medicine (RRIUM), Aligarh</td>
<td>Barān (Vitiligo), Dhayābēous Sukkaré Qism-i Thānī (Diabetes Mellitus Type-II), Óagāhō al-Dam Qawē Lāzimé (Essential Hypertension), Sayalān al-Rā‘īm (Leucorrhoea), Öu’f al-Ishtihā’ (Anorexia), Khafaqān (Palpitation), Sū’ al-Qinya (Anaemia), Niqris (Gout), Waja’ al-Mafānīl (Rheumatoid Arthritis), Nazla Muzmin (Chronic Rhinosinusitis), Siman Mufriō (Obesity), Litha Dāmīya (Bleeding Gums), Kathra al-Ōamth (Heavy Menstrual Bleeding), Sū’al YĀbis (Dry Cough), Sahar (Insomnia), Niqris (Gout)</td>
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<td>Regional Research Institute of Unani Medicine (RRIUM), Mumbai</td>
<td>Óagāhō al-Dam Qawē Lāzimé (Essential Hypertension), Waja’ al-Mafānīl (Rheumatoid Arthritis), Öu’f al-Dimāgh (Cerebrasthenia), Qulā’ (Stomatitis), Waja’ al-Asnān (Toothache), Sū’al Yābis (Dry Cough), Waram al-Ūlaq (Pharyngitis), Sharā Muzmin (Chronic Urticaria), Bawāsér ‘Amīya (Non-Bleeding Piles), Siman Mufriō (Obesity), Kathra al-Ōamth (Heavy Menstrual Bleeding), Öu’f al-Ishtihā’ (Anorexia)</td>
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<tr>
<td>Regional Research Institute of Unani Medicine (RRIUM), Srinagar</td>
<td>Barān (Vitiligo), Óagāhō al-Dam Qawē Lāzimé (Essential Hypertension), Únānā al-Kūlā (Nephrolithiasis), Sū’al Yābis (Dry Cough), Jarab (Scabies), Kathra al-Ōamth (Heavy Menstrual Bleeding), Nazla Muzmin (Chronic Rhinosinusitis), Khafaqān (Palpitation), Waja’ al-Mafānīl (Rheumatoid Arthritis), Óeq al-Nafās (Bronchial Asthma), Öu’f al-Ishtihā’ (Anorexia)</td>
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<td>Centre</td>
<td>Diseases</td>
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<td>Regional Research Institute of Unani Medicine (RRIUM), Kolkata</td>
<td>Bawāsēr Dāmiya (Bleeding Piles), Dēdān al-Amʿā (Helminthiasis), Nazla Muzmin (Chronic Rhinosinusitis), Suʿāl Yābis (Dry Cough), Khushūna al-Ūalaq (Sore Throat)</td>
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<td>Regional Research Institute of Unani Medicine (RRIUM), New Delhi</td>
<td>Baraṅ (Vitiligo), Dhayābēōus Sukkaré Qism-i Thāni (Diabetes Mellitus Type-II), Īqghō al-Dam Qawē Lāzimē (Essential Hypertension), Zaʿūr (Dysentery), Suʿāl Yābis (Dry Cough), Sūʿ al-Qinya (Anaemia), Īaŋā al-Kulya (Nephrolithiasis), Sayalān al-Rauʿūm (Leucorrhoea), Khafaqān (Palpitation), Ūf al-Islāhā (Anorexia), Nazla Muzmin (Chronic Rhinosinusitis), Wajaʿ al-Mafānīl (Rheumatoid Arthritis)</td>
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<td>Regional Research Centre (RRC), Allahabad</td>
<td>Dhayābēōus Sukkaré Qism-i Thāni (Diabetes Mellitus Type-II), Īaŋā al-Kulya (Nephrolithiasis), Khafaqān (Palpitation), Ishāl (Diarrhoea), Ūf al-Nafas (Bronchial Asthma), Jarāb (Scabies), Bawāsēr ‘Amiya (Non-Bleeding Piles), Zaʿūr (Dysentery), Suʿāl (Cough)</td>
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<td>Clinical Research Unit (CRU), Bengaluru</td>
<td>Dāʿ al-Ńadaf (Psoriasis), Dhayābēōus Sukkaré Qism-i Thāni (Diabetes Mellitus Type-II), Sūʿ al-Qinya (Anaemia), Ūf al-Islāhā (Anorexia), Waram al-Kabid (Hepatitis), Wajaʿ al-Mafānīl (Rheumatoid Arthritis)</td>
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<td>Clinical Research Unit (CRU), Meerut</td>
<td>Ūf al-Islāhā (Anorexia), Suʿāl Yābis (Dry Cough), Sūʿ al-Haʿōm (Dyspepsia), Zaʿūr (Dysentery), Ūf al-Nafas (Bronchial Asthma), Nazla Muzmin (Chronic Rhinosinusitis), Surʿa al-Inzāl (Premature Ejaculation) Sūʿ al-Qinya (Anaemia), Khafaqān (Palpitation), Wajaʿ al-Mafānīl (Rheumatoid Arthritis)</td>
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<td>Clinical Research Unit (CRU), Bhopal</td>
<td>Nūr Fārṣé (Eczema), Dāʿ al-Ńadaf (Psoriasis), Īaŋā al-Kulya (Nephrolithiasis), Sahar (Insomnia), Suʿāl Yābis (Dry Cough), Sudāʿ (Headache), Zaʿūr (Dysentery)</td>
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<td>Clinical Research Unit (CRU), Burhanpur</td>
<td>Niqrīs (Gout), Īaŋā al-Kulya (Nephrolithiasis), Suʿāl Yābis (Dry Cough), Waram al-Kabid (Hepatitis), Buthūr al-Jild (Macules/ Pustules)</td>
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<td>Clinical Research Unit (CRU), Edathala</td>
<td>Sayalān al-Rauʿūm (Leucorrhoea), Sahar (Insomnia), Nazla (Common Cold)</td>
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<td>Clinical Research Unit (CRU), Kurnool</td>
<td>Ūf al-Islāhā (Anorexia), Bawāsēr (Piles), Qulāʿ (Stomatitis), Zaʿūr (Dysentery), Litha Dāmiya (Bleeding Gums), Ghathayān (Nausea), Waram al-Kabid (Hepatitis), Sharā (Urticaria)</td>
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AMRĀÒ-I JILD (SKIN DISORDERS)

BARAÑ (VITILIGO)

Clinical studies on Barañ (Vitiligo) continued at Central Research Institute of Unani Medicine (CRIUM), Hyderabad. During the reporting period, the following studies were conducted:

Evaluation of therapeutic efficacy of a combination of coded Unani drugs UNIM-001 and UNIM-003 in Barañ (Vitiligo) patients (CRIUM, Hyderabad)

Therapeutic efficacy of a combination of two coded Unani drugs, UNIM-001 and UNIM-003, was evaluated in 3,612 patients of Barañ (Vitiligo). The drug UNIM-001 was given in the dose of two tablets (500 mg each) twice daily with water one hour after meals. Besides, paste of UNIM-003 was applied locally on the affected parts early in the morning followed by sun exposure for 10-15 minutes. The paste was washed off after 30 minutes of the application. The treatment was given for three months initially, which was extended till the maximum repigmentation was achieved.

