Clinical Research Programme

Preclinical Studies

Preclinical safety and pharmacological studies on eight Unani drugs, including 50% hydroalcoholic extract form of the drugs, were undertaken at the Central Research Institute of Unani Medicine, Hyderabad and Regional Research Institute of Unani Medicine, Srinagar. Summary of the studies undertaken is as under:

Preclinical safety evaluation of coded Unani formulation UNIM N-2000 in rats

Acute and 90-day repeated toxicity studies of UNIM N-2000, a polyherbal coded Unani formulation, were conducted in Sprague Dawley rats at CRIUM, Hyderabad. Considering the low acute toxicity potential, the limit test as per the OECD Guideline 425 was conducted at 2000 mg/kg body weight. The animals were weighed and observed for mortality and toxic signs and symptoms for 14 days after treatment. As no lethality was observed following treatment with UNIM N-2000 in three consecutive animals, dosing to further animals was stopped. All the three animals were sacrificed on day 15 and necropsy was performed. No treatment related gross pathological abnormality was observed. Under the given conditions, no toxic sign and symptom or mortality was observed at the dose of 2000 mg/kg bw of UNIM N-2000. Therefore, oral LD50 of UNIM N-2000 in the female Sprague-Dawley strain rat was estimated to be greater than 2000 mg/kg body weight.

Repeated dose oral toxicity potential of UNIM N-2000 was assessed by conducting a 90-day toxicity study as per the OECD Guideline 408. Sprague Dawley rats (100±20 gm body weight) were divided into four groups with 20 animals (10 males + 10 females) in each group including the control. UNIM N-2000 was orally administered at 300, 900 and 1500 mg/kg bw/day for three months. The control group was treated with vehicle only. The animals were periodically observed for clinical signs of toxicity, mortality, morbidity, body weight changes and feed consumption. At the end of the study, assessment of hematology, clinical biochemistry, electrolytes, gross necropsy and relative organ weight was performed.

Treatment with UNIM N-2000 showed no significant difference in survival and body weight gain. No adverse effect was observed in hematology and biochemistry profile except certain changes which were clinically insignificant as the values were within normal physiological range. No change was observed in relative organ weight data of the control and gross necropsy in UNIM N-2000 treated rats. Therefore, no-observed-adverse-effect-level (NOAEL) might be considered greater than 1500 mg/kg body weight, i.e. the highest tested dose.

Preclinical safety evaluation of coded Unani formulation UNIM N-2002 in rats

Acute and repeated toxicity studies on UNIM N-2002, a polyherbal coded Unani formulation, were conducted in Sprague Dawley rats at CRIUM, Hyderabad. Considering the low acute toxicity potential, the limit test as per the OECD Guideline 425 was conducted at 2000 mg/kg body weight. The animals were weighed and observed for mortality and toxic signs and symptoms for 14 days post-treatment. As no lethality was observed following treatment with UNIM N-2002 in three consecutive animals, dosing to further animals was stopped. All the three animals were sacrificed on day 15 and necropsy was performed. No treatment related gross

pathological abnormality was observed. Under the given conditions, no toxic sign and symptom or mortality was observed at the dose of 2000 mg/kg bw of UNIM N-2002. Therefore, oral LD50 of UNIM N-2002 in the female Sprague-Dawley strain rat was estimated to be greater than 2000 mg/kg body weight.

Repeated dose oral toxicity potential of UNIM N-2002 was assessed by conducting a 90-day toxicity study as per the OECD Guideline 408. Sprague Dawley rats (100±20 gm body weight) were divided into four groups with 20 animals (10 males + 10 females) in each group including the control. UNIM N-2002 was orally administered at the dose of 300, 900 and 1500 mg/kg bw/day for three months. The control group animals were treated with vehicle only. The animals were periodically observed for clinical signs of toxicity, mortality, morbidity, body weight changes and feed consumption. At the end of the study, assessment of hematology, clinical biochemistry, electrolytes, gross necropsy and relative organ weight was performed. Treatment with UNIM N-2002 showed no significant difference in survival, body weight gain, and hematology and biochemistry profile except certain isolated / inconsistent changes in serum globulin, platelets and feed consumption, which were clinically insignificant as the values were in the normal physiological range. The changes observed were incidental and within historical control ranges. No change was observed in the gross necropsy and relative organ weight data of the control and UNIM N-2002 treated rats. Based on the results, the NOAEL for UNIM N-2002 was considered as greater than 1500 mg/kg bw/day, the highest tested dose.

Preclinical safety evaluation of coded Unani formulation UNIM N-2003 in rats

Acute and repeated toxicity studies on UNIM N-2003, a polyherbal coded Unani formulation, were conducted in Sprague Dawley rats at CRIUM, Hyderabad. Considering the low acute toxicity potential, the limit test as per the OECD Guideline 425 was conducted at the dose of 2000 mg/kg body weight. The animals were weighed, observed for lethality and toxic signs and symptoms for 14 days after treatment. As no lethality was observed following treatment with UNIM N-2003 in three consecutive animals, dosing to further animals was stopped. All the three animals were sacrificed on day 15 and necropsy was performed. No treatment related gross pathological abnormality was observed. Under the given conditions, no toxic sign and symptom or mortality was observed at the dose of 2000 mg/kg bw of UNIM N-2003. Therefore, oral LD50 of UNIM N-2003 in the female Sprague-Dawley strain rat was estimated to be greater than 2000 mg/kg body weight.

Repeated dose oral toxicity study of UNIM N-2003 was conducted as per the OECD Guideline 408. Sprague Dawley rats (100±20 gm body weight) were divided into four groups with 20 animals (10 males + 10 females) in each group including the control. UNIM N-2003 was orally administered at the dose of 300, 900 and 1500 mg/kg bw/day for three months. The control group animals were treated with vehicle only. The animals were periodically observed for clinical signs of toxicity, mortality, morbidity, body weight changes and feed consumption. At the end of the study, hematology, clinical biochemistry, electrolytes, gross pathology, relative organ weight and histological examination were performed. Treatment with UNIM N-2003 showed no toxicologically significant change in body weight gain, feed consumption, hematology and biochemistry. The gross necropsy also did not reveal any significant observation in UNIM N-2003 treated rats. Since no alterations were found in the clinical signs, hematology and biochemistry profile of UNIM N-2003 treated animals compared with the control, the NOAEL of

UNIM N-2003 might be considered >1500 mg/kg bw in both male and female rats subject to the findings of histopathological evaluation.

Preclinical safety evaluation of *Ma'jūn Najāḥ* in rats

Chronic toxicity (180-day) study on *Ma'jūn Najāḥ* (MN) was conducted at CRIUM, Hyderabad. Ninety rats of about 5-6 weeks of age were randomly divided into three groups (15 male and 15 female in each group). Group-I served as control and was administered with aqueous suspension of 0.3% carboxymethyl cellulose orally. MN was orally administered at two dose levels *viz.* 1,000 and 2000 mg/kg bw/day for 180 days. The animals were periodically observed for clinical signs of toxicity, mortality, morbidity, body weight changes and feed consumption. At the termination of the study, blood samples were collected and subjected to hematology and clinical chemistry investigations. The animals were humanized and necropsy was performed. The animals in groups treated with MN did not show any abnormal behavior or clinical signs indicative of systemic toxicity. No toxicologically significant alteration was observed in hematological and biochemical parameters and gross necropsy of the control and MN treated rats of either sex. Therefore, the NOAEL of MN in SD rats might be considered >2000 mg/kg bw subject to the findings of histopathology.

Preclinical safety evaluation of *Jawārish Bisbāsā* in rats

Sub-chronic toxicity (90-day repeated dose study) of *Jawārish Bisbāsā* (JBS) was conducted at CRIUM, Hyderabad. The oral toxicity study was performed as per the OECD Guideline 408 in rats. 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 as vehicle orally. JBS was orally administered at two dose levels i.e., 1,000 mg/kg bw/day and a limit dose of 2000 mg/kg bw/day for 90 days. The animals were periodically observed for clinical signs of toxicity, mortality, morbidity, body weight changes and feed consumption. At the end of the study duration, blood samples were collected under isofluorane anaesthesia from retro-orbital plexus. Blood samples were subjected to hematology, clinical biochemistry, gross pathology and relative organ weight. Treatment with JBS showed no adverse effect on survival and body weight gain in animals throughout study duration. No overt findings were observed in the behavior of animals and no clinical signs indicative of any systemic toxicity were observed during clinical examination. No adverse effect was observed in hematology and biochemistry profile except certain changes which were clinically insignificant as the effects observed were not dose dependent and the values were well within the normal physiological range. No remarkable change was observed in relative organ weight data of the control and JBS treated rats. The gross necropsy of JBS treated or the control animals did not reveal any adverse findings. Therefore, the NOAEL might be considered to be greater than 2000 mg/kg body weight.

Preclinical safety evaluation of *Sharbat-i Dīnār* in rats

A 90-day repeated oral toxicity study on *Sharbat-i Dīnār* (SDR) was performed as per the OECD Guideline 408 at CRIUM, Hyderabad. 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 drinking water orally. SDR was orally administered at three dose levels i.e., 04, 10 and 20 ml/kg bw/day (equivalent to 1X, 2.5X and 5X of therapeutically equivalent dose, respectively) 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 duration, blood samples were collected under isofluorane anaesthesia from retro-orbital plexus. Blood samples were subjected to hematology and clinical biochemistry analysis. The rats were sacrificed under CO_2 euthanasia and gross necropsy examination was performed. Internal organs / tissues such as spleen, heart, liver, kidneys, adrenals and gonads were examined macroscopically, isolated, weighed and stored in the neutral buffered formalin. No mortality or morbidity was observed in any group throughout the study duration. Treatment with SDR showed no significant differences in survival, body weight gain, and hematology and biochemistry profile except certain isolated changes in serum globulin, platelets and feed consumption, which was considered toxicologically insignificant as the values were within the normal physiological range. There were no changes in the gross necropsy and relative organ weight data of the control and SDR treated rats. In the absence of any significant toxic effect, the NOAEL for SDR may be considered as greater than 20 ml/kg bw/day, the highest tested dose.

