

**Clinical Validation of Khamīra Banafsha
in Su‘āl Yābis (Dry Cough) (D-7.6)
A Technical Report**



Central Council for Research in Unani Medicine

**Clinical validation of
Unani pharmacopoeial formulation
Khamīra Banafsha in *Su'āl Yābis*
(Dry Cough) (D-7.6)**

A Technical Report



CENTRAL COUNCIL FOR RESEARCH IN UNANI MEDICINE

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ISBN: 978-93-94347-86-1

First published: January' 2026

Publisher

Central Council for Research in Unani Medicine
Ministry of AYUSH, Government of India
61-65, Institutional Area, Janakpuri, New Delhi - 110058
Telephone: +91-11-28521981, 28525982
Email: unanimedicine@gmail.com
Website: www.ccrum.res.in

Printed at

Hi-Tech Graphics
F-28/3, Okhla Industrial Area, Phase -II
New Delhi- 110 020

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Khamīra Banafsha in Su‘āl Yābis (Dry Cough) (D-7.6)
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PREFACE

Cough is a fundamental reflex of the respiratory system, which plays a critical role as a defense mechanism against irritants, such as secretions, microbes, or abnormal temperaments, such as *Sū'-i-Mizāj Hārr Sāda* (hot temperament disorders) (O-17.1.1.1). Although beneficial in maintaining respiratory health, persistent cough can lead to significant challenges in terms of the quality of life. It disrupts sleep, impairs daily functioning, and causes social and physical discomforts. Globally, respiratory illnesses, including those associated with chronic or acute cough, are among the leading causes of mortality and disability, highlighting the urgent need for effective interventions to manage these conditions.

Unani medicine, which takes a holistic approach to health, offers a unique perspective on cough management. Instead of focusing solely on alleviating symptoms, Unani therapeutics aim to address the underlying *Sū'-i Mizāj* (morbid temperament) (O-17), seeking to restore balance in the body through various methods, such as *Taltif* (attenuation), *Taskhīn* (calorific), *Tartīb* (moistening), and *Taskīn-i Su'āl* (anti-tussive therapy). *Khamīra Banafsha*, a Unani pharmaceutical formulation derived primarily from the plant *Viola odorata*, has great therapeutic potential. Historically valued for its *Munaffith* (expectorant) and *Taskīn-i Su'āl* (anti-tussive) properties, *Khamīra Banafsha* has long been used for treating respiratory ailments. In light of its historical relevance and clinical utility, the present study was undertaken to scientifically evaluate the safety and efficacy of *Khamīra Banafsha* using internationally accepted standards.

This clinical study, conducted across three prominent Unani research centers in Hyderabad, Delhi, and Aligarh, highlights the potential integration of traditional Unani formulations into contemporary clinical practice. This research focused on assessing the efficacy of *Khamīra Banafsha* in managing cough and respiratory discomfort in patients with a variety of underlying causes. The results of this study

provide valuable insights into the effectiveness of this time-tested remedy and emphasize the potential benefits of incorporating traditional treatments into modern healthcare settings.

The findings from this study suggest that *Khamīra Banafsha* shows promising results, offering relief to patients suffering from persistent coughs, with a focus on restoring balance to their morbid temperaments. By targeting the root causes of cough, such as *Sū'-i-Mizāj* (O-17), rather than merely treating symptoms, Unani medicine provides a holistic solution to respiratory health. The positive outcomes of this study validate the therapeutic value of *Khamīra Banafsha* and offer a potential avenue for integrating traditional remedies into the clinical practice.

Moreover, this research provides a solid foundation for future studies to explore the intersection between traditional medicine and modern healthcare. This opens up new possibilities for improving patient outcomes through a combined approach that integrates the best practices of both systems. As traditional medicine continues to gain recognition globally, the study of its efficacy in addressing contemporary health challenges, such as cough, will undoubtedly play a critical role in shaping future therapeutic strategies.

In conclusion, this study underscores the importance of exploring and validating traditional remedies such as *Khamīra Banafsha* within the context of modern healthcare. We hope that this research will inspire healthcare professionals and researchers to further investigate the synergies between traditional and contemporary medicine to improve patient outcomes and enrich therapeutic approaches.



Dr. N Zaheer Ahmed

Director General, CCRUM

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Abbreviations

ACE	= Angiotensin Converting Enzyme
AEC	=Absolute Eosinophilic Count
ADRs	= Adverse Drug Reactions
AEs	= Adverse Events
ALP	= Serum Alkaline Phosphatase
CCRUM	= Central Council for Research in Unani Medicine
CNS	= Central Nervous System
COAD	= Chronic Obstructive Airway Disease
CRF	= Case Record Form
CRU	= Clinical Research Unit
CTRI	= Clinical Trial Registry-India
DALY	= Disability-Adjusted Life-Years
DLC	= Differential Leukocyte Count
ESR	= Erythrocyte Sedimentation Rate
FU	= Follow-up
g	= Gram
GCP	= Good Clinical Practices
GERD	= Gastro Esophageal Reflux Disease
Hb	= Hemoglobin
HDL	= High Density Lipoprotein

ICF	= Informed Consent Form
IEC	= Institutional Ethics Committee
IGART	= Investigator Global Assessment of Response to Therapy
IQR	= Interquartile Range
IUMT	= International Unani Medicine Terminologies
KFTs	= Kidney Function Tests
LDL	= Low density Lipoprotein
LFTs	= Liver Function Tests
LRTI	= Lower Respiratory Tract Infection
NFUM	= National formulary of Unani medicine
NRIUMSD	= National Research Institute of Unani Medicine for Skin Disorders
NSAIDs	= Non-steroidal Anti-inflammatory Drugs
NUMC	= National Unani Morbidity Codes
PGART	= Patient Global Assessment of Response to Therapy
PIS	= Participant Information Sheet
Rf	= Retention Factors
RRIUM	= Regional Research Institute of Unani Medicine
R/M	= Routine/Microscopic
RSD	= Relative Standard Deviation
SAEs	= Serious Adverse Events
SEM	= Standard Error Mean
SGOT	= Serum Glutamic Oxaloacetic Transaminase

SGPT	= Serum Glutamic Pyruvic Transaminase
SPSS	= Statistical Package for Social Science
TLC	= Thin Layered Chromatography
TLC	= Total Leukocyte Count
URTI	= Upper Respiratory Tract Infection
VAS	= Visual Analogue Scale
WHO	= World Health Organization