During the reporting period, 1,099 new patients were registered, whereas 2,513 continued from the previous year bringing the total patients studied to 3,612. Out of them, 441 patients completed the study. Out of total 3,612 patients, 100% repigmentation was observed in one (0.2%) patient, 71-90% in 20 (4.5%) patients, 51-70% in 38 (8.6%) patients, 41-50% in 47 (10.7%) patients, and ≤40% in 321 (72.8%) patients whereas 14 (3.2%) patients showed no response. A total of 864 patients dropped out of the study whereas 2,307 were under study. The drugs showed significant therapeutic effects in arresting the exacerbation in the existing size of the patches and appearance of new patches, besides re-pigmenting the depigmented patches to a variable degree ranging from 50 to 100% depending upon the chronicity of the disease and the part of the body affected. No drug intolerance/ adverse effects were reported.

Evaluation of therapeutic efficacy of a combination of coded Unani drugs UNIM-004 and UNIM-005 in Barañ (Vitiligo) patients (CRIUM, Hyderabad)

Therapeutic efficacy of a combination of two coded Unani drugs, UNIM-004 and UNIM-005, was evaluated in 7,808 patients of Barañ (Vitiligo). The drug UNIM-004 was given in the dose of two tablets (500 mg each) twice daily with water one hour after meals. Besides, paste of UNIM-005 was applied locally on the affected parts early in the morning followed by sun exposure for 10-15 minutes. The paste was washed off after 30 minutes of the application. The treatment was given for a period of three months initially, which was extended till the maximum repigmentation was achieved.

During the reporting period, 3,474 new patients were registered, whereas 4,334 patients continued from the previous year, bringing the total patients studied to 7,808. Out of them, 521 patients completed the study. Of them, three (0.6%) patients showed 100% repigmentation, seven (1.3%) patients showed 71-90%, 15 (2.9%) patients showed 51-70%, 21 (4.0%) patients showed 41-50% and 438 (84.1%) patients showed ≤40% repigmentation, whereas 37 (7.1%) patients showed no response. A total of 1,867 patients dropped out of the study and 5,420 patients were under study. No drug intolerance/ adverse effects were reported. However, itching and blister formation were reported in some patients with sensitive skin. This was managed by diluting the concentration of the paste and applying coconut oil on the affected parts.
Preliminary screening of combinations of coded Unani drugs UNIM-044(O) + UNIM-044(L), UNIM-045(O) + UNIM-045(L), UNIM-046(O) + UNIM-046(L) and UNIM-047(O) + UNIM-047(L) with Munòij-Mushil therapy in Barañ (Vitiligo) patients (CRIUM, Hyderabad)

Preliminary screening of coded Unani drugs UNIM-044(O)+UNIM-044(L), UNIM-045(O)+UNIM-045(L), UNIM-046(O)+UNIM-046(L) and UNIM-047(O)+UNIM-047(L) with Munòij-Mushil therapy was conducted in 47 patients of Barañ (Vitiligo). The patients were divided into four treatment groups. In each group, the patients were first subjected to Munòij-Mushil therapy followed by treatment with the oral and local drugs. In Munòij-Mushil therapy, Munòij-i Balgham was given till the Nuòj appeared in urine followed by Mushil and Tabréd drugs for six days alternately.

After the completion of Munòij-Mushil therapy, the patients of the respective groups were treated with UNIM-044(O), UNIM-045(O), UNIM-046(O), and UNIM-047(O) in the dose of two capsules (500 mg each) orally twice daily along with local application of UNIM-044(L), UNIM-045(L), UNIM-046(L) and UNIM-047(L) on the affected parts early in the morning followed by sun exposure for 10-15 minutes. The paste was washed off after 30 minutes of the application. After Munòij-Mushil therapy, the treatment was given for a period of three months initially, which was extended till the maximum repigmentation was achieved.

In group-I, eight patients continued from the previous year were studied, of which six completed the study. Of them, five (83.3%) patients showed ≤40% repigmentation whereas one (16.7%) patient showed no response. Two patients dropped out of the study. The test drugs UNIM-044(O) and UNIM-044(L) were found well-tolerated and no adverse effects were observed.

In group-II, 22 patients continued from the previous year, of which 12 completed the study. Of them, one (8.3%) patient showed 41-50% repigmentation, five (41.7%) patients showed ≤40% repigmentation, whereas six (50%) patients showed no response. Ten patients dropped out of the study. The test drugs UNIM-045(O) and UNIM-045(L) were found well-tolerated and no adverse effects were observed.

In group-III, seven patients continued from the previous year, of which five completed the study. Of them, four (80.0%) patients showed ≤40% repigmentation whereas one (20%) patient showed no response. Two patients dropped out of the study. No adverse effects were found.

In group-IV, 10 patients continued from the previous year, of which nine completed the study. Of them, five (55.6%) patients showed ≤40% repigmentation whereas four (44.4%) showed no response. One patient dropped out of the study. No adverse effects were found.

Evaluation of therapeutic efficacy of Munòij-Mushil drugs (UNIM-040 + UNIM-041 + UNIM-042) in Barañ (Vitiligo) patients (CRIUM, Hyderabad)

Therapeutic efficacy of Munòij-Mushil drugs (UNIM-040 + UNIM-041 + UNIM-042) was evaluated in the patients of Barañ (Vitiligo). The Munòij drugs were given till the appearance of Nuòj in urine followed by Mushil and Tabréd drugs for six days alternately. During the reporting period, 173 new patients were registered, whereas 28 patients continued from the previous year, bringing the total patients studied to 201. Out of them, 177 patients completed the study. In these patients, Nuòj appeared in urine in 2-3 weeks of the treatment. There was definite sign
of repigmentation either in the form of islands of pigmentation or perilesional pigmentation or both. One (0.6%) patient showed 41-50% repigmentation, the process of repigmentation started in 142 (80.2%) patients, whereas 34 (19.2%) patients showed no response. No drug intolerance / side effects were reported. After the completion of Munòj-Mushil therapy, the patients were given the oral and local drugs. Ten patients dropped out of the study whereas 14 patients were under study.