Acute oral toxicity study of UNIM D-2000 in albino Wistar rats

Acute oral toxicity study (single dose 14-day study) of UNIM D-2000 was conducted in albino Wistar rats at RRIUM, Srinagar. The rats were randomly divided into four groups of 5 rats each. Group-I and II being the male and female control were treated with water orally (vehicle). Group-III and IV male and female rats were administered single oral dose (2000 mg/kg) of UNIM D-2000. The animals were weighed initially and at weekly intervals. The animals were observed periodically for water consumption and feed consumption on weekly basis. The animals were observed carefully for any behavioral and neurological changes for 24 hours after the administration of the drug, thereafter twice daily and sacrificed after 14 days of the drug administration. The gross examination of the tissues and organs was carried out. At the end of the study, hematology, clinical biochemistry, electrolytes, gross pathology, relative organ weight and histological examinations were performed. Treatment with UNIM D-2000 showed no significant clinical sign of toxicity, gross behavior, body weight gain, feed consumption, and hematology and biochemistry profile. Gross examination of the organs and tissues did not reveal any significant change. These observations conclude that UNIM D-2000 is safe up to the tested dose level. Based on the acute oral toxicity study data, the NOAEL of UNIM D-2000 might be considered >2000 mg/kg body weight in both male and female rats.

Acute oral toxicity study of 50% hydroalcoholic extract of UNIM D-2000 in albino Wistar rats

Acute oral toxicity study (single dose 14-day study) of 50% hydroalcoholic extract of UNIM D-2000 was conducted in albino Wistar rats at RRIUM, Srinagar. The animals were randomly divided into four groups each comprising five rats. Group-I and II being the male and female control were treated with water (vehicle) orally. Group-III and IV were orally administered once with 50% hydroalcoholic extract of UNIM D-2000 at the dose of 2000 mg/kg body weight. The animals were weighed initially and at weekly intervals. The effect of the extract on water consumption and feed consumption was monitored and recorded on weekly basis and careful observation was done for any behavioral and neurological changes for 24 hours after the administration of drug, thereafter twice daily. The animals were sacrificed after 14 days of the drug administration. Blood was collected for hematological and biochemical parameter analysis. The gross examination of the tissues and organs was carried out. Treatment with 50% hydroalcoholic extract of UNIM D-2000 showed no significant clinical signs of toxicity, body weight gain, feed consumption, and hematology and biochemistry profile. There was no treatment

related morphological changes in the vital organs of the rats such as brain, heart, lung, liver, kidney, spleen, adrenal, testes and ovaries at the tested dose level. These observations conclude that 50% hydroalcoholic extract of UNIM D-2000 is safe up to the tested dose level. Based on the acute oral toxicity study data, the NOAEL of 50% hydroalcoholic extract UNIM D-2000 may be considered >2000 mg/kg body weight in both male and female rats.

Acute oral toxicity study of UNIM M-2000 in albino Wistar rats

Acute oral toxicity study (single dose 14-day study) of UNIM M-2000 was conducted at RRIUM, Srinagar. The Wistar rats were randomly divided into four groups of five rats each. Group-I and II being the male and female control were orally treated with water (vehicle). Group-III and IV were administered single oral dose (2000 mg/kg) of UNIM M-2000. The animals were weighed initially and at weekly intervals. The effect of the drug UNIM M-2000 on water and feed consumption was monitored and recorded on weekly basis. The animals were observed carefully for any behavioral and neurological changes for 24 hours after the administration of the drug and twice daily thereafter. The animals were sacrificed after 14 days of the drug administration. Blood was collected for hematological and biochemical parameter analysis. The gross examination of tissues and organs was carried out. Treatment with UNIM M-2000 showed no significant clinical signs of toxicity, body weight gain, feed consumption, and hematology and biochemistry profile. The external observation of morphology of the organs revealed that the drug did not induce any morphological change among the treated rats. These observations conclude that UNIM M-2000 is safe up to the tested dose level. Based on the acute oral toxicity study data, the NOAEL of UNIM D-2000 may be considered >2000 mg/kg body weight in both male and female rats.

Acute oral toxicity study of 50% hydroalcoholic extract of UNIM M-2000 in albino Wistar rats

Acute oral toxicity study (single dose 14-day study) of 50% hydroalcoholic extract of UNIM M-2000 was conducted at RRIUM, Srinagar. The Wistar rats were randomly divided into four groups each consisting of five rats. Group-I and II being the male and female control were treated with water (vehicle) orally. Group-III and IV were administered single oral dose of 50% hydroalcoholic extract of UNIM M-2000 at the dose of 2000 mg/kg body weight. The animals were weighed initially and at weekly intervals. The effect of 50% hydroalcoholic extract UNIM M-2000 on water and feed consumption was monitored and recorded on weekly basis. The animals were observed carefully for any behavioral and neurological changes for 24 hours after the administration of the drug, thereafter twice daily. The animals were sacrificed after 14 days of the drug administration. The effect of the drug was observed on the physiological parameters. Blood was collected for hematological and biochemical parameter analysis. The gross examination of tissues and organs was carried out.

Treatment with 50% hydroalcoholic extract of UNIM M-2000 showed no significant signs of toxicity, body weight gain, feed consumption, and hematology and biochemistry profile. The external examination of the organs showed that the extract did not alter the morphology in terms of shape, size and texture. These observations conclude that 50% hydroalcoholic extract of UNIM M-2000 is safe up to the tested dose level. Based on the acute oral toxicity study data, the NOAEL of 50% hydroalcoholic extract UNIM M-2000 may be considered >2000 mg/kg body weight in both male and female rats.

Nephroprotective activity of coded Unani formulation UNIM N-2000 against Cisplatin induced acute renal damage in experimental animals

Procurement of the required animals, chemicals, kits and other consumables was under process at CRIUM, Hyderabad at the end of the reporting period.

Nephroprotective activity of coded Unani formulation UNIM N-2002 against Cisplatin induced acute renal damage in experimental animals

Procurement of the required animals, chemicals, kits and other consumables was under process at CRIUM, Hyderabad at the end of the reporting period.

Nephroprotective activity of coded Unani formulation UNIM N-2003 against Cisplatin induced acute renal damage in experimental animals

Procurement of the required animals, chemicals, kits and other consumables was under process at CRIUM, Hyderabad at the end of the reporting period.

Sub-chronic (90-day repeated dose toxicity study) of UNIM D-2000 in albino Wistar rats

Procurement of the required animals, chemicals, kits and other consumables was under process at RRIUM, Srinagar at the end of the reporting period.

Sub-chronic (90-day repeated dose toxicity study) of 50% hydroalcoholic extract of UNIM D-2000 in albino Wistar rats

Procurement of the required animals, chemicals, kits and other consumables was under process at RRIUM, Srinagar at the end of the reporting period.

Sub-chronic (90-day repeated dose toxicity study) of UNIM M-2000 in albino Wistar rats

Procurement of the required animals, chemicals, kits and other consumables was under process at RRIUM, Srinagar at the end of the reporting period.

Sub-chronic (90-day repeated dose toxicity study) of 50% hydroalcoholic extract of UNIM M-2000 in albino Wistar rats

Procurement of the required animals, chemicals, kits and other consumables was under process at RRIUM, Srinagar at the end of the reporting period.

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
- Regional Research Institute of Unani Medicine (RRIUM), New Delhi
- Regional Research Centre (RRC), Allahabad
- Regional Research Centre (RRC), Silchar
- Clinical Research Unit (CRU), Bengaluru
- Clinical Research Unit (CRU), Meerut
- Clinical Research Unit (CRU), Bhopal
- Clinical Research Unit (CRU), Burhanpur
- Clinical Research Unit (CRU), Edathala
- Clinical Research Unit (CRU), Kurnool

CENTRE-WISE ALLOCATION OF DISEASES FOR CLINICAL STUDIES ON SAFETY AND EFFICACY OF UNANI DRUGS

Centre	Diseases
Central Research Institute of Unani Medicine (CRIUM), Hyderabad	*Baraṣ* (Vitiligo), *Dhayābīṭus Sukkarī Qism-i Thāni* (Diabetes Mellitus Type-II), *Ḍaghṭ al-Dam Qawī Lāzimī* (Essential Hypertension), *Nazla Muzmin* (Chronic Rhinosinusitis), *Nisyān* (Amnesia), *Ḍu'f al-Dimāgh* (Cerebrasthenia), *Ḥaṣā al-Kulya* (Nephrolithiasis), *Khafaqān* (Palpitation), *Taḥajjur al-Mafāṣil* (Osteoarthritis), *Kathra al- Ṭamth* (Heavy Menstrual Bleeding), *Ḍīq al-Nafas* (Bronchial Asthma), *Litha Dāmiya* (Bleeding Gums), *Sayalān al-Raḥim* (Leucorrhoea), *Sahar* (Insomnia), *Ḍu'f al-Ishtihā'* (Anorexia), *Su'āl Yābis* (Dry Cough), *Ḍu'f al-Mi'da* (Functional Dyspepsia) and *Iḥtibās al-Ṭamth* (Amenorrhoea)
Central Research Institute of Unani Medicine (CRIUM), Lucknow	*Dhayābīṭus Sukkarī Qism-i Thāni* (Diabetes Mellitus Type-II), *Siman Mufriṭ* (Obesity), *Baraṣ* (Vitiligo), *Sū' al-Qinya* (Anaemia), *Dīdān al-Am'ā'* (Helminthiasis), *Sayalān al-Raḥim* (Leucorrhoea), *Niqris* (Gout), *Nisyān* (Amnesia), *Khafaqān* (Palpitation), *Nazla Muzmin* (Chronic Rhinosinusitis), *Ḍīq al-Nafas* (Bronchial Asthma),