List of NUMC/ICD-10/IUMT codes

<i>Sū'-i-Mizāj</i>	(O-17)
<i>Su'āl Yābis / Surfa Yubsiyya</i> (Dry Cough)	(D-7.6)
<i>Sū'-i-Mizāj Hārr Sāda</i> (morbid hot temperament)	(O-17.1.1.1)
<i>Sū'-i-Mizāj Bārid Sāda</i>	(O-17.1.1.2)
Acute or chronic respiratory tract infections	(J-98)
Chronic obstructive airway disease (COAD)	(J-44)
Pulmonary tuberculosis	(D-29)
Malignancies	(M-16.2)
Diabetes mellitus	(G-2)
Hypertension	(E-38)
Smoking	(F17.2)
Alcohol addiction	(N-36)
Drug addiction	(F19.220)
Pregnancy	(Z34)
Lactation	(Z39.1)
Sinusitis	(C-40)
Ulcer in nasal passage	(C-26)
<i>Rabw</i> (Asthma)	(D-4)
Gastro-esophageal reflux disease (GERD)	(F-42)
<i>Su'āl</i> (Cough)	(D-7)
<i>Nazla-o- Zukām</i> (Coryza and Catarrh)	(C-21)
<i>Khushūnat-i-Ḥalq</i> (Feeling of roughness in the throat)	(C-119)

<i>Sozish-i- Ḥalq</i> (Burning sensation in the throat)	(C-118)
<i>Dhāt al-Janb</i> (Pleurisy)	(D-17)
<i>Dhāt al-Ri'a</i> (Pneumonia)	(D-14)
<i>Waram-i-Lawzatayn</i> (Tonsillitis)	(C-107)
Peritonsillar abscesses	(J-36)
Alzheimer's	(G-30)
Parkinson's disease	(G-20)
Bronchitis	(D-7)
Pharyngitis	(C-98)
Allergic cough	(D-7.6)
<i>Ḥummā</i> (Fever)	(K-1)
Acute Lower Respiratory Tract Infections (ALRI or LRTI)	(J-22)
Lung abscess	(J-85)
Acute bronchitis	(D-33)
Chronic bronchitis	(D-34)
Emphysema	(D-35)
Bronchiectasis	(D-32)
Pulmonary oedema	(D-18)
Interstitial pulmonary fibrosis	(D-6.5)
Tumours of larynx	(D14.1)
Tumours of bronchi	(D-14.3)
Tumours of lungs	(D-14.3)
Bronchiolitis	(J-21)

Whooping cough	(D-25)
Pulmonary arterial hypertension (PAH)	(I-27)
Lymphangioma	(D18.1)
<i>Damawī</i> (sanguine) temperament	(O-11.1)
<i>Şafrawī</i> (bilious) temperament	(O-11.3)
<i>Balghamī</i> (phlegmatic) temperament	(O-11.2)
<i>Sawdawī</i> (melancholic) temperament	(O-11.4)
<i>Khilṭ-i-Dam</i>	(3.1.23)
<i>Khilṭ-i-Şafra'</i>	(3.1.39)
<i>Sū'-i Mizāj</i>	(O-17)

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EXECUTIVE SUMMARY

Cough is a reflex to irritating stimuli in the respiratory system, such as secretions, microbes, or *Sū'-i-Mizāj Ḥārr Sāda* (morbid hot temperament) (O-17.1.1.1). Globally, respiratory diseases are the third most common cause of death and fifth most common cause of disability. Cough can be classified based on its duration, characteristics, quality, and timing. Another categorization is *phlegm* production: dry or productive. While common, persistent cough can cause significant problems, including loss of sleep, exhaustion, irritability, cough syncope, social disability, and inability to perform daily activities.

Unani medicine addresses cough by correcting *Sū'-i-Mizāj* (morbid temperament) (O-17) using techniques such as *Taltif* (attenuation), *Taskhīn* (calorific), *Tartīb* (moistening), *Tajfif-o-Tanshif* (drying), or *Taghriya* (soothing), as required. Treatment also includes *Taskīn-i Su'āl* (anti-tussive therapy) and addressing the underlying cause. This study was designed to evaluate the safety and efficacy of the Unani pharmacopeial drug *Khamīra Banafsha* for *Su'āl Yābis / Surfa Yubsiyya* (Dry Cough) (D-7.6). *Khamīra Banafsha*, made primarily from *Viola odorata* L. flowers, is known for its *Munaffith* (expectorant) and *Taskīn-i Su'āl* (anti-tussive) properties.

STUDY DESIGN

This clinical trial was conducted at three Unani research centers: the Central Research Institute of Unani Medicine (CRIUM), Hyderabad; the Regional Research Institute of Unani Medicine (RRIUM), New Delhi; and the Regional Research Institute of Unani Medicine (RRIUM), Aligarh. Patients aged 18-60 years with *Su'āl Yābis / Surfa Yubsiyya* (D-7.6) lasting less than three weeks were included after obtaining written informed consent. The exclusion criteria were acute or chronic respiratory tract infections (J-98); chronic obstructive airway disease (COAD)(J-44); pulmonary tuberculosis (D-29); malignancies (M-16.2);

drug-induced cough; diabetes mellitus (G-2); hypertension (E-38); severe hepatic, renal, or cardiac conditions; and a history of addiction (smoking (F17.2), alcohol (N-36), or drugs (F19.220)). Pregnant (Z34) and lactating women (Z39.1) were excluded from this study.

The study sample size was 300 and distributed equally among the centers. Treatment lasted 7 days, with a study spanning two years. The participants received 7 g of *Khamīra Banafsha* twice a day. Baseline and post-treatment assessments included complete blood counts, liver function tests, kidney function tests, and random blood glucose levels. Safety was evaluated by comparing pre and post-treatment laboratory results and by observing adverse events. Efficacy was assessed using a 10-point cough visual analog scale (VAS), where 0 represented no cough and 10 represented the worst possible cough.

RESULTS

A total of 293 patients completed the study, with an age range of 18-60 years (mean age: 32.51 ± 11.36). The 18-29 age group had the highest representation (45.39%). The male to female ratio was 1.22:1. Most participants (96.59%) were non-vegetarian and of middle-class socioeconomic status (56.31%).

Temperament analysis showed that 39.93% of the patients were *Damawī* (sanguine) (O-11.1), 38.57% *Şafrāwī* (bilious) (O-11.3), 13.65% *Balghamī* (phlegmatic) (O-11.2), and 7.85% *Sawdāwī* (melancholic) (O-11.4). Most patients (99.32%) were newly diagnosed, with only 0.68% having a history of cough.