**DĀ’ AL-ÑADAF (PSORIASIS)**

Clinical study on Dā’ al-Ñadaf (Psoriasis) continued at CRIUM, Hyderabad. During the reporting period, the following study was conducted:

**Trial of coded Unani drugs UNIM-401(O) + UNIM-403(L) with and without Munòj-Mushil therapy in Dā’ al-Ñadaf (Psoriasis) patients (CRIUM, Hyderabad)**

Preliminary screening of coded Unani drugs UNIM-401(O) + UNIM-403(L) with and without Munòj-Mushil therapy was carried out in 197 patients of Dā’ al-Ñadaf (Psoriasis) in two groups. In group-I, the patients were first subjected to Munòj-Mushil therapy followed by the treatment with UNIM-401(O) + UNIM-403(L). In group-II, the patients were treated with UNIM-401(O) + UNIM-403(L) only. Munòj-i Sawedå’ was given till the Nuøj appeared in urine followed by Mushil and Tabréd drugs for six days alternately. After the completion of Munòj-Mushil therapy, UNIM-401(O) was given in the dose of two capsules (500 mg each) orally twice daily before meals along with local application of UNIM-403(L) on the affected parts for a period of three months initially, which was extended up to six months.

During the reporting period, five new patients were registered in group-I, whereas 48 continued from the previous year, bringing the total patients studied to 53. Out of them, 31 completed the study, of which 20 (64.5%) patients were relieved, nine (29.0%) partially relieved and one (3.3%) patient showed fair response, whereas one (3.2%) patient showed no response. Twenty-two patients dropped out of the study.

In group-II, 73 new patients were registered, whereas 71 continued from the previous year, bringing the total patients studied to 144. Out of them, 63 completed the study, of which 22 (34.9%) were relieved, 22 (34.9%) partially relieved, 15 (23.8%) showed fair response, whereas four (6.4%) patients showed no response. Eighty-one patients dropped out of the study.

**AMRĀÒ-I TARSÉLÉ (COMMUNICABLE DISEASES)**

Clinical study on Amrāò-i Tarsélé (communicable diseases) namely Dā’ al-Fél (Lymphatic Filariasis) continued at RRIUM, Bhadrak during the reporting period.

**DĀ’ AL-FÉL (LYMPHATIC FILARIASIS)**

Comparative clinical trial of two combinations of coded Unani drugs UNIM-268 + UNIM-270 + UNIM-271 + UNIM-272 and UNIM-269 + UNIM-270 + UNIM-271 + UNIM-272 with and without Munòj-Mushil therapy in Dā’ al-Fél (Lymphatic Filariasis) patients (RRIUM, Bhadrak)
Therapeutic efficacy of two combinations of coded Unani drugs UNIM-268 + UNIM-270 + UNIM-271 + UNIM-272 and UNIM-269 + UNIM-270 + UNIM-271 + UNIM-272 with and without Munòij-Mushil therapy was compared in 65 patients of Dä’ al-Fél (Lymphatic Filariasis) in four treatment groups.

In group-I, the patients were given UNIM-268 in the dose of two tablets (500 mg each) orally twice daily along with Naöül (irrigation) of UNIM-271 followed by local application of the paste of UNIM-270 and UNIM-272 on the affected part at bedtime for 80 days.

In group-II, the patients were first subjected to Munòij-Mushil therapy followed by the treatment with the combination of the drugs as in group-I. The Munòij drugs were given till the appearance of Nuòj in urine followed by Mushil and Tabréd drugs alternately for six days. Thereafter, the treatment was given as in group-I.

In group-III, the patients were given UNIM-269 in the dose of two tablets (500 mg each) orally twice daily along with Naöül (irrigation) of UNIM-271 followed by local application of the paste of UNIM-270 and UNIM-272 on the affected parts at bedtime. The treatment was given for a period of 80 days.

In group-IV, the patients were first subjected to Munòij-Mushil therapy followed by the treatment with the combination of the drugs as in group-III. The Munòij drugs were given till the appearance of Nuòj in urine followed by Mushil and Tabréd drugs alternately for six days. Thereafter, the treatment was given as in group-III.

In group-I, nine new patients were registered, whereas 14 continued from the previous year, bringing the total patients studied to 23. Out of them, 16 completed the study. Of them, three (18.7%) patients were cured, 11 (68.8%) relieved and two (12.5%) partially relieved. Seven patients dropped out of the study.

In group-II, eight new patients were registered, whereas two continued from the previous year, bringing the total patients studied to 10. Out of them, four completed the study. Of them, one (25.0%) patient was cured and three (75.0%) relieved. Six patients dropped out of the study.

In group-III, eight new patients were registered, whereas 14 continued from the previous year, bringing the total patients studied to 22. Out of them, seven completed the study. Of them, two (28.6%) patients were cured, four (57.1%) relieved and one (14.3%) partially relieved. Fifteen patients dropped out of the study.

In group-IV, eight new patients were registered, whereas two continued from the previous year, bringing the total patients studied to 10. Out of them, seven completed the study. Of them, two (28.7%) patients were cured, four (57.1%) relieved and one (14.2%) partially relieved. Three patients dropped out of the study.

MARAÒ-I TAJÃWéF-I ANF (DISEASE OF SINUS)

ILTIHÃB TAJÃWÉF AL-ANF (SINUSITIS)

The following clinical study on Itihâb Tajâwéf al- Anf (Sinusitis) continued at CRIUM, Hyderabad during the reporting period:
Evaluation of therapeutic efficacy of coded Unani drugs UNIM-054(O) and UNIM-055(V) with and without Munòij-Mushil therapy in Iltihâb Tajâwéf al-Anf (Sinusitis) patients (CRIUM, Hyderabad)

Therapeutic efficacy of coded Unani drugs UNIM-054(O) and UNIM-055 (V) with and without Munòij-Mushil therapy was evaluated in 49 patients of Iltihâb Tajâwéf al-Anf (Sinusitis) in two groups. In group-I, the patients were first subjected to Munòij-Mushil therapy followed by the treatment with UNIM-054(O) and UNIM-055 (V). Munòij-i Balgham was given till Nuòj appeared in urine followed by Mushil and Tabréd drugs for six days alternately. After the completion of Munòij-Mushil therapy, UNIM-054 was given in the dose of two capsules (500 mg each) orally twice daily. Steam inhalation of UNIM-055 was also given at bedtime. In group-II, the patients were given UNIM-054(O) and UNIM-055 (V) as in group-I. The treatment was given for 90 days in both groups, excluding Munòij-Mushil therapy period in group-I. The patients were also advised to follow prescribed diet schedule.

In group-I, 17 new patients were registered, whereas 16 continued from the previous year, bringing the total patients studied to 33. Out of them, 12 completed the study. Of them, six (50%) patients were cured, three (25%) relieved, one (8.3%) partially relieved, whereas two (16.7%) showed no response. Twenty-one patients dropped out of the study. No drug intolerance / side effects were reported.