Centre	Diseases
	Sur'a al-Inzāl (Premature Ejaculation), *Nazla* (Common Cold), *Ḍu'f al-Dimāgh (Cerebrasthenia), Sahar* (Insomnia), *Ḥummā* (Fever), *Iḥtibās al-Ṭamth* (Amenorrhoea), *Ḍu'f al-Ishtihā'* (Anorexia) and *Kathra al-Ṭamth* (Heavy Menstrual Bleeding)
Regional Research Institute of Unani Medicine (RRIUM), Chennai	*Baraṣ* (Vitiligo), *Ṣudā'* (Headache), *Dhayābīṭus Sukkarī Qism-i Thāni* (Diabetes Mellitus Type-II), *Waja' al-Asnān* (Toothache), *Niqris* (Gout), *Ḥaṣā al-Kulya* (Nephrolithiasis), *Sharā Muzmin* (Chronic Urticaria), *Bawāsīr 'Umya* (Non Bleeding Piles), *Khushūna al-Ḥalaq* (Sore Throat), *Ḍu'f al-Ishtihā'* (Anorexia), *Kathra al- Ṭamth* (Heavy Menstrual Bleeding), *Zaḥīr* (Dysentery), *Ḥummā* (Fever) and *Qubā'* (Dermatophytosis)
Regional Research Institute of Unani Medicine (RRIUM), Bhadrak	*Jarab* (Scabies), *Buthūr al-Jild* (Macules / Pustules), *Sharā Muzmin* (Chronic Urticaria), *Bawāsīr Dāmiya* (Bleeding Piles), *Ḍu'f al-Ishtihā'* (Anorexia), *Dīdān al-Am'ā'* (Helminthiasis), *Khushūna al-Ḥalaq* (Sore Throat), *Zaḥīr* (Dysentery), *Waja' al-Mafāṣil* (Rheumatoid Arthritis), *Ḍu'f al-Mi'da* (Functional Dyspepsia), *Sur'a al-Inzāl* (Premature Ejaculation) and *Ḍu'f al-Dimāgh* (Cerebrasthenia)
Regional Research Institute of Unani Medicine (RRIUM), Patna	*Sayalān al-Raḥim* (Leucorrhoea), *Waja' al-Asnān* (Toothache), *Sharā Muzmin* (Chronic Urticaria), *Jarab* (Scabies), *Ḍu'f al-Ishtihā'* (Anorexia), *Nazla* (Common Cold), *Khafaqān* (Palpitation), *Ḍīq al-Nafas* (Bronchial Asthma), *Sū' al-Qinya* (Anaemia), *Nazla Muzmin* (Chronic Rhinosinusitis), *Qubā'* (Dermatophytosis) *and Niqris* (Gout)
Regional Research Institute of Unani Medicine (RRIUM), Aligarh	*Baraṣ* (Vitiligo), *Dhayābīṭus Sukkarī Qism-i Thāni* (Diabetes Mellitus Type-II), *Ḍaghṭ al-Dam Qawī Lāzimī* (Essential Hypertension), *Sayalān al-Raḥim* (Leucorrhoea), *Ḍu'f al-Ishtihā'* (Anorexia), *Khafaqān* (Palpitation), *Sū' al-Qinya* (Anaemia), *Niqris* (Gout), *Waja' al-Mafāṣil* (Rheumatoid Arthritis), *Nazla Muzmin* (Chronic Rhinosinusitis), *Siman Mufriṭ* (Obesity), *Litha Dāmiya* (Bleeding Gums), *Kathra al- Ṭamth* (Heavy Menstrual Bleeding), *Su'āl Yābis* (Dry Cough), *Sahar* (Insomnia), *Niqris* (Gout), *Ghathayān* (Nausea), *Ḍīq al-Nafas* (Bronchial Asthma) and *Ḍu'f al-Mi'da* (Functional Dyspepsia)
Regional Research Institute of Unani Medicine (RRIUM), Mumbai	*Ḍaghṭ al-Dam Qawī Lāzimī* (Essential Hypertension), *Waja' al-Mafāṣil* (Rheumatoid Arthritis), *Ḍu'f al-Dimāgh* (Cerebrasthenia), *Waja' al-Asnān* (Toothache), *Sharā Muzmin* (Chronic Urticaria), *Bawāsīr 'Umya* (Non-Bleeding Piles),

Centre	Diseases
	Siman Mufriṭ (Obesity), *Kathra al- Ṭamth* (Heavy Menstrual Bleeding), *Ḍu'f al-Ishtihā'* (Anorexia), *Ḥaṣā al-Kulya* (Nephrolithiasis), *Sū' al-Qinya* (Anaemia), Nisyān (Amnesia), *Iḥtibās al-Ṭamth* (Amenorrhoea), *Niqris* (Gout) and *Qubā'* (Dermatophytosis)
Regional Research Institute of Unani Medicine (RRIUM), Srinagar	*Baraṣ* (Vitiligo), *Ḍaghṭ al-Dam Qawī Lāzimī* (Essential Hypertension), *Ḥaṣā al-Kulya* (Nephrolithiasis), *Jarab* (Scabies), *Kathra al- Ṭamth* (Heavy Menstrual Bleeding), *Nazla Muzmin* (Chronic Rhinosinusitis), *Khafaqān* (Palpitation), *Waja' al-Mafāṣil* (Rheumatoid Arthritis), *Ḍīq al-Nafas* (Bronchial Asthma), *Ḍu'f al-Ishtihā'* (Anorexia), *Ḍu'f al-Mi'da* (Functional Dyspepsia), *Sayalān al-Raḥim* (Leucorrhoea) and *Ḥummā* (Fever)
Regional Research Institute of Unani Medicine (RRIUM), Kolkata	*Bawāsīr Dāmiya* (Bleeding Piles), *Dīdān al-Am'ā'* (Helminthiasis), *Nazla Muzmin* (Chronic Rhinosinusitis), *Su'āl Yābis* (Dry Cough), *Khushūna al-Ḥalaq* (Sore Throat), *Su'āl Raṭab* (Productive Cough) and *Ḍu'f al-Ishtihā'* (Anorexia)
Regional Research Institute of Unani Medicine (RRIUM), New Delhi	*Baraṣ* (Vitiligo), *Dhayābīṭus Sukkarī Qism-i Thāni* (Diabetes Mellitus Type-II), *Ḍaghṭ al-Dam Qawī Lāzimī* (Essential Hypertension), *Zaḥīr* (Dysentery), *Su'āl Yābis* (Dry Cough), *Sū' al-Qinya* (Anaemia), *Ḥaṣā al-Kulya* (Nephrolithiasis), *Sayalān al-Raḥim* (Leucorrhoea), *Khafaqān* (Palpitation), *Ḍu'f al-Ishtihā'* (Anorexia), *Nazla Muzmin* (Chronic Rhinosinusitis), *Waja' al-Mafāṣil* (Rheumatoid Arthritis), *Sahar* (Insomnia), *Buthūr al-Jild* (Macules / Pustules), *Kathra al-Ṭamth* (Heavy Menstrual Bleeding)
Regional Research Centre (RRC), Allahabad	*Dhayābīṭus Sukkarī Qism-i Thāni* (Diabetes Mellitus Type-II), *Ḥaṣā al-Kulya* (Nephrolithiasis), *Khafaqān* (Palpitation), *Ishāl* (Diarrhoea), *Ḍīq al-Nafas* (Bronchial Asthma), *Jarab* (Scabies), *Bawāsīr 'Umya* (Non-Bleeding Piles), *Zaḥīr* (Dysentery), *Su'āl* (Cough), *Nazla* (Common Cold) and *Niqris* (Gout)
Regional Research Centre (RRC), Silchar	*Nazla* (Common Cold), *Waja' al-Mafāṣil* (Rheumatoid Arthritis), *Ghathayān* (Nausea) and *Buthūr al-Jild* (Macules / Pustules)
Clinical Research Unit (CRU), Bengaluru	*Dhayābīṭus Sukkarī Qism-i Thāni* (Diabetes Mellitus Type-II), *Sū' al-Qinya* (Anaemia), *Ḍu'f al-Ishtihā'* (Anorexia), *Waram al-Kabid* (Hepatitis), *Waja' al-Mafāṣil* (Rheumatoid Arthritis), *Nazla* (Common

Centre	Diseases
	Cold) and *Waja' al-Asnān* (Toothache)
Clinical Research Unit (CRU), Meerut	*Ḍu'f al-Ishtihā'* (Anorexia), *Su'āl Yābis* (Dry Cough), *Zaḥīr* (Dysentery), *Ḍīq al-Nafas* (Bronchial Asthma), *Nazla Muzmin* (Chronic Rhinosinusitis), *Nazla* (Common Cold), *Sur'a al-Inzāl* (Premature Ejaculation), *Sū' al-Qinya* (Anaemia), *Khafaqān* (Palpitation) and *Sayalān al-Raḥim* (Leucorrhoea)
Clinical Research Unit (CRU), Bhopal	*Ḥaṣā al-Kulya* (Nephrolithiasis), *Sahar* (Insomnia), *Su'āl* (Cough), *Ṣudā'* (Headache), *Zaḥīr* (Dysentery), *Dīdān al-Am'ā'* (Helminthiasis), *Ḍu'f al-Ishtihā'* (Anorexia) and *Nazla* (Common Cold)
Clinical Research Unit (CRU), Burhanpur	*Niqris* (Gout), *Su'āl Yābis* (Dry Cough), *Waram al-Kabid* (Hepatitis), *Su'āl* (Cough), *Sur'a al-Inzāl* (Premature Ejaculation), *Nazla* (Common Cold), *Ḍu'f al-Ishtihā'* (Anorexia) and *Ṣudā'* (Headache)
Clinical Research Unit (CRU), Kerala	*Sahar* (Insomnia), *Nazla* (Common Cold), *Sur'a al-Inzāl* (Premature Ejaculation) and *Ḍu'f al-Ishtihā'* (Anorexia)
Clinical Research Unit (CRU), Kurnool	*Ḍu'f al-Ishtihā'* (Anorexia), *Bawāsīr Dāmiya* (Bleeding Piles), *Zaḥīr* (Dysentery), *Litha Dāmiya* (Bleeding Gums), *Ghathayān* (Nausea), *Waram al-Kabid* (Hepatitis), *Sharā* (Urticaria), *Jarab* (Scabies) and *Waja' al-Asnān* (Toothache)

Clinical Studies on *Baraṣ* (Vitiligo)

Clinical studies on *Baraṣ* (Vitiligo) continued at the 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 *Baraṣ* (Vitiligo) patients

Therapeutic efficacy of a combination of two coded Unani drugs, UNIM-001 and UNIM-003, was evaluated in 2,957 patients of *Baraṣ* (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, 650 new patients were registered, whereas 2,307 continued from the previous year bringing the total patients studied to 2,957. Out of them, 503 patients completed the study. The repigmentation was 91-99% in four (0.8%) patients, 71-90% in 23 (4.6%) patients, 51-70% in 52 (10.3%) patients, 41-50% in 68 (13.5%) patients and ≤40% in 340 (67.6%) patients, whereas 16 (3.2%) patients showed no response. A total of 1,455 patients dropped out of the study whereas 999 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 repigmenting the depigmented patches to a variable degree ranging from 50 to 99% depending upon the chronicity of the disease and the part of the body affected. No drug intolerance / adverse effect was reported.