The treatment outcomes varied according to age and sex. Among the patients aged 18-29 years, 46 showed good response (30-59% improvement), 35 showed very good response (60-89%), and 32 showed poor response (<30%).

DISCUSSION

This study highlights the prevalence and effective management of dry cough in diverse populations. The higher incidence among younger adults (18-29 years) underscores the importance of early interventions. *Khamīra Banafsha* demonstrated significant *Taskīn-i Su'āl* (anti-tussive) and expectorant effects, particularly in males, which may be linked to physiological and anatomical differences. Most participants were middle class, emphasizing the need for holistic lifestyle assessments in cough management.

CONCLUSION

Khamīra Banafsha is effective and safe for managing dry cough, with notable anti-tussive and antimicrobial benefits. This study reinforces the importance of patient-specific approaches in treating cough, accounting for factors such as age, sex, and lifestyle. Further research is needed to expand our understanding and management of cough.

INTRODUCTION

Su'āl (Cough) is a sudden repetitive reflex to clear large breathing passages of secretions, irritants, foreign particles, and microbes.^{1,2} Cough is the same to the lungs as sneezing is to the brain.¹ *Su'āl Yābis* (Dry cough) (D-7.6) can arbitrarily be defined as a cough which produces no sputum.³

Cough can be classified based on its duration, character, quality, and timing. The duration can be acute (present for less than 3 weeks), subacute (present from 3 to 8 weeks), or chronic (present for more than 8 weeks). In addition, cough can be categorized as dry or productive (when sputum is coughed).⁴

A cough is a reflex to large amounts of inhaled material,² large amounts of mucus due to excessive secretions or impaired mucociliary clearance,³ and large amounts of abnormal substances such as edema fluid or pus. Thus, cough serves

a useful function but it can also lead to a variety of problems, including exhaustion (57%), feeling self-conscious (55%), insomnia (45%), life-style change (45%), musculoskeletal pain (45%), hoarseness (43%), excessive perspiration (42%), and urinary incontinence (39%).⁵ Besides it can lead to irritability, cough syncope, social disability, and inability to perform daily activities.⁶ It can also be a cause for vomiting, incontinence of urine and stool.⁷

Globally, Respiratory diseases rank the third most common cause of death and the fifth most common cause of disability.⁸ In India, chronic respiratory disease was estimated to account for 7% of all deaths and 3% of disability-adjusted life-years (DALYs) lost.⁹ Tobacco smoking is observed to be the most important risk factor associated with chronic respiratory morbidity.¹⁰ The prevalence of cough was found to be between 2.4 and 5.6 percent in the rural areas and 1.7 to 5.4 percent in the urban areas in different centers in India.¹¹ In another study by Gupta et al, the prevalence of cough was 2.2 percent and phlegm 2 percent in subjects living in houses without environmental tobacco smoke exposure and cough was 2.6 percent and phlegm was 2.2 percent in houses with environmental tobacco exposure and exposure to biomass fuels.¹²

The causes of *Su'āl Yābis* (Dry Cough) (D-7.6) is either *Su'-i-Mizāj Sāda* (abnormal temperament) (O-17.1.1) or *Su'-i-Mizāj Māddī* (abnormal substantial temperament) (O-17.1.2) such as *Damwī*, *Balghamī*, *Safrāwī*, and *Sawdāwī*.^{1,2,7,13} inflammation of nasal passages, sinuses (C-40),^{1,7,14,15} ulcers (C-26)⁷, foreign body (dust, smoke, cold air)^{2,7,16,17} hot and spicy foods,² disorders of stomach, spleen, liver, breast^{1,7} asthma (D-4)⁵ post infectious^{16,17} post viral¹⁸, ACE inhibitors, and gastro-esophageal reflux disease (GERD) (F-42)¹⁹.

The types of *Su'āl Yābis/Surfa Yubsiyya* (D-7.6) (Dry Cough) are as follows^{1,7}:

1. *Su'āl-e-Yabis Ḥārr Sāda*: It is caused by *Sū'-i-Mizāj Ḥārr Sāda* (O-17.1.1.1).
2. *Su'āl-e-Yabis Bārid Sāda*: It is caused by *Sū'-i-Mizāj Bārid Sāda* (O-17.1.1.2).

The clinical features of *Su'āl Yābis/Surfa Yubsiyya* (D-7.6) (Dry Cough) are as follows.

- In case of *Sū'-i-Mizāj Ḥārr Sāda* (O-17.1.1.1) patient feels thirsty, throat becomes dry, and hot places aggravates the cough. Cold air and Cold water soothes it^{1,7}.
- In case of *Sū'-i-Mizāj Bārid Sāda* (O-17.1.1.2) patient will not feel thirsty, and cold air and water aggravates the cough.
- If cough is severe at the time of *Imtilā'-i-Mi'da* (full stomach), involvement of the stomach should be considered.
- In cases of inflammation or ulcers in the lungs, the cough is aggravated by dust, smoke, talking, and reading, *Nabz* (Pulse) would be *Sari* and *Bawl* is *Garam*.

The line of treatment recommended for cough includes anti-histamines, decongestants, cough suppressants, and antibiotics. Whereas, the line of treatment according to Unani Medicine is *Ta'dīl-i-Sū'-i Mizāj* (Correction of morbid temperament) through *Taltif* (Attenuant), *Taskhīn* (calefaction), *Tartīb* (Moistening), *Tajfīf-o-Tanshīf* (Drying) or *Taghriya* (Soothing) as required; *Taskīn-i-Su'āl* (Anti-tussive) and removal of causative factor²⁰. Drugs with cold temperament are used when cough is due to *Sū'-i-Mizāj Ḥārr Sāda* (simple hot derangement of temperament) (O-17.1.1.1) and drugs with hot temperament are used when cough is due to *Sū'-i-Mizāj Bārid Sāda* (simple cold derangement of temperament) (O-17.1.1.2)⁷. Drugs beneficial for this condition are leaves of *Gāozabān* (*Borago officinalis* L.) *Sankhaholī* (*Onosma bracteatum* Wall.), *Tukhm Khaṭmī* (*Althaea officinalis* Linn.), *Sapistān* (*Cordia dichotoma* G.Forst.), roots of *Muleṭhī* (*Glycyrrhiza glabra* Linn.), fruits of 'Unnāb (*Ziziphus jujuba* Mill.) and *Kākrā Sīnghī* (*Rhus succedanea* L.). In addition, *Zardī-i-Bayḍ Nīm Brisht* (half boiled egg yolk) with *Hiltīt* (*Ferula assafoetida* L.) was used for the same purpose, as both provided heat⁷. The massage of *Rawghan Bādām Shīrīn* on the chest is

also very useful, as is *Sharbat Gūlar*, *Sharbat Khashkhāsh*, and the decoction of *Tukhm-i-Khashkhāsh* or *Post Khashkhāsh*.²⁰

DRUG PROFILE

Khamīra Banafsha is a Unani Pharmacopeial formulation containing the decoction of *Gul-i-Banafsha* (flowers of *Viola odorata* L.) as the main ingredient. *Khamīra* is a semisolid preparation made up of a decoction of plant parts in the base (*Qiwam*) made of purified sugar. The composition of *Khamīra Banafsha* is listed in Table 3.