In group-II, 13 new patients were registered, whereas three continued from the previous year, bringing the total to 16 patients. Out of them, nine completed the study. Of the completed cases, three (33.3%) patients were cured, one (11.2%) relieved and three (33.3%) partially relieved, whereas two (22.2%) showed no response. Seven patients dropped out of the study.

AMRÃÒ-I GHAYR TARSÉLÉ (NON-COMMUNICABLE DISEASES)

KATHRA SHAÙM AL-DAM (HYPERLIPIDAEMIA)

The following clinical study on Kathra Shaùm al-Dam (Hyperlipidaemia) continued at CRIUM, Hyderabad during the reporting period.

Preliminary study of a coded Unani drug UNIM-763 in Kathra Shaùm al-Dam (Hyperlipidaemia) patients (CRIUM, Hyderabad)

Preliminary screening of a coded Unani drug UNIM-763 was carried out in 41 patients of Kathra Shaùm al-Dam (Hyperlipidaemia). The drug UNIM-763 was given in the dose of two capsules (500 mg each) orally twice daily after meals. The treatment was given for a period of 90 days initially, which was extended up to six months. The patients were also advised to follow prescribed diet schedule.

During the reporting period, 18 new patients were registered, whereas 23 continued from the previous year bringing the total to 41 patients. Out of them, 13 completed the study. Of the completed cases, nine (69.2%) were relieved and four (30.8%) showed no response. Twenty-eight patients dropped out of the study.
Multi-centric Randomized Controlled Trials

A multi-centric, single blind, randomized, parallel group, controlled study to compare the efficacy and safety of coded Unani formulations UNIM-001+UNIM-003 with Psoralen in the treatment of Barañ (Vitiligo) (CRIUM, Hyderabad; RRIUMs, Aligarh, New Delhi and Srinagar)

A multi-centric clinical study to compare the efficacy and safety of coded Unani formulations UNIM-001 + UNIM-003 with Psoralen was carried out in the patients of Barañ (Vitiligo) at CRIUM, Hyderabad; and RRIUMs, Aligarh, New Delhi and Srinagar. The patients were divided into two groups. Group-I received UNIM-001 orally in the dose of two tablets (800 mg each) twice daily one hour after meals and UNIM-003 for local application on the affected area, whereas group-II received two tablets (10 mg each) of Psoralen orally twice daily and Psoralen in lotion form for local application on the affected area. The total treatment duration was eight months.

During the reporting period, 242 new patients were registered, whereas 194 patients continued from the previous year, bringing the total to 436 patients. Out of them, 179 patients completed the study. Out of the completed cases, 18 (10.1%) patients were relieved, 133 (74.3%) partially relieved and 28 (15.6%) showed no response. A total of 159 patients dropped out of the study whereas 98 patients were under study. The test drugs were found well-tolerated and no adverse effects were observed.

A multi-centric, single blind, randomized, parallel group study to compare the efficacy and safety of coded Unani formulation UNIM-221 with Metformin in the patients of Dhayäbéöus Sukkaré Qism-i Thäni (Diabetes Mellitus Type-II) (CRIUMs, Hyderabad and Lucknow; RRIUMs, Aligarh and New Delhi)

A multi-centric clinical study to compare the efficacy and safety of a coded Unani formulation UNIM-221 with Metformin was carried out in the patients of Dhayäbéöus Sukkaré Qism-i Thäni (Diabetes Mellitus Type-II) at CRIUMs, Hyderabad and Lucknow; and RRIUMs, Aligarh and New Delhi. The patients were divided into two groups; group-I received UNIM-221 in the dose of 10 gm twice daily half an hour before meals, while group-II received anti-diabetic drug Metformin 500 mg twice daily. The total treatment duration was 12 weeks.

During the reporting period, 222 new patients were registered, whereas 60 patients continued from the previous year, bringing the total to 282 patients. Out of them, 112 patients completed the study. Of the completed cases, 11 (9.8%) patients were relieved, 70 (62.5%) partially relieved and 31 (27.7%) showed no response. A total of 110 patients dropped out of the study and 60 patients were under study. The test drug was found well-tolerated and no adverse effects were observed.

A multi-centric, single blind, randomized, parallel group study to compare the efficacy and safety of coded Unani formulation UNIM-904 with Amlodipine in the patients with Æaghö øl-Dam Qawé Läzimé (Essential Hypertension) (CRIUM, Hyderabad; RRIUMs, Aligarh, Srinagar, Mumbai and New Delhi)
A multi-centric clinical study to compare the efficacy and safety of a coded Unani formulation UNIM-904 with Amlodipine was carried out in the patients of Óaghô al-Dam Qawé Lázimé (Essential Hypertension) at CRIUM, Hyderabad; and RRIUMs, Aligarh, Srinagar, Mumbai and New Delhi. The patients were divided into two groups; group-I received UNIM-904 (granules) in the dose of five gm twice daily half an hour before meals, while group-II received standard anti-hypertensive drug Amlodipine 5 mg once daily before breakfast. The total treatment duration was 12 weeks.

During the reporting period, 261 new patients were registered, whereas 50 continued from the previous year, bringing the total to 311 patients. Out of them, 150 patients completed the study. Of the completed cases, 46 (30.6%) patients were relieved, 94 (62.7%) partially relieved and 10 (6.7%) showed no response. A total of 112 patients dropped out of the study, whereas 49 patients were under study. The test drug was found well-tolerated and no adverse effects were observed.

A multi-centric, single blind, randomized, parallel group study to compare the efficacy and safety of coded Unani formulation UNIM-118 with Silymarin in the patients with Waram al-Kabid (Acute Hepatitis A/B/C/E & Chronic Active Hepatitis B/C) (CRIUM, Hyderabad; RRIUM, Chennai)

A multi-centric clinical study to compare the efficacy and safety of a coded Unani formulation UNIM-118 with Silymarin in the patients of Waram al-Kabid (Acute Hepatitis A/B/C/E & Chronic Active Hepatitis B/C) was carried out at CRIUM, Hyderabad and RRIUM, Chennai. The patients were divided into two groups. Group-I received UNIM-118 in the dose of two tablets (500 mg each) thrice daily after meals, while group-II received Silymarin one tablet (70 mg) thrice daily after meals. The total treatment duration was eight weeks for Acute Hepatitis A/B/C/E and 12 weeks for Chronic Active Hepatitis B and C.

During the reporting period, no new case was registered in the study. So far, four patients in the test group and three in the control group have completed the study.

Validation of Unani Pharmacopoeial Drugs

Clinical validation of a Unani pharmacopoeial formulation Qurs-e-Deedan in Dédän al-Am’â’ (Helminthiasis) (CRIUM, Lucknow; RRIUMs, Bhadrak and Kolkata)

A study on validation of a Unani pharmacopoeial formulation Qurs-e-Deedan in the patients of Dédän al-Am’â’ (Helminthiasis) was carried out at CRIUM, Lucknow; and RRIUMs, Bhadrak and Kolkata. The patients received Qurs-e-Deedan in the dose of one tablet (250 mg) orally twice daily before meals for two weeks.