Evaluation of therapeutic efficacy of a combination of coded Unani drugs UNIM-004 and UNIM-005 in *Baraṣ* (Vitiligo) patients

Therapeutic efficacy of a combination of two coded Unani drugs, UNIM-004 and UNIM-005, was evaluated in 7,254 patients of *Baraṣ* (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, 1,834 new patients were registered, whereas 5,420 patients continued from the previous year, bringing the total patients studied to 7,254. Out of them, 611 patients completed the study, six (1.0%) patients showed 71-90%, 21 (3.4%) patients showed 51-70%, 57 (9.3%) patients showed 41-50% and 503 (82.3%) patients showed ≤40% repigmentation, whereas 24 (3.9%) patients showed no response. A total of 2,338 patients dropped out of the study and 4,305 patients were under study. So far, 5,308 patients have completed the study.

No drug intolerance / adverse effect was reported. However, itching and blister formation were reported in some patients with sensitive skin. It was managed by diluting the concentration of the paste and applying coconut oil on the affected parts.

Evaluation of therapeutic efficacy of *Munḍij-Mushil* drugs (UNIM-040 + UNIM-041 + UNIM-042) in *Baraṣ* (Vitiligo) patients

Therapeutic efficacy of *Munḍij-Mushil* drugs (UNIM-040 + UNIM-041 + UNIM-042) was evaluated in the patients of *Baraṣ* (Vitiligo). The *Munḍij* drugs were given till the appearance of *Nuḍj* in urine followed by *Mushil* and *Tabrīd* drugs for six days alternately. During the reporting period, 94 new patients were registered, whereas 13 patients continued from the previous year, bringing the total patients studied to 107. Out of them, 92 patients completed the study. In these patients, *Nuḍj* 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. No drug intolerance / side effect was reported. After the completion of *Munḍij-Mushil* therapy, the patients were given the oral and local drugs. Nine patients dropped out of the study whereas six patients were under 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 *Baraṣ* (Vitiligo)

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 *Baraṣ* (Vitiligo) at CRIUM, Hyderabad; and RRIUMs, Aligarh, Chennai, 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, 187 new patients were registered, whereas 89 patients continued from the previous year, bringing the total to 276 patients. Out of them, 75 patients completed the study. Out of the completed cases, 17 (23%) patients were relieved, 43 (57%) partially relieved and 15 (20%) showed no response. A total of 126 patients dropped out of the study, whereas 75 patients were under study. The test drugs were found well-tolerated and no adverse effect was 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 *Dhayābīṭus Sukkarī Qism-i Thāni* (Diabetes Mellitus Type-II)

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 *Dhayābīṭus Sukkarī Qism-i Thāni* (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, 189 new patients were registered, whereas 68 patients continued from the previous year, bringing the total to 257 patients. Out of them, 116 patients completed the study. Of the completed cases, 31 (27%) patients were relieved, 42 (36%) partially relieved and 43 (37%) showed no response. A total of 106 patients dropped out of the study and 35 patients were under study. The test drug was found well-tolerated and no adverse effect was 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 of *Ḍaghṭ al-Dam Qawī Lāzimī* (Essential Hypertension)

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 *Ḍaghṭ al-Dam Qawī Lāzimī* (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, 123 new patients were registered, whereas 40 continued from the previous year, bringing the total to 163 patients. Out of them, 79 patients completed the study. Of the completed cases, 31 (39%) patients were relieved, 42 (53%) partially relieved and 6 (8%) showed no response. A total of 59 patients dropped out of the study, whereas 25 patients were under study. The test drug was found well-tolerated and no adverse effect was observed.

Validation of Unani Pharmacopoeial Drugs

Clinical validation of a Unani pharmacopoeial formulation *Qurs-i Dīdān* in *Dīdān al-Am'a'* (Helminthiasis)

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

During the reporting period, 22 patients were studied, of which 15 completed the study. Out of the completed cases, 9 (60%) patients were relieved, 6 (40%) partially relieved. One patient was under study and six patients dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of Unani pharmacopoeial formulations *Iṭrīfal Shāhtara* and *Marham Khārish Jadīd* in *Jarab* (Scabies)

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

During the reporting period, 62 patients were studied, of which 26 completed the study. Out of the completed cases, 13 (50%) patients were relieved, 11 (42%) partially relieved and two (8%) showed no response. Three patients were under study and 33 dropped out of the study. The test drugs were found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Ma'jūn Chobchīnī* in *Jarab* (Scabies)

A study on validation of a Unani pharmacopoeial formulation *Ma'jūn Chobchīnī* in the patients of *Jarab* (Scabies) was carried out at RRIUMs, Bhadrak and Patna; and RRC Allahabad. The patients received *Ma'jūn Chobchīnī* in the dose of five gm orally twice daily after meals for four weeks.

During the reporting period, 120 patients were studied; of which 72 patients completed the study. Out of the completed cases, 18 (25%) patients were relieved, 38 (53%) partially relieved and 16 (22%) showed no response. Seventeen patients were under study and 31 dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Qurṣ-i Dhayābīṭus Khās* in *Dhayābīṭus Sukkarī Qism-i Thāni* (Diabetes Mellitus Type-II)

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

During the reporting period, 77 patients were studied, of which 27 completed the study. Out of the completed cases, 2 (7%) were relieved, 23 (85%) partially relieved and 2 (7%) patients showed no response. Fifteen patients were under study and 35 dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of Unani pharmacopoeial formulations *Maʻjūn Suranjān* and *Ḥabb-i Azarāqī* in *Niqris* (Gout)

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

During the reporting period, 13 patients were studied; of which 8 completed the study. Out of the completed cases, 4 (50%) patients were relieved, 2 (25%) partially relieved and 2 (25%) showed no response. Four patients were under study and one dropped out of the study. The test drugs were found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Safūf Ḥajr al-Yahūd* in *Ḥaṣā al-Kulya* (Nephrolithiasis)

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

During the reporting period, 55 patients were studied, of which 39 completed the study. Out of the completed cases, 10 (26%) patients were relieved, 21 (54%) partially relieved and eight (21%) showed no response. Ten patients were under study and six dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Ḥabb-i Tursh Mushtahī* in *Ḍuʻf al-Ishtihā'* (Anorexia)

A study on validation of a Unani pharmacopoeial formulation *Ḥabb-i Tursh Mushtahī* in the patients of *Ḍuʻf al-Ishtihā'* (Anorexia) was carried out at RRIUMs, Mumbai, Srinagar and Aligarh. The patients received *Ḥabb-i Tursh Mushtahī* one pill (250 mg) orally thrice daily for two weeks.

During the reporting period, 131 patients were studied, of which 85 completed the study. Out of the completed cases, 33 (39%) patients were relieved, 46 (54%) partially relieved and six (7%) showed no response. Ten patients were under study and 36 dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of Unani pharmacopoeial formulations *Safūf Patthar Phorī* and *Sharbat Bazūri Muʻtadil* in *Ḥaṣā al-Kulya* (Nephrolithiasis)

A study on validation of Unani pharmacopoeial formulations *Safūf Patthar Phorī* and *Sharbat Bazūri Muʻtadil* in the patients of *Ḥaṣā al-Kulya* (Nephrolithiasis) was carried out at RRC, Allahabad; and CRU Bhopal. The patients received *Safūf Patthar Phorī* three gm and *Sharbat Bazūri Muʻtadil* 25 ml orally twice daily for eight weeks.

During the reporting period, 62 patients were studied, of which 24 completed the study. Out of the completed cases, 16 (67%) patients were relieved, seven (29%) partially relieved and one (4%). Fifteen patients were under study and 23 dropped out of the study. The test drugs were found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Sharbat-i Belgirī* in *Zaḥīr* (Dysentery)

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

During the reporting period, 47 patients were studied, of which 29 completed the study. Out of the completed cases, 11 (38%) patients were relieved, 10 (34%) partially relieved and eight (28%) patients showed no response. Eighteen dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Damawī* in *Sū' al-Qinya* (Anaemia)

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

During the reporting period, 221 patients were studied, of which 81 completed the study. Out of the completed cases, 19 (23%) patients were relieved, 44 (54%) partially relieved and 18 (22%) showed no response. Sixty eight patients were under study and 72 patients dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Iṭrīfal Muqawwi Dimāgh* in *Nisyān* (Amnesia)

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

During the reporting period, 54 patients were studied; of which 27 completed the study. Out of the completed cases, seven (26%) patients were relieved, five (19%) partially relieved and 15 (56%) showed no response. Seven patients were under study and 20 dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Ma'jūn Supārī Pāk* in *Sayalān al-Raḥīm* (Leucorrhoea)

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

During the reporting period, 95 patients were studied, of which 60 patients completed the study. Out of the completed cases, 26 (43%) patients were relieved, 27 (45%) partially relieved and

seven (12%) showed no response. Eleven patients were under study and 24 dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Ḥabb-i Asgand* in *Waja' al-Mafāṣil* (Rheumatoid Arthritis)

A study on validation of a Unani pharmacopoeial formulation *Ḥabb-i Asgand* in *Waja' al-Mafāṣil* (Rheumatoid Arthritis) was carried out at RRIUMs, New Delhi, Mumbai and Aligarh; and CRU, Bengaluru. The patients received *Ḥabb-i Asgand* one pill twice daily for six weeks.