Viola odorata, popularly known as “*Banafsha*” in Asia and frequently recognized as wood violet, sweet violet, English violet, common violet, florist's violet, or garden violet, is cultivated and grows spontaneously in six continents with Mediterranean and temperate climates. In India, it is distributed in Kashmir, the Western Himalayan region, at an altitude of 1500–1800 m. It is a versatile herb that has medicinal, ornamental, and aromatic properties.²¹

Botanical Description

Viola odorata belongs to the family *Violaceae* and is characterized by heart-shaped leaves, fragrant flowers, and trailing growth habits. (Fig 1, 2, 3, 4) The plant thrives in regions with Mediterranean and temperate climates, making it widespread across the six continents.

The plant is a low-growing, creeping herbaceous perennial that thrives in cool, moist, well-drained soils, often found in woods and hedgerows. It grows from a short, knotty rootstock, spreading both by seeds and creeping rhizomes. The plant bears heart-shaped, serrated leaves that are thick and soft in texture. Its solitary, fragrant flowers arise from the leaf axils, typically purple or violet, though white varieties also occur. Each flower has five petals, with the lower one forming a distinct spur at the back. Besides its showy spring blooms, the plant also produces cleistogamous (self-pollinating) flowers later in summer. The fruit is a small

capsule that splits open near the ground to release turbinate (top-shaped) seeds, aiding in its propagation.²² Microscopic examination of *Viola odorata* reveals distinct anatomical features in its rootstock, stems, leaves, and flowers. The rootstock is stout, knotty, and sometimes branched, brown in color, and often bears remnants of old leaf stalks and stipules. From it arise slender creeping stolons that root at the nodes, aiding vegetative propagation. The stolons have a single-layered epidermis, a parenchymatous cortex with intercellular spaces, and collateral vascular bundles where phloem encircles a cup-shaped xylem. The leaves, basal and broadly heart-shaped with crenate margins, are amphistomatic with anisocytic stomata on both surfaces. They possess various trichomes, including multicellular glandular hairs on margins, cylindrical and conical aglandular hairs on both surfaces and petioles, and deflexed hairs on petioles. The mesophyll shows clusters of calcium oxalate crystals (druses). In the flowers, smooth, spherical, tricolpate pollen grains with a single germ pore are observed. The petal epidermis has papillary projections, while the endothecium cells display characteristic thickenings. The floral tissues contain spiral vessels, rosette crystals, unicellular trichomes, polygonal parenchyma, and long, aseptate fibers, reflecting the plant's complex internal architecture.²²

Distribution

In India, *Viola odorata* is a hirsute or glabrous runner found throughout the temperate Himalayas upto an altitude of 2000m predominantly found in the Kashmir Valley and Western Himalayan regions like Meghalya, Nagaland and Manipur. Its adaptability to these ecological zones has rendered it a valuable component of traditional medicine in the region.²¹

Traditional Uses in Unani Medicine

The flowers of *Viola odorata*, known as *Gul-i-Banafsha*, are extensively valued for their therapeutic properties. The key medicinal actions attributed to the flowers are *Mulattif* (Attenuant), *Mu'arriq* (Diaphoretic), *Munaffith-i-Balgham* (Expectorant),

Musakkin-i-Dimāgh (Sedative), *Muhallil-i-Waram* (Anti-inflammatory) and *Dafī'-i-Hummā* (Antipyretic). *Banafsha* soothes and protects mucous membranes, facilitates mucus expulsion, alleviates respiratory tract congestion, reduces irritation in the respiratory tract, promotes sweating, reduces swelling and pain, calms the mind and nervous system, and aids in the management of fever and detoxification. Hence it is indicated in *Su'āl* (Cough) (D-7), *Nazla-o-Zukam* (Coryza and Catarrh) (C-21), *Khushūnat-i-Halaq* (Feeling of roughness in the throat) (C-119) and *Sozish-i-Halaq* (Burning sensation in the throat) (C-118), *Dhāt al-Janb* (Pleurisy) (D-17) and *Dhāt al-Ri'a* (Pneumonia) (D-14). It is known to relieve dry and productive cough by moistening the throat, relieving throat irritation and burning sensation, in addition to alleviating nasal congestion and a runny nose. It is also known to mitigate inflammation of the pleura, reduce pain and discomfort in the chest, and assist in relieving the symptoms of pneumonia by soothing the respiratory tract.^{23- 27}

Preclinical and Clinical Studies

- Several experimental and clinical studies have confirmed the pharmacological benefits of *Viola odorata*, aligning with its traditional use. *Viola odorata* extracts have demonstrated potent anti-inflammatory effects, helping reduce swelling and pain in conditions such as pleurisy and respiratory infections. In addition, the plant exhibits antibacterial and antifungal activities, which make it effective against a variety of pathogens. This property supports its use in treating infections, such as tonsillitis (C-107), peritonsillar abscesses (J-36), and respiratory ailments.²⁸
- Clinical studies have indicated that violet syrup, when used as an adjuvant with short-acting β -agonists, enhances cough suppression in children with intermittent asthma. It also provides relief from respiratory discomfort and improves quality of life. Based on these facts, clinicians find a niche in the management of respiratory disorders such as cough (D-7), asthma (D-4), tonsillitis (C-107), and

peritonsillar abscess (J-36). *Violet* syrup enhances the efficacy of bronchodilators, offering relief from cough and respiratory distress. Decoctions made from *Gul-i-Banafsha* have been shown to reduce the frequency and severity of these conditions, highlighting its antimicrobial potential. It is also effective for fever and detoxification. Its diaphoretic action reduces fever and promotes toxin elimination via perspiration. As a natural sedative, *Viola odorata* aids in calming the nervous system and can be used for pre-anesthetic care also.