During the reporting period, 33 patients were studied, of which 28 completed the study. Out of the completed cases, 16 (57.2%) patients were completely relieved, nine (32.1%) partially relieved and three (10.7%) showed no response. No patients were under study and five patients dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.
Clinical validation of a Unani pharmacopoeial formulation Jawarish Ood Shireen in Õu‘f al-Ishtihā’ (Anorexia) (RRIUM, Bhadrak; CRUs, Meerut and Kurnool)

A study on validation of a Unani pharmacopoeial formulation Jawarish Ood Shireen in the patients of Õu‘f al-Ishtihā’ (Anorexia) was carried out at RRIUM, Bhadrak; and CRUs, Meerut and Kurnool. The patients received Jawarish Ood Shireen in the dose of five gram orally twice daily before meals for two weeks.

During the reporting period, 53 patients were studied, of which 39 completed the study. Out of the completed cases, three (7.7%) patients were relieved, 34 (87.2%) partially relieved and two (5.1%) showed no response. No patients were under study and 14 patients dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

Clinical validation of a Unani pharmacopoeial formulation Sharbat-e-Ejaz in Su‘āl Yābis (Dry Cough) (RRIUMs, Mumbai, New Delhi and Srinagar; CRU, Meerut)

A study on validation of a Unani pharmacopoeial formulation Sharbat-e-Ejaz in the patients of Su‘āl Yābis (Dry Cough) was carried out at RRIUMs, Mumbai, New Delhi and Srinagar; and CRU, Meerut. The patients received Sharbat-e-Ejaz in the dose of 20 ml mixed with 40 ml of lukewarm water orally twice daily for two weeks.

During the reporting period, 74 patients were studied, of which 45 completed the study. Out of the completed cases, 29 (64.4%) patients were relieved and 16 (35.6%) partially relieved. No patients were under study and 29 patients dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

Clinical validation of Unani pharmacopoeial formulations Itrifal Shahtara and Marham Kharish Jadeed in Jarab (Scabies) (RRIUMs, Bhadrak and Srinagar; CRU, Bhopal)

A study on validation of Unani pharmacopoeial formulations Itrifal Shahtara and Marham Kharish Jadeed in the patients of Jarab (Scabies) was carried out at RRIUMs, Bhadrak and Srinagar; and CRU, Bhopal. The patients received Itrifal Shahtara in the dose of six gm orally twice daily after meals along with local application of Marham Kharish Jadeed for two weeks. The patients were advised to wash the affected area with Aab-i-Neem before applying Marham.

During the reporting period, 90 patients were studied, of which 45 completed the study. Out of the completed cases, 13 (28.9%) patients were relieved, 28 (62.2%) partially relieved and four (8.9%) showed no response. Three patients were under study and 42 dropped out of the study. The test drugs were found well-tolerated and no adverse effects were observed.

Clinical validation of Unani a pharmacopoeial formulation Majoon Chobchini in Jarab (Scabies) (RRIUMs, Bhadrak and Patna; RRC, Allahabad)

A study on validation of a Unani pharmacopoeial formulation Majoon Chobchini in the patients of Jarab (Scabies) was carried out at RRIUMs, Bhadrak and Patna; and RRC Allahabad. The patients received Majoon Chobchini in the dose of five gram orally twice daily after meals for four weeks.
During the reporting period, 138 patients were studied; of which 95 patients completed the study. Out of the completed cases, 53 (55.8%) patients were relieved, 35 (36.8%) partially relieved and seven (7.4%) showed no response. Thirteen patients were under study and 30 dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

Clinical validation of a Unani pharmacopoeial formulation Qurs-e-Ziabetus Khas in Dhayābēōus Sukkarē Qism-i Thānī (Diabetes Mellitus Type-II) (CRIUM, Hyderabad; RRIUM, Chennai; RRC, Allahabad; CRU, Bengaluru)

A study on validation of a Unani pharmacopoeial formulation Qurs-e-Ziabetus Khas in the patients of Dhayābēōus Sukkarē Qism-i Thānī (Diabetes Mellitus Type-II) was carried out at CRIUM, Hyderabad; RRIUM, Chennai; RRC, Allahabad; and CRU, Bengaluru. The patients received Qurs-e-Ziabetus Khas in the dose of two tablets orally twice daily half an hour before meals for 12 weeks.

During the reporting period, 133 patients were studied, of which 81 completed the study. Out of the completed cases, 17 (21.0%) were relieved, 38 (46.9%) partially relieved and 26 (32.1%) patients showed no response. Seventeen patients were under study and 35 dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

Clinical validation of Unani pharmacopoeial formulations Majoone-Suranjan and Habb-e-Azaraqi in Niqris (Gout) (CRIUM, Lucknow; RRIUMs, Aligarh and Chennai; CRU, Burhanpur)

A study on validation of Unani pharmacopoeial formulations Majoone-Suranjan and Habb-e-Azaraqi in the patients of Niqris (Gout) was carried out at CRIUM, Lucknow; RRIUMs, Aligarh and Chennai; and CRU, Burhanpur. The patients received Majoone-Suranjan five gm and Habb-e-Azaraqi one pill twice daily after meals for eight weeks.

During the reporting period, 84 patients were studied; of which 53 completed the study. Out of the completed cases, 39 (73.6%) patients were relieved, four (7.5%) partially relieved and 10 (18.9%) showed no response. Four patients were under study and 27 dropped out of the study. The test drugs were found well-tolerated and no adverse effects were observed.

Clinical validation of a Unani pharmacopoeial formulation Dawaul Misk Motadil Sada in Khafaqān (Palpitation) (RRIUM, Aligarh; RRC, Allahabad; CRU Burhanpur)

A study on validation of a Unani pharmacopoeial formulation Dawaul Misk Motadil Sada in the patients of Khafaqān (Palpitation) was carried out at RRIUM, Aligarh; RRC, Allahabad; and CRU Burhanpur. The patients received Dawaul Misk Motadil Sada five gm orally twice daily for four weeks.

During the reporting period, 103 patients were studied, of which 62 completed the study. Out of the completed cases, 30 (48.4%) patients were relieved, 27 (43.5%) partially relieved and five (8.1%) showed no response. Two patients were under study and 39 dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.
Clinical validation of a Unani pharmacopoeial formulation *Safooof Hajrul Yahood* in *Úañana al-Kulya* (Nephrolithiasis) (CRIUM, Hyderabad; RRIUMs, Chennai, New Delhi and Srinagar)

A study on validation of a Unani pharmacopoeial formulation *Safooof Hajrul Yahood* in the patients of *Úañana al-Kulya* (Nephrolithiasis) was carried out at CRIUM, Hyderabad; and RRIUMs, Chennai, New Delhi and Srinagar. The patients received *Safooof Hajrul Yahood* five gm orally twice daily for eight weeks.