During the reporting period, 180 patients were studied, of which 97 completed the study. Out of the completed cases, 34 (35%) patients were relieved, 49 (51%) partially relieved and 14 (14%) showed no response. Thirty-five patients were under study and 48 dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Ḥabb-i Bawāsīr Dāmiya* in *Bawāsīr* (Piles)

A study on validation of a Unani pharmacopoeial formulation *Ḥabb-i Bawāsīr Dāmiya* in the patients of *Bawāsīr* (Piles) was carried out at RRIUMs, Bhadrak and Kolkata; and CRU, Kurnool. The patients received *Ḥabb-i Bawāsīr Dāmiya* one pill twice daily for two weeks.

During the reporting period, 96 patients were studied, of which 68 completed the study. Out of the completed cases, 35 (51%) patients were relieved, 30 (44%) partially relieved and three (4%) showed no response. Two patients were under study and 26 dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Safūf Hābis al-Dam* in *Kathra al-Ṭamth*

A study on validation of a Unani pharmacopoeial formulation *Safūf Hābis al-Dam* in *Kathra al-Ṭamth* (Heavy Menstrual Bleeding) was carried out at CRIUM, Hyderabad; and RRIUMs, Aligarh, Chennai and Srinagar. The patients received *Safūf Hābis al-Dam* 2.5 gm twice daily for ten days in a month starting from the 1st day of the menstrual cycle for three consecutive months.

During the reporting period, 88 patients were studied, of which 38 completed the study. Out of the completed cases, 29 (76%) patients were relieved and six (16%) showed 3 (8%) no response. Twenty one patients were under study and 29 dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Jawārish Shāhī in Khafaqān* (Palpitation)

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

During the reporting period, 147 patients were studied, of which 82 completed the study. Out of the completed cases, 60 (73%) patients were relieved, 20 (24%) partially relieved and two (2%) showed no response. Seven patients were under study and 58 dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Khamīra Ṣandal Sāda* in *Khafaqān* (Palpitation) (CRIUM, Hyderabad; RRIUM, New Delhi; CRU, Meerut)

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

During the reporting period, 65 patients were studied, of which 41 completed the study. Out of the completed cases, 12 (29%) patients were relieved, 14 (34%) partially relieved and 15 (37%) showed no response. Eleven patients were under study and 13 dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *La'ūq-i Bādām* in *Khushūnat al-Ḥalaq* (Sore Throat)

A study on validation of a Unani pharmacopoeial formulation *La'ūq-i Bādām* in the patients of *Khushūnat al-Ḥalaq* (Sore Throat) was carried out at RRIUMs, Bhadrak, Chennai and Kolkata. The patients received *La'ūq-i Bādām* five gm twice daily for two weeks.

During the reporting period, 102 patients were studied, of which 90 completed the study. Out of the completed cases, 75 (83%) patients were relieved, 13 (14%) partially relieved and two (2%) showed no response. Three patients were under study and nine dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Iṭrīfal Ustukhuddūs* in *Nazla Muzmin* (Chronic Rhinosinusitis)

A study on validation of a Unani pharmacopoeial formulation *Iṭrīfal Ustukhuddūs* in the patients of *Nazla Muzmin* (Chronic Rhinosinusitis) was carried out at CRIUMs, Hyderabad and Lucknow; and RRIUM, Srinagar. The patients received *Iṭrīfal Ustukhuddūs* seven gm twice daily for six weeks.

During the reporting period, 127 patients were studied, of which 76 completed the study. Out of the completed cases, 43 (57%) patients were relieved and 33 (43%) partially relieved. Eight patients were under study and 43 dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Ma'jūn Muqawwi-i Raḥīm* in *Sayalān al-Raḥīm* (Leucorrhoea)

A study on validation of a Unani pharmacopoeial formulation *Ma'jūn Muqawwi-i Raḥīm* in the patients of *Sayalān al-Raḥīm (Leucorrhoea)* was carried out at CRIUM Lucknow; and RRIUMs, New Delhi and Aligarh. The patients received *Ma'jūn Muqawwi-i Raḥīm* five gm twice daily for two weeks.

During the reporting period, 120 patients were studied, of which 79 completed the study. Out of the completed cases, 34 (43%) patients were relieved, 38 (48%) partially relieved and seven (9%) showed no response. Forty one patients dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Sharbat-i Ṣadr* in *Su‘āl* (Cough)

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

During the reporting period, 35 patients were studied, of which 31 completed the study. Out of the completed cases, eight (26%) patients were relieved, 16 (52%) partially relieved and seven (23%) showed no response. Two patients were under study and two dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Ma‘jūn Dabīd al-Ward* in *Waram al-Kabid* (Hepatitis)

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

During the reporting period, 71 patients were studied, of which 56 completed the study. Out of the completed cases, six (11%) patients were relieved, 35 (63%) partially relieved and 15 (27%) showed no response. Two patients were under study and 13 dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *La‘ūq-i Katāɳ* in *Ḍīq al-Nafas* (Bronchial Asthma)

A study on validation of a Unani pharmacopoeial formulation *La‘ūq-i Katāɳ* in the patients of *Ḍīq al-Nafas* (Bronchial Asthma) was carried out at CRIUM, Lucknow; RRC, Allahabad; and CRU, Meerut. The patients received *La‘ūq-i Katāɳ* five gm twice daily for two weeks.

During the reporting period, 77 patients were studied, of which 56 completed the study. Out of the completed cases, 23 (41%) patients were relieved, 22 (39%) partially relieved and 11 (20%) showed no response. Eleven patients were under study and 10 dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Khamīra Gāozabāɳ Sāda* in *Ḍu‘f al-Dimāgh* (Cerebrasthenia)

A study on validation of a Unani pharmacopoeial formulation *Khamīra Gāozabāɳ Sāda* in the patients of *Ḍu‘f al-Dimāgh* (Cerebrasthenia) was carried out at CRIUMs, Hyderabad and Lucknow; and RRIUM, Mumbai. The patients received *Khamīra Gāozabāɳ Sāda* five gm twice daily for six weeks.

During the reporting period, 137 patients were studied, of which 106 completed the study. Out of the completed cases, three (3%) patients were relieved, 47 (44%) partially relieved and 56 (53%) showed no response. Four patients were under study and 27 dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Ḥabb-i Hiltīt* in *Ḍu'f al-Ishtihā'* (Anorexia)

A study on validation of a Unani pharmacopoeial formulation *Ḥabb-i Hiltīt* in the patients of *Ḍu'f al-Ishtihā'* (Anorexia) was carried out at RRIUMs, Chennai, Patna and New Delhi. The patients received *Ḥabb-i Hiltīt* one pill twice daily for two weeks.

During the reporting period, 158 patients were studied, of which 136 completed the study. Out of the completed cases, 105 (77%) patients were relieved, 28 (21%) partially relieved and three (2%) showed no response. Eight patients were under study and 14 dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Iṭrīfal Faulādi* in *Sū' al-Qinya* (Anaemia)

A study on validation of a Unani pharmacopoeial formulation *Iṭrīfal Faulādi* in the patients of *Sū' al-Qinya* (Anaemia) was carried out at RRIUM, Patna and CRU, Meerut and Bangalore. The patients received *Iṭrīfal Faulādi* seven grams twice daily for six weeks.

During the reporting period, 54 patients were studied, of which 39 completed the study. Out of the completed cases, 23 (59%) patients were relieved, 12 (31%) partially relieved and four (10%) showed no response. Eleven patients were under study and four dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Ḥabb-i Tinkār* in *Ḍu'f al-Ishtihā'* (Anorexia)

A study on validation of a Unani pharmacopoeial formulation *Ḥabb-i Tinkar* in the patients of *Ḍu'f al-Ishtihā'* (Anorexia) was carried out at CRIUM, Hyderabad, Lucknow and CRU, Bengaluru. The patients received *Ḥabb-i Tinkar* two pills (250 mg each) twice daily for two weeks.

During the reporting period, 133 patients were studied, of which 94 completed the study. Out of the completed cases, 23 (24%) patients were relieved, 68 (72%) partially relieved and three (3%) showed no response. Three patients were under study and 36 dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Ḥabb-i Suranjān* in *Waja' al-Mafāṣil* (Rheumatoid Arthritis)

A study on validation of a Unani pharmacopoeial formulation *Ḥabb-i Suranjān* in the patients of *Waja' al-Mafāṣil* (Rheumatoid Arthritis) was carried out at RRIUMs, Srinagar and Bhadrak and RRC, Silchar. The patients received *Ḥabb-i Suranjān* one pill (360 mg each) twice daily for six weeks.

During the reporting period, 29 patients were studied, of which 18 completed the study. Out of the completed cases, seven (39%) patients were relieved, 10 (56%) partially relieved and and six (3%) showed no response. Seven patients were under study and four dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Iṭrīfal Mulayyin* in *Ṣudā‘ Muzmin* (Chronic Headache)

A study on validation of a Unani pharmacopoeial formulation *Iṭrīfal Mulayyin* in the patients of *Ṣudā‘ Muzmin* (Chronic Headache) was carried out at RRIUM, Chennai, CRU, Bhopal and Burhanpur. The patients received *Iṭrīfal Mulayyin* seven grams once a day at bed time for seven days.

During the reporting period, 30 patients were studied, of which 24 completed the study. Out of the completed cases, 17 (71%) patients were relieved, four (17%) partially relieved and three (13%) showed no response. Six patients were dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Ḥabb-i Bawāsīr ‘Umya* in *Bawāsīr ‘Umya* (Non-Bleeding Piles)

A study on validation of a Unani pharmacopoeial formulation *Ḥabb-i Bawāsīr ‘Umya* in the patients of *Bawāsīr ‘Umya* (Non-Bleeding Piles) was carried out at RRIUM, New Delhi and Mumbai, and RRC, Allahabad. The patients received *Ḥabb-i Bawāsīr ‘Umya* one pill (250 mg) twice daily for two weeks.

During the reporting period, 43 patients were studied, of which 36 completed the study. Out of the completed cases, 13 (36%) patients were relieved, 10 (28%) partially relieved and 13 (36%) showed no response. Three patients were under study and four dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Safūf-i Tīn* in *Zaḥīr* (Dysentery)

A study on validation of a Unani pharmacopoeial formulation *Safūf-i Tīn* in the patients of *Zaḥīr* (Dysentery) was carried out at RRIUM, Bhadrak, CRU, Kurnool and RRC, Allahabad. The patients received *Safūf-i Tīn* seven grams twice daily for six weeks.