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- *Khamīra Banafsha* exhibits antihypertensive potential through its relaxation of vascular smooth muscles, reduction of peripheral resistance, diuretic effects, promotion of sodium and water excretion to lower blood pressure, and antioxidant actions that combat free radicals implicated in hypertension pathophysiology.³⁰ Thus, *Khamīra Banafsha* can be a complementary therapy for managing mild-to-moderate hypertension.
- Studies suggest that *Khamīra Banafsha* possesses neuro-protective properties owing to its ability to reduce oxidative stress in neuronal tissues and protect brain cells from degeneration. It modulates the inflammatory pathways in the nervous system and prevents neuro-inflammation. It also has a calming effect on the nervous system, potentially aiding in anxiety, stress, and neurodegenerative conditions, such as Alzheimer's (G-30) and Parkinson's disease (G-20). Its sedative and calming properties make it a promising option for the management of neurological disorders linked to oxidative damage and inflammation.³¹
- Dyslipidemia, characterized by elevated LDL and triglycerides and low HDL levels, is a major risk factor for cardiovascular disease. *Khamīra Banafsha* helps by lowering LDL cholesterol, increasing HDL cholesterol, and reducing triglycerides. The flavonoids in *Viola odorata* inhibit lipid peroxidation and reduce oxidative damage to cholesterol. It supports lipid metabolism, improves overall lipid profiles, and modulates the liver enzymes involved in lipid synthesis. These

properties suggest its role in the prevention of atherosclerosis and coronary artery disease.³⁰

- The hepatoprotective effects of *Khamīra Banafsha* arises from its ability to neutralize toxins, reduce inflammation, and support liver regeneration. The antioxidants in *Viola odorata* scavenge free radicals that damage liver cells, downregulate pro-inflammatory cytokines in the liver, and promote repair mechanisms in hepatocytes. Its use may be beneficial for conditions such as fatty liver disease, drug-induced liver injury, and chronic liver diseases.^{24 - 27}
- The *Taskīn-i Su'āl* (antitussive) properties of *Khamīra Banafsha* are among the most recognized benefits of this Unani medicine. It soothes irritated mucous membranes in the throat and the respiratory tract. It reduces the frequency and intensity of cough, whether dry or productive, and exhibits mild sedative effects, calming cough reflexes.²⁹

These actions make it particularly effective in conditions such as bronchitis (D-7), pharyngitis (C-98), asthma (D-4), and allergic coughs (D-7.6). The pharmacological properties of *Viola odorata* can be attributed to its rich bioactive compound composition. These include flavonoids, alkaloids, saponins, and essential oils. Flavonoids contribute to their anti-inflammatory, antimicrobial, and antioxidant activities, whereas their alkaloids are responsible for their sedative and calming effects. Saponins aid in expectoration and mucous membrane protection, while their essential oils provide the characteristic fragrance and contribute to antimicrobial activity.^{26,27}

Compound Formulations in Unani Medicine with *Banafsha* are:

- ***Ḥabb-i-Banafsha***:- For *Ṣudā'* (Headache) (A-36), *Su'āl* (Cough) (D-7), and Asthmatic bronchitis (D-4).
- ***Sharbat-i-Banafsha***: For *Su'āl* (Cough) (D-7), *Zukām* (Coryza) (C-36), and *Ḥummā* (Fever) (K-1).

- ***Iṭrīfal Zamānī***: For *Su'āl* (Cough) (D-7) and Nasal congestion.
- ***Mufid Joshānda***: For *Ḥummā* Fever (K-1), *Zukām* (Coryza) (C-36), and Inflammation.
- ***Qurṣ-i-Dhāt-al-Janb***: Specifically for *Dhāt-al-Janb* (Pleurisy) (D-17).

Additional formulations, such as *Dayāqūza*, *Ḥabb-i-Lobān Qawī*, and *Qayrūṭī Muḥallil* further highlight its integration into the Unani pharmacopoeias.²⁴

Viola odorata holds a distinct place in Unani medicine because of its multipurpose therapeutic actions, including its role as a natural sedative, expectorant for respiratory relief, and antimicrobial agent for infections. In modern clinical settings, it complements treatments for respiratory disorders, enhances the efficacy of conventional bronchodilators, and provides symptomatic relief from cough (D-7) and asthma (D-4). Its diaphoretic and detoxifying properties make it valuable for managing fever and purifying the blood.²⁵⁻²⁷

Though, *Viola odorata* is generally safe for use, rare cases of hypersensitivity have been reported; hence, its use should be cautious in individuals with a history of allergies. Its excessive use may lead to gastrointestinal discomfort. Therefore, proper dosing, as guided by healthcare professionals, is crucial. Limited data are available on its safety during pregnancy and lactation; hence, it should only be used under medical supervision.³²

STANDARDIZATION OF *KHAMĪRA BANAFSHA*

Khamīra Banafsha is a Unani Pharmacopeial formulation with *Banafsha* (*Viola odorata* L.) as its principal component. Unani physicians consider *Khamīra Banafsha* to be an *Taskīn-i Su'āl* (anti-tussive) and *Mulayyin* (laxative).²³



Fig 1: Flowers of *Banafsha (Viola odorata L.)*



Fig 2: Flowers of *Banafsha (Viola odorata L.)*



Fig 3: Dried plant of *Banafsha* (*Viola odorata* L.)



Fig 4: Plant of *Banafsha* (*Viola odorata* L.)

Detailed Elaboration: Thin Layer Chromatography (TLC)

Thin-layer chromatography (TLC) is used to separate, identify, and analyze compounds present in a mixture. It is commonly employed in pharmaceutical analysis to verify the authenticity and quality of herbal and traditional medicinal formulations.

Steps for the TLC Analysis:

1. Preparation of the Test Solution

Sample Extraction:

- Take 5 g of the formulation (e.g., *Khamīra Banafsha*).
- Reflux the sample with 100 ml of alcohol to extract the active compounds.
- Filter the extract to remove any insoluble impurities.
- Concentrate the filtered extract to 10 ml for analysis.

2. Plate Preparation and Sample Application

- TLC Plate:

A precoated silica gel 60F254 TLC plate, which has a fluorescent indicator for UV detection, was used. The dimensions of the plates were 10×10 cm.

- Sample Application:

The test extract (10 µL) was applied to the TLC plate as a band at a height of 10 mm from the base of the plate.