During the reporting period, 168 patients were studied, of which 81 completed the study. Out of the completed cases, 26 (32.1%) patients were relieved, 28 (34.6%) partially relieved and 27 (33.3%) showed no response. Twenty-two patients were under study and 65 dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

Clinical validation of a Unani pharmacopoeial formulation *Habb-e-Tursh Mushtahi* in *Òu’f al-Ishtiäh’* (Anorexia) (RRIUMs, Mumbai, Srinagar and Aligarh)

A study on validation of a Unani pharmacopoeial formulation *Hab-e-Tursh Mushtahi* in the patients of *Òu’f al-Ishtiäh’* (Anorexia) was carried out at RRIUMs, Mumbai, Srinagar and Aligarh. The patients received *Habb-e-Tursh Mushtahi* one pill (250 mg) orally thrice daily for two weeks.

During the reporting period, 265 patients were studied, of which 157 completed the study. Out of the completed cases, 112 (71.4%) patients were relieved, 41 (26.1%) partially relieved and four (2.5%) showed no response. Six patients were under study and 102 dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

Clinical validation of Unani pharmacopoeial formulations *Safooof Pathar Phori* and *Sharbat-e-Bazoori Motadil* in *Úañana al-Kulya* (Nephrolithiasis) (RRC, Allahabad; CRU Bhopal)

A study on validation of Unani pharmacopoeial formulations *Safooof Pathar Phori* and *Sharbat-e-Bazoori Motadil* in the patients of *Úañana al-Kulya* (Nephrolithiasis) was carried out at RRC, Allahabad; and CRU Bhopal. The patients received *Safooof Pathar Phori* three gm and *Sharbat-e-Bazoori Motadil* 25 ml orally twice daily for eight weeks.

During the reporting period, 46 patients were studied, of which 22 completed the study. Out of the completed cases, 14 (63.6%) patients were relieved and eight (36.4%) partially relieved. Nine patients were under study and 15 patients dropped out of the study. The test drugs were found well-tolerated and no adverse effects were observed.

Clinical validation of a Unani pharmacopoeial formulation *Sharbat-e-Belgiri* in *Zauër* (Dysentery) (RRIUM, New Delhi; CRUs, Meerut and Bhopal)

A study on validation of a Unani pharmacopoeial formulation *Sharbat-e-Belgiri* in the patients of *Zauër* (Dysentery) was carried out at RRIUM, New Delhi; and CRUs, Meerut and Bhopal. The patients received *Sharbat-e-Belgiri* 25 ml orally twice daily for two weeks.

During the reporting period, 104 patients were studied, of which 57 completed the study. Out of the completed cases, 36 (63.1%) patients were relieved, 12 (21.1%) partially relieved and
nine (15.8%) patients showed no response. Three patients were under study and 44 dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

Clinical validation of a Unani pharmacopoeial formulation *Damawé* in *Sū’ al-Qinya* (Anaemia) (CRIUM, Lucknow; RRIUMs, New Delhi and Aligarh)

A study on validation of a Unani pharmacopoeial formulation *Damawé* in the patients of *Sū’ al-Qinya* (Anaemia) was carried out at CRIUM, Lucknow; and RRIUMs, New Delhi and Aligarh. The patients received *Damawé* two tablets once daily for eight weeks.

During the reporting period, 229 patients were studied, of which 66 completed the study. Out of the completed cases, 14 (21.2%) patients were relieved, 43 (65.2%) partially relieved and nine (13.6%) showed no response. Fifty-two patients were under study and 111 patients dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

Clinical validation of a Unani pharmacopoeial formulation *Itrifal Muqawwi Dimagh* in *Nisyān* (Amnesia) (CRIUMs, Hyderabad and Lucknow; RRIUM, Mumbai)

A study on validation of a Unani pharmacopoeial formulation *Itrifal Muqawwi Dimagh* in the patients of *Nisyān* (Amnesia) was carried out at CRIUMs, Hyderabad and Lucknow; and RRIUM, Mumbai. The patients received *Itrifal Muqawwi Dimagh* five gm orally twice daily for eight weeks.

During the reporting period, 161 patients were studied; of which 93 completed the study. Out of the completed cases, three (3.2%) patients were relieved, 33 (35.5%) partially relieved and 57 (61.3%) showed no response. Fourteen patients were under study and 54 dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

Clinical validation of Unani pharmacopoeial formulations *Majoon Jograj Gugal* and *Raghan Malkangani* in *Waja‘al-Mafāñil* (Rheumatoid Arthritis) (CRIUM, Lucknow; RRIUM, Patna; CRU, Meerut)

A study on validation of Unani pharmacopoeial formulations *Majoon Jograj Gugal* and *Raghan Malkangani* in the patients of *Waja‘al-Mafāñil* (Rheumatoid Arthritis) was carried out at CRIUM, Lucknow; RRIUM, Patna; and CRU, Meerut. The patients received *Majoon Jograj Gugal* five gm twice daily and *Raghan Malkangani* for local application on the affected joints for 12 weeks.

During the reporting period, 170 patients were studied, of which 126 completed the study. Out of the completed cases, 31 (24.6%) patients were relieved, 70 (55.6%) partially relieved and 25 (19.8%) showed no response. No patients were under study and 44 patients dropped out of the study. The test drugs were found well-tolerated and no adverse effects were observed.

Clinical validation of a Unani pharmacopoeial formulation *Zimad-e-Bars* in *Kalaf* (Melasma) (RRIUM, Chennai)

A study on validation of a Unani pharmacopoeial formulation *Zimad-e-Bars* in the patients of *Kalaf* (Melasma) was carried out at RRIUM, Chennai. The patients were given *Zimad-e-Bars* for local application on the affected parts twice daily for eight weeks.
During the reporting period, eight patients were studied, of which six completed the study. Out of the completed cases, one (16.7%) patient was relieved, four (66.6%) were partially relieved and one (16.7%) showed no response. Two patients dropped out of the study and no patients were under study. The test drug was found well-tolerated and no adverse effects were observed.

Clinical validation of a Unani pharmacopoeial formulation *Majoon Supari Pak* in *Sayalān al-Raiūm* (Leucorrhoea) (CRIUM, Hyderabad; RRIUMs, Patna and Aligarh)

A study on validation of a Unani pharmacopoeial formulation *Majoon Supari Pak* in the patients of *Sayalān al-Raiūm* (Leucorrhoea) was carried out at CRIUM, Hyderabad; and RRIUMs, Patna and Aligarh. The patients received *Majoon Supari Pak* seven gm twice daily for eight weeks.