During the reporting period, 41 patients were studied, of which 22 completed the study. Out of the completed cases, 11 (50%) patients were relieved and 11 (50%) partially relieved. Six patients were under study and 13 dropped out of the study. The test drug was found well-tolerated and no adverse effect was 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 pharmacopoeial formulation *Ḥabb Muṣaffī-i Khūn* in *Buthūr al-Jild*
- Clinical validation of a pharmacopoeial formulation *Ḥabb-i Hindī Ḍīqī* in *Ḍīq al-Nafas*
- Clinical validation of a pharmacopoeial formulation *Ḥabb Khabth al-Ḥadīd* in *Sū’ al-Qinya*
- Clinical validation of a pharmacopoeial formulation *Jawārish-i Pudīna* in *Ḍu‘f al-Ishtihā’*
- Clinical validation of a pharmacopoeial formulation *Ma‘jūn Ḥajr al-Yahūd* in *Ḥaṣā al-Kulya*

- Clinical validation of a pharmacopoeial formulation *Ma'jūn Ispand Sokhtānī* in *Sur'a al-Inzāl*
- Clinical validation of a pharmacopoeial formulation *Ma'jūn Sangdāna Murgh* in *Ḍu'f al-Mi'da*
- Clinical validation of a pharmacopoeial formulation *Ma'jūn Sohāg Sonth* in *Sayalān al-Raḥim*
- Clinical validation of a pharmacopoeial formulation *Rawghan-i Qaranful* in *Waja' al-Asnān*
- Clinical validation of a pharmacopoeial formulation *Rawghan Baiḍa-i Murgh* in *Dā' al-Tha'lab*
- Clinical validation of a pharmacopoeial formulation *Sharbat-i Anjabār* in *Kathra al- Ṭamth*
- Clinical validation of a pharmacopoeial formulation *Tiryāq-i Nazla* in *Nazla*
- Clinical validation of a pharmacopoeial formulation *Iṭrīfal Kishnīz* in *Nazla Muzmin*
- Clinical validation of a pharmacopoeial formulation *Sharbat-i Khāksī* in Recurrent Fever
- Clinical validation of a pharmacopoeial formulation *Ḥabb-i Mudir* in *Iḥtibās al-Ṭamth*
- Clinical validation of a pharmacopoeial formulation *Safūf-i Āmla* in '*Usr al-Bawl*
- Clinical validation of a pharmacopoeial formulation *Safūf-i Chobchīnī* in *Niqris*

Validation of Unani Pharmacopoeial Fast-Acting Drugs

The Council continued the programme of validating the efficacy and safety of some Unani pharmacopoeial fast-acting drugs in different disease conditions at the various clinical centres of the Council.

During the reporting period, clinical validation of nine Unani pharmacopoeial drugs was carried out in eight disease conditions. The summary of the studies is as follows:

Clinical validation of a Unani pharmacopoeial formulation *Rawghan Iksīr* for symptomatic relief in *Waja' al-Asnān* (Toothache)

Clinical validation of a Unani pharmacopoeial formulation *Rawghan Iksīr* was conducted in the patients of *Waja' al-Asnān* (Toothache) at RRIUMs, Mumbai, Chennai, Bhadrak and Patna; and CRU, Kurnool. The study drug *Rawghan Iksīr* was applied locally on the aching tooth twice daily for seven days.

During the reporting period, 59 patients were studied, of which 49 completed the study. Out of the completed cases, 33 (67%) patients were relieved and 16 (33%) partially relieved. Ten patients dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Quṛṣ Aṣfar* for symptomatic relief in *Sharā'* (Urticaria)

Clinical validation of a Unani pharmacopoeial formulation *Quṛṣ Aṣfar* was conducted in the patients of *Sharā'* (Urticaria) at RRIUMs, Mumbai, Chennai, Bhadrak and Patna; and CRU, Kurnool. The study drug *Quṛṣ Aṣfar* one tablet (775 mg) was given orally twice daily for 14 days.

During the reporting period, 150 patients were studied, of which 116 completed the study. Out of the completed cases, 69 (59%) patients were relieved and 33 (18%) partially relieved whereas 14 (12%) showed no response. Twenty nine patients dropped out of the study and five were under study at the end of the reporting period. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Rawghan Labūb Ṣabā* in the patients of *Sahar* (Insomnia)

Clinical validation of a Unani pharmacopoeial formulation *Rawghan Labūb Ṣabā* was conducted in the patients of *Sahar* (Insomnia) at CRIUMs, Hyderabad and Lucknow; and RRIUM, New Delhi. The study drug *Rawghan Labūb Ṣabā* was applied locally on scalp at bedtime once a day for seven days.

During the reporting period, 108 patients were studied, of which 82 completed the study. Out of the completed cases, 42 (51%) patients were relieved, 32 (39%) partially relieved, whereas eight (10%) showed no response. Twenty six dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Ḥabb-i Surfa* in the patients of *Su'āl* (Cough)

Clinical validation of a Unani pharmacopoeial formulation *Ḥabb-i Surfa* was conducted in the patients of *Su'āl* (Cough) at RRC, Allahabad; and CRUs, Bhopal and Burhanpur. The study drug *Ḥabb-i Surfa* one pill (125 mg) was given orally twice daily for seven days.

During the reporting period, 40 patients were studied, of which 32 completed the study. Out of the completed cases, 13 (41%) patients were relieved and 14 (44%) partially relieved, whereas five (18%) showed no response. Two patients were under study and six dropped out of the study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *La'ūq Sapistāṉ* in the patients of *Nazla* (Common Cold)

Clinical validation of a Unani pharmacopoeial formulation *La'ūq Sapistāṉ* in the patients of *Nazla* (Common Cold) was conducted at CRIUM, Lucknow; CRUs, Bhopal, Kerala, Meerut; and RRC, Silchar. The study drug *La'ūq Sapistāṉ* was given orally in the dose of five gm twice daily for seven days.

During the reporting period, 90 patients were studied, of which 80 completed the study. Out of the completed cases, 33 (41%) patients were relieved, 35 (44%) partially relieved and 12 (15%) showed no response. Nine patients dropped out of the study and one patient was under study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Rawghan-i Kāhu* in *Sahar* (Insomnia)

Clinical validation of a Unani pharmacopoeial formulation *Rawghan-i Kāhu* in the patients of *Sahar* (Insomnia) was conducted at RRIUM, Aligarh, CRU, Bhopal and Kerala. The study drug *Rawghan-i Kāhu* was applied locally on scalp at bedtime once a day for seven days.

During the reporting period, 14 patients were studied, of which all completed the study. Out of the completed cases, three (21%) patients were relieved, one (07%) partially relieved and 10 (71%) showed no response. No patient was under study and there was no drop out. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Khamīra Banafshā* in *Su'āl Yābis* (Dry Cough)

Clinical validation of a Unani pharmacopoeial formulation *Khamīra Banafshā* was conducted in the patients of *Su'āl Yābis* (Dry Cough) at CRIUM, Hyderabad, RRIUMs, Aligarh and New Delhi. The study drug *Khamīra Banafshā* was given orally in the dose of seven grams twice daily for seven days.

During the reporting period, 19 patients were studied, of which 17 completed the study. Out of the completed cases, one (6%) patient was relieved and six (35%) patients were partially relieved, whereas 10 (59%) showed no response. No patient dropped out of the study and two patients were under study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *Sanūn Mukhrij-i Ruṭūbat* in *Litha Dāmiya* (Bleeding Gums)

Clinical validation of a Unani pharmacopoeial formulation *Sanūn Mukhrij-i Ruṭūbat* was conducted in the patients of *Litha Dāmiya* (Bleeding Gums) at CRIUM, Hyderabad, RRIUM, Aligarh, CRU, Kurnool. The study drug *Sanūn Mukhrij-i Ruṭūbat* in a dose of one gram was applied locally on the gums twice a day for seven days.

During the reporting period, 37 patients were studied, of which 33 completed the study. Out of the completed cases, 14 (42%) patients were relieved and 17 (52%) partially relieved, whereas two (6%) showed no response. Four patients dropped out of the study and no patients were under study. The test drug was found well-tolerated and no adverse effect was observed.

Clinical validation of a Unani pharmacopoeial formulation *La'ūq Khayarshambar* in *Nazla* (Common Cold)

Clinical validation of a Unani pharmacopoeial formulation *La'ūq Khayarshambar* was conducted in the patients of *Nazla* (Common Cold) at CRIUM, Lucknow; RRIUM, Patna; and CRU, Kerala. The study drug *La'ūq Khayarshambar* in the dose of 10 grams twice daily was given for seven days.

During the reporting period, 75 patients were studied, of which 56 completed the study. Out of the completed cases, 26 (46%) patients were relieved and 27 (48%) partially relieved, whereas three (5%) showed no response. Eighteen patients dropped out of the study and one patients were under study. The test drug was found well-tolerated and no adverse effect was observed.

New Studies

Besides the above, the following study under validation of Unani pharmacopoeial fast-acting drugs was allotted / initiated during the reporting period:

- Clinical validation of a Unani pharmacopoeial formulation *Jawārish Anārain* in *Ghathayān* (Nausea)

Validation of Regimen Therapies

Apart from pharmacotherapy, Unani Medicine also offers *'Ilāj bi'l-Tadbīr* (Regimen Therapy), such as *Ḥijāma* (Cupping), *Ta'līq al-'Alaq* (Leeching), *Dalk* (Massage), *ḤammāmYābis* (Sauna), *Ḥammām al-Bukhār* (Steam Bath), etc. for certain disease conditions. During the reporting period, various regimen therapy procedures were performed in a total of 13,751 patients with different diseases. These patients showed significant therapeutic effects in subsiding the signs and symptoms of the diseases.