3. Development of the TLC Plate

- Mobile Phase Composition:

A mixture of toluene and ethyl acetate at a ratio of 9:1 was used as the mobile phase. This solvent system facilitated the separation of compounds based on their polarity.

- Development Process:

The TLC plate was placed in a developing chamber containing the mobile phase. Ensure that the solvent level does not exceed the height of the applied sample.

The plate was allowed to develop until the solvent front reached 9 cm from the base.

Remove the plate and let it dry in the air.

4. Visualization of Spots

- Detection Reagent:

The TLC plate was sprayed uniformly with 5% vanillin sulfuric acid reagent, which reacted with the compounds to produce visible-colored spots.

- Heating:

The plate was heated at 105°C until the color of the spots or bands appeared clear, but charring was avoided.

5. Observation and Analysis

Observe the R_f values (Retention factors) and colors of the spots.

The R_f value is calculated using the formula:

$$R_f = \frac{\text{Distance traveled by the compound}}{\text{Distance traveled by the solvent front}}$$
$$R_f = \frac{\text{Distance traveled by the solvent front}}{\text{Distance traveled by the compound}}$$

Expected Results

Spots Identified:

Four spots should appear at the following R_f values and colors:

- R_f = 0.14 (Light grey)
- R_f = 0.24 (Grey)
- R_f = 0.82 (Grey)
- R_f = 0.95 (Violet)

Comparison:

- The TLC profile of the test solution should match the standard TLC profile of *Khamīra Banafsha* with respect to R_f values and spot characteristics.
- For the test to be considered valid, the relative standard deviation (RSD) of the R_f values must not exceed 2.0%.

Significance of Each Step

- **Extraction:**
Ensures that the active compounds are isolated in a concentrated form suitable for analysis.
- **TLC Plate Preparation:**
Silica gel provides a polar stationary phase, which is critical for separating compounds based on their polarity and interaction with the mobile phase.
- **Mobile Phase Selection:**
The toluene: ethyl acetate mixture was non-polar to moderately polar, enabling optimal separation of the components in the formulation.
- **Visualization with Vanillin Sulphuric Acid:**
This reagent reacts with organic compounds, highlighting the separated spots for easy identification.
- **R_f Value Matching:**
It ensures consistency with the standard profile of *Khamīra Banafsha*, verifying its authenticity and composition.

Key Considerations for Validation

- **Reproducibility:**

The Rf values must be within the acceptable range ($RSD \leq 2.0\%$) to ensure precision and reliability.

- Charring Prevention:

Controlled heating avoids damage to the plate and ensures clear visualization of spots.

- Comparison with Standards:

The TLC profile of the test solution must match that of the reference standard in order to confirm its quality and identity.

After confirming the TLC profile consistency, the physicochemical parameters of *Khamīra Banafsha* were evaluated to ensure compliance with Unani Pharmacopeial standards (Table 1).

Physicochemical parameters:

Table 1: Physicochemical standards of *Khamīra Banafsha*

S. No.	Physicochemical Standards	Mean \pm SEM
1	Loss of weight on drying at 105 °C (%)	≤ 105
2	Ash value in (% w/w)	
	Total Ash	≤ 1
	Acid Insoluble Ash	≤ 0.05
	Water Soluble Ash	0.44 ± 0.001
3	pH value	
	pH at 1%	5-6
4	Solubility in %	

	Alcohol Soluble extractive	≤13
	Water Soluble extractive	≤ 79
5	Sugar content in %	
	Reducing	≤ 12
	Non Reducing	≤ 27

STUDY RATIONALE

Cough is one of the most prevalent symptoms of respiratory diseases, ranging from acute to chronic. It serves as a protective reflex that clears the airways of irritants, mucus, and pathogens. Despite its utility, persistent coughing can significantly impact the quality of life by causing fatigue, sleeplessness, and discomfort. In conventional medicine, the primary treatment options for cough are suppressants and antihistamines. While these drugs provide symptomatic relief, their prolonged use is associated with adverse effects such as sedation, impaired alertness and productivity, constipation, which affects gastrointestinal health, and addiction. Prolonged use can lead to dependency, limiting long-term utility. Given these limitations, there is growing interest in alternative and traditional medicine systems that offer effective and safer remedies for cough management.

Unani Medicine has a rich repository of single and compound herbal formulations for the treatment of respiratory ailments. *Su'āl Yābis /Surfa Yubsiyya* (Dry Cough) (D-7.6), characterized by the absence of sputum, is a common complaint addressed in Unani medicine. Several Unani remedies are known for their safety, efficacy, and ability to restore balance in the body's temperament. These remedies are designed not only to suppress cough, but also to address the underlying cause, making them particularly useful for long-term management.

Among the various formulations, *Khamīra Banafsha* is a well-known pharmacopoeial preparation in Unani medicine. (Table 2) It is prepared from the flowers of *Viola odorata* (*Banafsha*), which are known for their medicinal properties.

Khamīra Banafsha is a known *Munaffith* (expectorant) and *Taskīn-i-Su'āl* (Cough Suppressant). It facilitates the expulsion of mucus and clears the respiratory passages. It is also known to alleviate the frequency and intensity of coughing by soothing the throat and the respiratory mucosa. Because of these properties, *Khamīra Banafsha* is traditionally used for the treatment of all types of *Su'āl* (Cough) (D-7), including *Su'āl Yābis /Surfa Yubsiyya* (Dry Cough) (D-7.6), and other respiratory ailments such as colds, catarrh, and mild bronchial conditions.^{23,}

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Despite its extensive use in Unani medicine and the anecdotal evidence supporting its efficacy, scientific data on the safety and effectiveness of *Khamīra Banafsha* remain limited. In the modern era of evidence-based medicine, it is crucial to validate traditional remedies using standardized scientific methodologies. Therefore, there is a need to systematically study the mechanism of action and effectiveness of *Khamīra Banafsha* in suppressing dry cough. While Unani medicine considers it a safe formulation, empirical evidence on its safety profile during short and long-term use is lacking (Table 3). In addition, pharmacological and clinical studies are essential for establishing the consistent quality and reproducibility of the formulation.

With this in mind, the current study aimed to evaluate the efficacy of *Khamīra Banafsha* in the treatment of *Su'āl Yābis /Surfa Yubsiyya* (Dry Cough) (D-7.6) and to validate its safety through clinical trials, ensuring that it is a safer alternative to conventional cough suppressants and antihistamines, particularly for long-term use. This research also aligns with the growing trend of integrating traditional medicine into modern healthcare practices and offering holistic treatment options

to patients. Scientific validation of the Unani pharmacopeial formulation *Khamīra Banafsha* will bolster its credibility and encourage its adoption in mainstream healthcare.