During the reporting period, 205 patients were studied, of which 143 patients completed the study. Out of the completed cases, 31 (21.7%) patients were relieved, 96 (67.1%) partially relieved and 16 (11.2%) showed no response. Eight patients were under study and 54 dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

Clinical validation of a Unani pharmacopoeial formulation *Habb-e-Asgand* in *Waja‘ al-Mafāṇil* (Rheumatoid Arthritis) (RRIUMs, New Delhi, Mumbai, Aligarh; CRU, Bengaluru)

A study on validation of a Unani pharmacopoeial formulation *Habb-e-Asgand* in *Waja‘ al-Mafāṇil* (Rheumatoid Arthritis) was carried at RRIUMs, New Delhi, Mumbai and Aligarh; and CRU, Bengaluru. The patients received *Habb-e-Asgand* one tablet twice daily for six weeks.

During the reporting period, 165 patients were studied, of which 56 completed the study. Out of the completed cases, 10 (17.8%) patients were relieved, 30 (53.6%) partially relieved and 16 (28.6%) showed no response. Fifty-one patients were under study and 58 dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

Clinical validation of a Unani pharmacopoeial formulation *Habb-e-Bawaseer Damiya* in *Bawäsér* (Piles) (RRIUMs, Bhadrak and Kolkata; CRU, Kurnool)

A study on validation of a Unani pharmacopoeial formulation *Habb-e-Bawaseer Damiya* in the patients of *Bawäsér* (Piles) was carried out at RRIUMs, Bhadrak and Kolkata; and CRU, Kurnool. The patients received *Hab-e-Bawaseer Damiya* one tablet twice daily for two weeks.

During the reporting period, 167 patients were studied, of which 131 completed the study. Out of the completed cases, 87 (66.4%) patients were relieved, 39 (29.8%) partially relieved and five (3.8%) showed no response. Three patients were under study and 33 dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

Clinical validation of a Unani pharmacopoeial formulation *Sāfoof-e-Habis-ud-Dam* in *Kathra al-Öamth* (CRIUM, Hyderabad; RRIUMs, Aligarh, Chennai and Srinagar)

A study on validation of a Unani pharmacopoeial formulation *Sāfoof-e-Habis-ud-Dam* in *Kathra al-Öamth* (Heavy Menstrual Bleeding) was carried out at CRIUM, Hyderabad; and RRIUMs, Aligarh, Chennai and Srinagar. The patients received *Sāfoof-e-Habis-ud-Dam* 2.5 gm twice daily for ten days in a month starting from the 1<sup>st</sup> day of the menstrual cycle for three consecutive months.
During the reporting period, 42 patients were studied, of which 14 completed the study. Out of the completed cases, 11 (78.6%) patients were relieved and three (21.4%) showed no response. Fifteen patients were under study and 13 dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

Clinical validation of a Unani pharmacopoeial formulation Jawarish-e-Shahi in Khafaqān (Palpitation) (CRIUM, Lucknow; RRIUMs, Aligarh and Srinagar)

A study on validation of a Unani pharmacopoeial formulation Jawarish-e-Shahi in Khafaqān (Palpitation) was carried out at CRIUM Lucknow; and RRIUMs, Aligarh and Srinagar. The patients received Jawarish-e-Shahi five gm orally twice daily for two weeks.

During the reporting period, 83 patients were studied, of which 49 completed the study. Out of the completed cases, 24 (49.0%) patients were relieved, 22 (44.9%) partially relieved and three (6.1%) showed no response. Four patients were under study and 30 dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

Clinical validation of a Unani pharmacopoeial formulation Khamira Sandal Sada in Khafaqān (Palpitation) (CRIUM, Hyderabad; RRIUM, New Delhi; CRU, Meerut)

A study on validation of a Unani pharmacopoeial formulation Khamira Sandal Sada in the patients of Khafaqān (Palpitation) was carried out at CRIUM, Hyderabad; RRIUM, New Delhi; and CRU, Meerut. The patients received Khamira Sandal Sada five gm twice daily for two weeks.

During the reporting period, 72 patients were studied, of which 30 completed the study. Out of the completed cases, 18 (60.0%) patients were relieved, eight (26.7%) partially relieved and four (13.3%) showed no response. Twenty patients were under study and 22 dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

Clinical validation of a Unani pharmacopoeial formulation Laooq-e-Badam in Khushūnā al-Úalaq (Sore Throat) (RRIUMs, Bhadrak, Chennai and Kolkata)

A study on validation of a Unani pharmacopoeial formulation Laooq-e-Badam in the patients of Khushūnā al-Úalaq (Sore Throat) was carried out at RRIUMs, Bhadrak, Chennai and Kolkata. The patients received Laooq-e-Badam five gm twice daily for two weeks.

During the reporting period, 53 patients were studied, of which 45 completed the study. Out of the completed cases, 33 (73.3%) patients were relieved and 12 (26.7%) partially relieved. No patients were under study and eight dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

Clinical validation of a Unani pharmacopoeial formulation Itrifal Ustukhuddus in Nazla Muzmin (Chronic Rhinosinusitis) (CRIUMs, Hyderabad and Lucknow; RRIUM, Srinagar)

A study on validation of a Unani pharmacopoeial formulation Itrifal Ustukhuddus in the patients of Nazla Muzmin (Chronic Rhinosinusitis) was carried out at CRIUMs, Hyderabad and Lucknow; and RRIUM, Srinagar. The patients received Itrifal Ustukhuddus seven gm twice daily for six weeks.
During the reporting period, 92 patients were studied, of which 60 completed the study. Out of the completed cases, 36 (60.0%) patients were relieved and 24 (40.0%) partially relieved. Fourteen patients were under study and 18 dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

**Clinical validation of a Unani pharmacopoeial formulation Majoon Muqawwi-e-Rahem in Sayalân al-Raùém (Leucorrhoea) (CRIUM, Lucknow; RRIUMs, New Delhi and Aligarh)**

A study on validation of a Unani pharmacopoeial formulation Majoon Muqawwi-e-Rahem in the patients of Sayalân al-Raùém (Leucorrhoea) was carried out at CRIUM Lucknow; and RRIUMs, New Delhi and Aligarh. The patients received Majoon Muqawwi-e-Rahem five gm twice daily for two weeks.

During the reporting period, 343 patients were studied, of which 219 completed the study. Out of the completed cases, 46 (21.0%) patients were relieved, 137 (62.6%) partially relieved and 36 (16.4%) showed no response. Forty-four patients were under study and 80 dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

**Clinical validation of a Unani pharmacopoeial formulation Sharbat-e-Sadar in Su‘āl (Cough) (RRIUM, Kolkata; CRU, Burhanpur)**

A study on validation of a Unani pharmacopoeial formulation Sharbat-e-Sadar in the patients of Su‘āl (Cough) was carried out at RRIUM Kolkata; and CRU, Burhanpur. The patients received Sharbat-e-Sadar 10 ml thrice daily for two weeks.