Ḥijāma bilā-Sharṭ (Dry Cupping) was performed in 5,246 patients with different diseases, including *Taḥajjur al-Mafāṣil* (Osteoarthritis), *'Irq al-Nasā* (Sciatica), *Taḥajjur Mafāṣil al-'Unuq* (Cervical Spondylosis), *Taḥajjur Mafāṣil al-Ẓahr* (Lumbar Spondylosis), *Katif Mujammad* (Frozen Shoulder), *Waja' al-Ẓahr* (Backache), *Waja' al-Katif* (Shoulder Pain), *Waja' al-'Unuq* (Neck Pain), *Waja' al-Rukba* (Knee Pain), *Waja' al-'Aqib* (Achillodynia), *Dawālī* (Varicose Veins), *Kathra al-Ṭamth* (Menorrhagia), *'Usr al-Ṭamth* (Dysmenorrhoea), *Ṣudā*' (Headache), *Ṣala'* (Baldness), *Ḥuzn* (Depression), etc. at CRIUMs, Hyderabad and Lucknow; and RRIUMs, Chennai, Bhadrak, Patna, New Delhi, Aligarh, Srinagar and Mumbai.

Ḥijāma bi'l-Sharṭ (Wet Cupping) was performed in 2,826 patients with different diseases, including *Nār Fārsī* (Eczema), *Buthūr Labaniyya* (Acne Vulgaris), *Dā' al-Tha'lab* (Alopecia), *Bawāsīr* (Haemorrhoid), *Ḍaghṭ al-Dam Qawī* (Hypertension), '*Uqr* (Infertility), *Waja' al-Mafāṣil* (Rheumatoid Arthritis), *Taḥajjur al-Mafāṣil* (Osteoarthritis), *'Irq al-Nasā* (Sciatica) and other musculoskeletal disorders at CRIUMs, Hyderabad and Lucknow; and RRIUMs, Bhadrak, Patna, New Delhi, Srinagar and Mumbai.

Ḥijāma bi'l-Nār (Fire Cupping) was performed in 538 patients with different diseases, including *Waja' al-Mafāṣil* (Rheumatoid Arthritis), *Taḥajjur al-Mafāṣil* (Osteoarthritis), *'Irq al-Nasā* (Sciatica), *Waja' al-Ẓahr* (Backache), *Katif Mujammad* (Frozen Shoulder), *Waja' al-Katif* (Shoulder Pain) and *Waja' al-Rukba* (Knee Pain) at RRIUMs, Chennai, Patna, Mumbai, Srinagar and New Delhi.

Ḥijāma Muzliqa (Moving Cupping) was performed in 337 patients with different diseases, including *Waja' al-Ẓahr* (Backache) and *Katif Mujammad* (Frozen Shoulder) at RRIUMs, Chennai and New Delhi.

Ta'liq al-'Alaq (Leeching) was performed in 110 patients with different diseases, including *Dawālī* (Varicose veins), *Takhaththur al-Dam* (Deep Vein Thrombosis), *Qadam Dhayābīṭusiyya* (Diabetic Foot), *Khaṣar-wa-Taṣqī'* (Frostbite), *Taḥajjur al-Mafāṣil* (Osteoarthritis), *Katif Mujammad* (Frozen Shoulder), *Nār Fārsī* (Eczema), *Dā' al-Tha'lab* (Alopecia), *Ṣala*' (Baldness) and *Baraṣ* (Vitiligo) at RRIUMs, Chennai, Patna, Bhadrak, Aligarh, Srinagar and New Delhi.

Ḥammām al-Bukhār (Steam Bath) was performed in 1,276 patients with different diseases, including *Waja' al-Katif* (Upper Back Pain), *Buthūr al-Jild* (Macules / Papules / Pustules), *Qūbā* (Ringworm), *Siman Mufriṭ* (Obesity) and *Bafā* (Dandruff) at RRIUM, New Delhi.

Dalk Mu'tadil (Moderate Massage) was performed in 1,791 patients with different diseases, including *Waja' al-Mafāṣil* (Rheumatoid Arthritis), *Taḥajjur al-Mafāṣil* (Osteoarthritis), *Taḥajjur Mafāṣil al-'Unuq* (Cervical Spondylosis), *Katif Mujammad* (Frozen Shoulder), *Waja' al-Ẓahr* (Backache), *Waja' al-Katif* (Shoulder Pain) and *Waja' al-'Aqib* (Achillodynia) at RRIUMs, Chennai, Bhadrak, Aligarh and New Delhi.

Naṭūl (Fomentation) was performed in 540 patients of *Waja' al-Mafāṣil* (Rheumatoid Arthritis) at CRIUM Lucknow, RRIUMs Bhadrak, Srinagar and New Delhi.

Inkibāb (Vaporisation) was performed in 283 patients of *Waja' al-Mafāṣil* (Rheumatoid Arthritis) and *Waja' al-Katif* (Frozen Shoulder) at RRIUM, New Delhi.

Munḍij-Mushil therapy was performed in 804 patients of *Baraṣ* (Vitiligo) at CRIUM, Hyderabad.

Validation of Fundamentals

Theory of *Akhlāṭ* wa *Mizāj* (Humours and Temperament)

The objective of the project was to test scientifically the concept of *Akhlāṭ* (Humours) and *Mizāj* (Temperament), and its relevance to the states of health and disease. This project was undertaken at the Central Research Institute of Unani Medicine (CRIUM), Hyderabad. The project was aimed at studying the clinical, physiological, pathological, biochemical and genetic parameters of the subjects of different temperaments, conducting clinical assessment of *Mizāj* (Temperament) in different diseases, and scientifically establishing correlation among them.

Genetic studies on the theory of Humours

Genetic studies on the theory of Humours with special reference to Diabetes Mellitus, Essential Hypertension, Vitiligo, Hepatitis, *Sawdāwī* and other related diseases were carried out; and healthy volunteers served as control. Pharmacogenomic studies of Unani formulations in Vitiligo were also conducted. The studies carried out in each participant included determination of dominant temperament by *Ajnās-i 'Ashara* and special CRF on assessment of temperament, genetic marker studies in relation to temperament, studies of biochemical, physiological and pathological parameters, and pulse wave analysis and its component study in relation to the temperament. During the reporting period, the following studies were carried out in 132 (130+02) healthy volunteers and patients. So far, 1180 cases have completed the studies. The 1st part of the project is an observational study; the subjects are being analyzed for dominant temperament according to *Ajnās-i 'Ashara*. In the second part; the subjects and patients are then divided and referred for Genetic Marker Studies, Biochemical, Physiological, Pathological and Pulse wave analysis studies.

Genetic studies on theory of Humours with special reference to Diabetes Mellitus and Essential Hypertension

During the reporting period compilation of genetic studies on theory of Humours with special reference to Essential Hypertension was completed.

Drug metabolizing genes GSTT1 and GSTM1 were also studied in 100 Hypertensive patients and 100 healthy controls registered during the previous years. In case of GSTT1 genotype frequency was H/H was 68% and that of control was 90% where in case of Null it was 32% in patients and 10% in controls. In case of GSTM1 the Genotype frequency in H/H was 66% in patients while it was 96% in controls Null was 34% in patients and 4% in controls.

In Diabetes Mellitus studies continued with the patients of Diabetes registered in the previous years and Healthy controls. Primers were designed and genotyping was done to see pro12 Ala polymorphism for PPAR – Gamma gene in Diabetic patients and *Damawī* controls. In genotype frequency Alleles CC was 52.2% in male patients compared to a control which was 38.43% and

CG was 53% in relation to controls which was 39.8%. In case of females, Alleles CC was 51.05% in relation to controls which is 36.3% and CG 52.42% in patients in relation to 35.85% in controls. The GC Genotype was 11% in male controls and 15% in Diabetic patients' male while in case of female it was 7% and 8% respectively. In case of CC Genotype the gender genotype was 43% in control male and 40% in Diabetic patient, while in female it was 39% and 37% in female diabetic patients. Serum concentration level of Lipid peroxidase and Glutathione S Transferase were studied in Diabetic patients and controls and there were significant alteration. Apart from these primers were designed, standardized and polymorphism studies for GSTT1 and GSTM1 (Drug metabolizing genes) to see genotype frequency in patients suffering from diabetes using gene tool software. The results are in the process of analysis and may vary with the sample size and inference can be drawn only after final analysis and compilation.

Genetic studies on theory of Humours with special reference to Vitiligo

The study continued on 202 patients of Vitiligo registered during the previous year. All the patients were of *Balghamī* temperament. During the reporting period, Polymorphism studies were carried out in Vitiligo patients in relation to controls. Primers were designed and standardized for NLRP1 Gene-rs2670660 (A/G) polymorphism in Balghamī controls. In the genotype frequency of rs 2670660 polymorphism in NLRP1 gene, genotype or alleles GA is 49 in patients whereas 70 in controls, GG is 15 in Patients and 06 in controls, AA is 36 in patients and 24 in controls. The Biolevels serum concentration levels of Glutathione S Transferase were measured and they were significant differences in relation to control.

Apart from the above drug metabolizing genes were also studied (GSTT1 and GSTM1) in Vitiligo patients and controls. In GSTM1 H/H was 73% in controls in relation to patients who were 80% whereas in Null 27% in patients and 20% in control. In GST T1 H/H is 68% in Vitiligo whereas 91% in control. Null it is 32% and control 9%. The results may vary with the sample size. The combine genotypes H/H were 59% in patients and 76% in control whereas null was 15% in patients and 4% in control.

Genetic studies on theory of Humours with special reference to Hepatitis and other *Ṣafrāwī* related diseases

During the reporting period, 02 patients of Hepatitis and other *Ṣafrāwī* related diseases were registered and enrollment completed. The studies continued with total 114 patients of Hepatitis and other *Ṣafrāwī* related diseases during the previous and present year. All the patients were of *Ṣafrāwī* temperament. In molecular biology studies drug metabolizing genes GSTT1 and GSTM1 were studied to see the genotype frequency of the two genes in patients along with controls using gene tool software. The results are in the process of analysis.

Genetic studies on theory of humours with special reference to cancer and other *Sawdāwī* related diseases

During the reporting period, molecular biology work was carried out on the patients registered during the previous years. In Genetic studies, Drug metabolizing genes (GSTT1 and GSTM1) were studied and the result is in the process of analysis.

Genetic studies on theory of Humours with special reference to healthy volunteers:

During the reporting period, 130 healthy volunteers were studied, who served as control. Of the 130 healthy volunteers 37 were *Damawī*, 26 *Balghamī* 35 *Ṣafrāwī* and 32 *Sawdāwī*. So far, 441 healthy volunteers have completed the study. The allotted sample size for this study is 500. Drug metabolizing (GSTT1 and GSTM1) genes were studied and the result is in the process of analysis.