STUDY OBJECTIVES

- To evaluate the safety of the Unani Pharmacopeial formulation *Khamīra Banafsha* in cases of *Su'āl Yābis /Surfa Yubsiyya* (Dry Cough) (D-7.6).
- To evaluate the efficacy of the Unani Pharmacopeial formulation *Khamīra Banafsha* in cases of *Su'āl Yābis /Surfa Yubsiyya* (Dry Cough) (D-7.6).

STUDY DESIGN

The study was designed as an open-label, single group, multicentric clinical trial carried out at three institutes of the Central Council for Research in Unani Medicine. Patients of *Su'āl Yābis* (Dry Cough) were enrolled in accordance with selection criteria mentioned in the protocol. Subjects were given research drug *Khamīra Banafsha* for a period of 7 days in the prescribed dose. All the clinical follow ups and laboratory investigations were done at the baseline and at the end of the treatment.

CTRI Registration Number:

The protocol was registered in the Clinical Trial Registry, India, with registration number CTRI/2018/08/015446.

STUDY SITE(S)

The clinical study was conducted at the following centres:

- Central Research Institute of Unani Medicine (CRIUM), Hyderabad
- Regional Research Institute of Unani Medicine (RRIUM), New Delhi

- Regional Research Institute of Unani Medicine (RRIUM), Aligarh

SELECTION CRITERIA

Patients with clinically-diagnosed *Su‘āl Yābis/ Surfa Yubsiyya* (Dry cough) (D-7.6) attending OPD of respective centers were included in the study according to the following inclusion criteria:

Inclusion Criteria

- Patients of either sex in the age group of 18-60
- *Su‘āl Yābis/ Surfa Yubsiyya* (Dry cough) (D-7.6) of < 3 weeks duration

Exclusion Criteria

The patients with following conditions were excluded from the study:

- Acute Upper Respiratory Tract Infections (URI or URTI) (J-6.9)
- Acute Lower Respiratory Tract Infections (LRI or LRTI) (J-22) include pneumonia (D-14), lung abscess (J-85), and acute bronchitis (D-33).
- Chronic obstructive airway disease (COAD) (J-44) including Chronic Bronchitis (D-34) and emphysema (D-35).
- Bronchiectasis (D-32), Pulmonary tuberculosis (D-29), Pulmonary Oedema (D-18), interstitial Pulmonary Fibrosis (D-6.5)
- Tumours of larynx (D-14.1), bronchi (D-14.3), and lungs (D-14.3)
- Drug-induced Cough (e.g., ACE Inhibitors)
- Known cases of severe hepatic, renal or cardiac ailments such as Diabetes Mellitus (G-2), Hypertension (E-38)
- H/o addiction (smoking, alcohol, drugs)
- Pregnant and lactating women

SAMPLE SIZE

The Study is executed at three peripheral centers of the council, each center allocated a sample size of 100, bring a total sample size of 300 complete cases, considering of 95% Confidence Interval with 5% Alpha error and allowance of 20% for attrition (loss of follow-up, drop out, withdrawal, non-compliance, etc.) However, there was no restriction on the number of participants to be recruited by each center. A center can recruit more than its expected share, and the study will be terminated once the target of 300 SS is achieved.

DURATION OF PROTOCOL THERAPY

The total duration of treatment was 7 days.

DURATION OF STUDY

The required number of trial subjects was supposed to be attained in the institute's OPD within two years. Hence, the duration of the research project was fixed at two years. The study was started in January 2018 and ended in October 2021, and the time period of the study was extended due to the COVID-19 pandemic.

MATERIAL AND METHODS

After initial screening, patients diagnosed with *Su'āl Yābis/ Surfa Yubsiyya* (Dry cough) (D-7.6) were enrolled based on protocol-defined eligibility criteria and administered the trial drug *Khamīra Banafsha* for a period of 7 days in prescribed doses i.e.7gms BD. All participants were provided with bilingual Patient Information Sheet (PIS) and a written Informed-Consent was obtained prior to any study-related procedures. Demographic details, current disease status, co-morbidities, and concurrent therapies were documented, followed by comprehensive physical and systemic examinations. Dry cough-related signs and symptoms were recorded in the Case Report Form (CRF), and vital signs,

including blood pressure, heart rate, temperature, and respiratory rate, were also recorded. Laboratory investigations were conducted at baseline and after the treatment, covering haematological profile (Hb%, TLC, DLC, RBCs, PCV, ESR), lipid profile (Total Cholesterol, LDL, VLDL, HDL, Triglycerides), liver function tests (S. Bilirubin, SGOT, SGPT, S. Alkaline Phosphatase), kidney function tests (S. Urea, S. Creatinine, S. Uric Acid), fasting blood sugar (baseline only to exclude diabetics), insulin levels baseline only, thyroid profile (T3, T4, TSH at baseline), and routine/microscopic urine analysis. Clinical assessments were conducted fortnightly, and the efficacy of *Khamīra Banafsha* was evaluated based on changes in a Cough Visual Analog Scale (VAS) and relevant clinical parameters.

STUDY DRUG DETAILS

The Drug required for the clinical study will be procured from GMP certified pharmacy of National Research Institute of Unani Medicine for Skin disorders (NRIUMSD), Hyderabad with standardization and quality control.

Table 2: Details of *Khamīra Banafsha* usage

Study drug	Drug form	Route of administration	Dose	Frequency	Instructions
<i>Khamīra Banafsha</i>	Semi-solid	Oral	7 gm	BD	Administered with water

Table 3: Ingredients of *Khamīra Banafsha*:²³

S.No.	Name of the Ingredient	Botanical/English name	Part used	Quantity
1.	<i>Gul-i-Banafsha</i>	<i>Viola odorata</i> Linn.	Flower	200 gm

2.	<i>Āb</i>	Purified water	Liquid	3 ltr
3.	<i>Qand Safayd</i>	<i>Saccharum officianale</i>	Crystals	1.6 kg

CONCOMITANT/ADJUVANT THERAPY

No concomitant medication was allowed.

FOLLOW-UP EVALUATION

The patients were assessed clinically after one week. The subjective and objective clinical observations were recorded in the follow-up sheet.