During the reporting period, 35 patients were studied, of which 32 completed the study. Out of the completed cases, 10 (31.3%) patients were relieved, 16 (50.0%) partially relieved and six (18.8%) showed no response. One patient was under study and two dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

**Clinical validation of a Unani pharmacopoeial formulation Majoon-e-Dabeed-ul-Ward in Waram al-Kabid (Hepatitis) (CRUs, Burhanpur and Kurnool)**

A study on validation of a Unani pharmacopoeial formulation Majoon-e-Dabeed-ul-Ward in the patients of Waram al-Kabid (Hepatitis) was carried out at CRUs, Burhanpur and Kurnool. The patients received Majoon-e-Dabeed-ul-Ward five gm twice daily for six weeks.

During the reporting period, 62 patients were studied, of which 44 completed the study. Out of the completed cases, five (11.4%) patients were relieved, 28 (63.6%) partially relieved and 11 (25.0%) showed no response. Eight patients were under study and 10 dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

**Clinical validation of a Unani pharmacopoeial formulation Laooq-e-Katan in Óéq al-Nafas (Bronchial Asthma) (CRIUM, Lucknow; RRC Allahabad; CRU, Meerut)**

A study on validation of a Unani pharmacopoeial formulation Laooq-e-Katan in the patients of Óéq al-Nafas (Bronchial Asthma) was carried out at CRIUM, Lucknow; RRC, Allahabad; and CRU, Meerut. The patients received Laooq-e-Katan five gm twice daily for two weeks.
During the reporting period, 21 patients were studied, of which 15 completed the study. Out of the completed cases, five (33.3%) patients were relieved, nine (60.0%) partially relieved and one (6.7%) showed no response. Three patients were under study and three dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

**Clinical validation of a Unani pharmacopoeial formulation Khamira-e-Gaozaban Sada in Ēou'f al-Dimāgh (Cerebrasthenia) (CRIUMs, Hyderabad and Lucknow; RRIUM, Mumbai)**

A study on validation of a Unani pharmacopoeial formulation Khamira-e-Gaozaban Sada in the patients of Ēou’f al-Dimāgh (Cerebrasthenia) was carried out at CRIUMs, Hyderabad and Lucknow; and RRIUM, Mumbai. The patients received Khamira-e-Gaozaban Sada five gm twice daily for six weeks.

During the reporting period, 57 patients were studied, of which 43 completed the study. Out of the completed cases, 29 (67.4%) patients were relieved, 11 (25.6%) partially relieved and three (7.0%) showed no response. Three patients were under study and 11 dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

**Clinical validation of a Unani pharmacopoeial formulation Habb-e-Hilteet in Ēou’f al-Ishtihā’ (Anorexia) (RRIUMs, Chennai, Patna and New Delhi)**

A study on validation of a Unani pharmacopoeial formulation Habb-e-Hilteet in the patients of Ēou’f al-Ishtihā’ (Anorexia) was carried out at RRIUMs, Chennai, Patna and New Delhi. The patients received Habb-e-Hilteet one tablet twice daily for two weeks.

During the reporting period, 145 patients were studied, of which 106 completed the study. Out of the completed cases, 49 (46.3%) patients were relieved, 47 (44.3%) partially relieved and 10 (9.4%) showed no response. Nine patients were under study and 30 dropped out of the study. The test drug was found well-tolerated and no adverse effects were observed.

**New Studies**

In addition to the above, the following studies under validation of Unani pharmacopoeial drugs were allotted / initiated during the reporting period:

- Clinical validation of a Unani pharmacopoeial formulation Itrifal Fauladi in Sū’ al-Qinya (Anaemia)
- Clinical validation of a Unani pharmacopoeial formulation Habb-e-Tinkar in Ēou’f al-Ishtihā’ (Anorexia)
- Clinical validation of a Unani pharmacopoeial formulation Habb-e-Suranjan in Waja’ al-Mafāñil (Rheumatoid Arthritis)
- Clinical validation of a Unani pharmacopoeial formulation Itrifal Mulayyin in Ńudā’ Muzmin (Chronic Headache)
- Clinical validation of a Unani pharmacopoeial formulation Safoof-e-Sailan in Sayalān al-Raiém (Leucorrhea)
- Clinical validation of a Unani pharmacopoeial formulation Habb-e-Bawaseer Amya in Bawāṣèr Ḍamiya (Non-Bleeding Piles)
• Clinical validation of a Unani pharmacopoeial formulation *Safoof-e-Teen* in Zaúér (Dysentery)
• Clinical validation of a pharmacopoeial formulation *Habb-e-Musaffi Khoon* in Buthür al-Jild
• Clinical validation of a pharmacopoeial formulation *Habb-e-Hindi Zeeqi* in Ìëq al-Nafas
• Clinical validation of a pharmacopoeial formulation *Habb-e-Khabsal-Hadeed* in Anaemia
• Clinical validation of a pharmacopoeial formulation *Jawarish-e-Pudina* in Ìù’f al-Isťihā’
• Clinical validation of a pharmacopoeial formulation *Khamira Abresham Saada* in Khafaqān (Palpitation)
• Clinical validation of a pharmacopoeial formulation *Majoon-e-Hajr-ul-Yahood* in Uaņā al-Kulya
• Clinical validation of a pharmacopoeial formulation *Majoon-e-Ispand Sokhtani* in Sur’a al-Inzāl (Premature Ejaculation)
• Clinical validation of a pharmacopoeial formulation *Majoon-e-Sangdana Murgh* in Ìù’f-i Mi’dāa
• Clinical validation of a pharmacopoeial formulation *Majoon-e-Sohag Sonth* in Sayalān al-Ra’aim
• Clinical validation of a pharmacopoeial formulation *Roghan-e-Qaranful* in Waja’ al-Asnān
• Clinical validation of a pharmacopoeial formulation *Roghan-e-Baiza-e-Murgh* in Dā’ al-Tha’lab
• Clinical validation of a pharmacopoeial formulation *Sharbat-e-Anjabar* in Kathra al-Öamth
• Clinical validation of a pharmacopoeial formulation *Tiryaq-e-Nazla* in Nazla
• Clinical validation of a pharmacopoeial formulation *Itrifal Kishneez* in Nazla Muzmin
• Clinical validation of a pharmacopoeial formulation *Sharbat-e-Khaksi* in Recurrent Fever
• Clinical validation of a pharmacopoeial formulation *Habb-e-Mudir* in Ìutibās al-Öamth
• Clinical validation of a pharmacopoeial formulation *Safoof-e-Amla* in Ìusr al-Bawl
• Clinical validation of a pharmacopoeial formulation *Safoof Chobchini* in Niqris