Pharmacogenomics of Unani formulations in Vitiligo

For the Pharmacogenomic studies, blood samples were collected in paxgene blood RNA tubes from 69 Vitiligo patients and 30 controls till date. The real time primers were designed for *NLRP1, MIF* and *GAPDH* gene as an internal control gene using gene tool software. The isolated RNA was converted into cDNA using reverse transcriptase enzyme; and then the converted cDNA samples were subjected to expression studies using RT-PCR. Expression studies were completed for 69 Vitiligo patients' samples and 30 controls samples for *NLRP1* gene and *MIF* gene by using *GAPDH* as an internal control.

Clinical Assessment of *Mizāj* (Temperament)

During the reporting period, assessment of temperament of 2,867 patients attending the OPD of CRIUM, Hyderabad was done. These included 2,579 patients of *Baraṣ* (Vitiligo), 49 patients of *Sayalān al-Raḥim* (Leucorrhoea), 73 patients of *Dhayābīṭus Sukkarī* (Diabetes Mellitus type-2), three patients of *Ḍu'f al-Dimāgh* (Cerebroasthenia), two patients of *Kathra al-Ṭamth* (Heavy Menstrual Bleeding), 20 patients *of Sahar* (Insomnia), five patients of *Khafaqān* (Palpitation), two patients of *Nisyān* (Amnesia), 14 cases of *Iltihāb al-Kabid* (Asymptomatic Hepatitis B healthy carriers), nine patients of *Ḍaghṭ al-Dam Qawī Lāzimī* (Essential Hypertension), 21 patients of *Ḥasā al-Kulya* (Nephrolithiasis), four patients of *Taḥajjur al-Mafāṣil* (Osteoarthritis), 24 patients of *Nazla Muzmin* (Chronic Rhinosinusitis), 50 patients of *Waja' al-Mafāṣil* (Rheumatoid Arthritis), nine patients of *Ḍu'f al-Istihā'* (Anorexia) and three patients of *Su'āl* (Cough).

- In *Baraṣ* (Vitiligo), 349 (13.5%) patients showed *Damawī* (Sanguine) temperament, 2,115 (82.0%) showed *Balghamī* (Phlegmatic) temperament, 108 (4.2%) showed *Ṣafrāwī* (Bilious) temperament and seven (0.3%) showed *Sawdāwī* (Melancholic) temperament.
- In *Sayalān al-Raḥim* (Leucorrhoea), 17 (34.7%) patients showed *Damawī* temperament, 22 (44.9%) *Balghamī*, nine (18.4%) *Ṣafrāwī* temperament and one (2.0%) case was of *Sawdāwī* (Melancholic) temperament.
- In *Dhayābīṭus Sukkarī* (Diabetes Mellitus type-2), 68 (93.2%) patients were of *Damawī* temperament and five (6.8%) of *Balghamī* temperament.
- In *Ḍu'f al-Dimāgh* (Cerebroasthenia), one (33.3%) patient was of *Damawī* temperament and two (66.7%) were of *Balghamī* temperament.
- In *Kathra al-Ṭamth* (Heavy Menstrual Bleeding), two (100%) patients showed *Balghamī* temperament.
- In *Sahar* (Insomnia), eight (40.0%) patients were of *Damawī* temperament, 10 (50%) of *Balghamī* and two (10.0%) of *Ṣafrāwī* temperament.
- In *Khafaqān* (Palpitation), five (100%) patients were of *Damawī* temperament.

- In *Nisyān* (Amnesia), two (100%) patients were of *Balghamī* temperament.
- In *Iltihāb al-Kabid* (Asymptomatic Hepatitis B healthy carriers), two (14.3%) cases were of *Damawī* temperament, two (14.3%) of *Balghamī*, nine (64.3%) of *Ṣafrāwī* temperament and one (7.1%) case was of *Sawdāwī* (Melancholic) temperament.
- In *Ḍaghṭ al-Dam Qawī Lāzimī* (Essential Hypertension), five (55.6%) patients were of *Damawī* temperament, two (22.2%) of *Balghamī*, one (11.1%) of *Ṣafrāwī*, and one (11.1%) of *Sawdāwī* temperament.
- In *Ḥasā al-Kulya* (Nephrolithiasis), 20 (95.2%) patients belonged to *Damawī* temperament and one (4.8%) to *Ṣafrāwī* temperament.
- In *Taḥajjur al-Mafāṣil* (Osteoarthritis), three (75%) patients belonged to *Damawī* temperament and one (25%) to *Balghamī* temperament.
- In *Nazla Muzmin* (Chronic Rhinosinusitis), 11 (45.8%) patients were of *Damawī* temperament, 10 (41.7%) of *Balghamī* temperament and three (12.5%) to *Ṣafrāwī* temperament.
- In *Waja' al-Mafāṣil* (Rheumatoid Arthritis), 36 (72%) patients were of *Damawī* temperament and 14 (28 %) of *Balghamī* temperament.
- In *Ḍu'f al-Istihā'* (Anorexia), seven (77.8%) patients were of *Damawī* temperament and two (22.2%) of *Balghamī* temperament.
- In *Su'āl* (Cough), one (33.3%) patient was of *Balghamī* temperament and two (66.7%) were of *Ṣafrāwī* temperament.

In these patients, susceptibility for acquiring diseases in relation to different temperaments was also studied. An interim analysis of data revealed that the individuals of *Balghamī* temperament were more susceptible to *Baraṣ* (Vitiligo) followed by *Damawī, Ṣafrāwī* and *Sawdāwī* temperaments. Similarly, persons of *Damawī* temperament were more susceptible to *Nazla Muzmin* (Chronic Rhinosinusitis), followed by *Balghamī* and *Ṣafrāwī* temperament. The persons of *Ṣafrāwī* temperament were susceptible to *Su'āl* (Cough) followed by *Balghamī* temperament.

It was also observed that the persons with *Balghamī* temperament were more susceptible than others to *Nisyān* (Amnesia), *Sayalān al-Raḥim* (Leucorrhoea), *Kathra al-Ṭamth* (Heavy Menstrual Bleeding), *Ḍu'f al-Dimāgh* (Cerebroasthenia) and *Sahar* (Insomnia). The people of *Damawī* temperament were more susceptible to *Dhayābīṭus Sukkarī* (Diabetes Mellitus type-2), *Ḍaghṭ al-Dam Qawī Lāzimī* (Essential Hypertension), *Ḥasā al-Kulya* (Nephrolithiasis), *Khafaqān* (Palpitation), *Nazla Muzmin* (Chronic Rhinosinusitis), *Waja' al-Mafāṣil* (Rheumatoid Arthritis), *Ḍu'f al-Istihā'* (Anorexia) and *Taḥajjur al-Mafāṣil* (Osteoarthritis), whereas the persons with *Ṣafrāwī* temperament were more susceptible to *Iltihāb al-Kabid* (Asymptomatic Hepatitis B healthy carriers).

Research-oriented Healthcare

General Outpatient Department (GOPD) Programme

The CCRUM undertakes GOPD Programme which also includes Geriatric OPD and RCH/ MCH OPD. It is aimed at promoting, protecting and preserving public health through Unani Medicine. Besides, OPDs for Post-trial Treatment Access (PTA) is also conducted in order to provide

treatment facility to the research patients after completing the trial. During the reporting period, this programme continued at Central Research Institutes of Unani Medicine (CRIUMs), Hyderabad and Lucknow; Regional Research Institutes of Unani Medicine (RRIUMs), Chennai, Bhadrak, Patna, Aligarh, Mumbai, Srinagar, Kolkata and New Delhi; Regional Research Centres, Allahabad and Silchar; Clinical Research Units (CRUs), Bengaluru, Bhopal, Burhanpur, Meerut, Kurnool and Edathala; Clinical Research Pilot Project, Manipur; Hakim Ajmal Khan Institute for Literary and Historical Research in Unani Medicine, New Delhi; AYUSH Wellness Centre, President's Estate, New Delhi; and All India Institute of Ayurveda, New Delhi. During the reporting period, a total of 4,96,384 patients comprising 4,43,785 patients in GOPDs, 25,078 in Geriatric OPDs, 9,542 in RCH / MCH OPDs, and 17,979 in OPDs for Post-trial Treatment Access (PTA) were treated at different centres. These patients were also assessed for their temperaments and various other factors responsible for occurrence of the disease, thus generating data for research feedback and Unani treatment was prescribed accordingly. These patients were treated with Unani pharmacopoeial formulations.

Mobile Clinical Research Programme

The Mobile Clinical Research Programme is aimed at providing healthcare to the population residing in rural areas, urban slums, scheduled caste and scheduled tribe pockets, besides reducing the disease burden in the society by creating health awareness among them. Under this programme, rural areas, urban slums and pockets predominantly inhabited by Scheduled Caste (SC) / Scheduled Tribe (ST) population with no medical facility are covered. The Council's researchers visit the adopted pockets at regular intervals and provide free Unani treatment to the patients at their door steps, and thus serve as a potential source of healthcare delivery to the masses. The cases of different ailments are referred to the Council's institutes / units and also to other hospitals for treatment of specific diseases for clinical research. Besides, health awareness is created among the population under coverage particularly the women and senior citizens through health lectures and group meetings on the preventive, promotive and curative health aspects based on the principles of Unani Medicine. They are also made aware of the therapeutic uses of medicinal plants growing in their vicinity in the management of different common / seasonal ailments.

During the reporting period, this programme continued at Central Research Institutes of Unani Medicine (CRIUMs), Hyderabad and Lucknow; Regional Research Institutes of Unani Medicine (RRIUMs), Chennai, Bhadrak, Patna, Mumbai, New Delhi and Srinagar; Regional Research Centre (RRC), Allahabad; and Clinical Research Unit (CRU), Burhanpur. During the reporting period, 21 rural pockets / urban slums covering over 1.40 lakh population was covered. A total of 20,075 patients were treated with Unani pharmacopoeial formulations in 414 mobile visits made to these pockets. Predominant diseases as observed were Cough, Skin Infections, Fever, Joint Pain, Osteoarthritis, Leucorrhoea, Rheumatoid Arthritis, Piles, etc.