Scheduling Follow-Up Visits

If any follow-up visit was missed, the visit was rescheduled as soon as possible within an interval of +/ – 3 days.

ASSESSMENT OF *MIZĀJ* (TEMPERAMENT)

Assessment of *Mizāj* (Temperament) was done at baseline and at the end of treatment (*Annexure-III*).

LABORATORY INVESTIGATIONS

Each case of *Su'āl Yābis/ Surfa Yubsiyya* (Dry Cough) (D-7.6) selected for the study was subjected to the following pathological and biochemical investigations at baseline and at the end of treatment, and the reports received from the laboratory were attached to the case record form.

Pathological Investigations

- Haemogram (Hb%, TLC, DLC, AEC, ESR)

Biochemical Investigations

- Liver Function Tests (LFTs): Serum Bilirubin, SGPT, SGOT, S. Alkaline Phosphatase

- Kidney Function Tests (KFTs): Serum Creatinine, Serum Urea, Serum Uric Acid
- Blood Glucose (Random): at baseline only

Radiological Investigations

- X-ray Chest PA view

PARAMETERS FOR ASSESSMENT OF SAFETY

1. Clinical Parameters:

- Adverse Events

2. Laboratory Parameters

- CBC (Hb%, TLC, DLC, ESR)
- LFT (S. Bilirubin, SGOT, SGPT, S. Alkaline phosphatase)
- KFT (S. Urea, S. Creatinine, Serum uric acid)
- Urine R/M

PARAMETERS FOR ASSESSMENT OF EFFICACY

Cough Visual Analogue Scale (Cough VAS)

Cough severity was assessed and recorded using a cough visual analog scale (VAS). The cough VAS is a vertically marked 10-points (0-9) linear scale that responds to changes in cough severity. All patients were asked to mark cough severity on the Cough VAS. The extremes of the scale ranged from 0 ("no cough") to 9 ("worst cough ever") (minimum significant change = 1.5)¹⁷.

Worst Cough 9 –

8 –

7 –

6 –

5 –

4 –

3 –

2 –

1 –

No Cough 0 –

COUGH VISUAL ANALOGUE SCALE (VAS)

STATISTICAL ANALYSIS

The results of the study were analyzed using SPSS V26.0. Baseline and follow-up values of clinical subjective parameters and pathological and biochemical parameters were statistically analyzed using the Friedman post hoc test, Wilcoxon signed-rank test, and Student's paired t-test. A p-value of less than 0.05 ($p < 0.05$) was considered statistically significant, while $p < 0.01$ and $p < 0.001$ were regarded as highly and very highly significant, respectively.

ETHICAL APPROVAL

Written approval for the study was obtained from the Institutional Ethics Committees (IECs) of the respective centers prior to enrolment of the subjects in the trial.

ASSESSMENT OF RESULTS

The results of the study were recorded in terms of percentage efficacy as calculated from the reduction in cough.

RESULTS

Demographic Characteristics

The study enrolled a total of 293 patients diagnosed with *Su’āl Yābis/Surfa Yubsiyya* (Dry Cough) (D-7.6), aged between 18 and 60 years, with a mean age of 32.51 ± 11.36 years (Table 4). A significant proportion of the participants (45.39%) were in the 18–29 years age group, followed by 26.96% in the 30–39 years age group, 17.06% in the 40–49 years age group, and 10.58% in the 50–60 years age group (Table 5, Figure 5).

Table 4: Age distribution of patients (Mean \pm SD, Range)

Characteristics		Number of Cases
Age	Mean \pm SD	32.51 \pm 11.36
	Range	18-60

Table 5: Age-wise distribution of the patients

Age Group (in Years)	Total Number of Patients		Percentage (%)
	Male	Female	
18-29	73	60	45.39
30-39	43	36	26.96
40-49	24	26	17.06
50-60	22	9	10.58
Total	293		100.00
Mean \pm S.D	32.51\pm11.36		

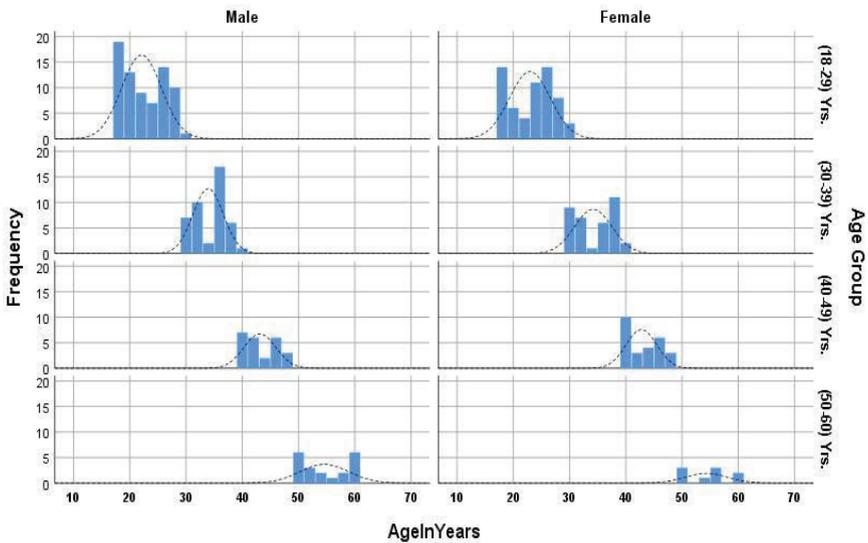
The sex distribution revealed that 55% of the patients were male (n=162) and 45% were female (n=131), indicating a slightly higher prevalence of dry cough among males (Table 6). This may be attributed to anatomical and physiological differences

between sexes, which are discussed further in the subsequent sections. It is evident that the sample was not perfectly balanced, with 162 males and 131 females. The data therefore show a near-balanced gender distribution.

Table 6: Gender-wise distribution of the patients

Gender	Number of Cases	Percentage (%)
Male	162	55%
Female	131	45%

Fig 5: Age and Gender-wise distribution of the patients



Dietary and Socioeconomic Status

The majority of the participants (**96.59%**) were non-vegetarians, with only 3.41% identified as vegetarians (Table 7, Figure 6). This dietary habit was notable across the sample, and may reflect regional or cultural dietary preferences. Additionally,

most participants (**56.31%**) belonged to the middle socioeconomic class, followed by 42.67% in the lower class, and only 1.02% in the higher class (Table 8, Figure 7). The prevalence of dry cough in the middle class may be associated with environmental or occupational exposure and access to health care.

Table 7: Dietary Habits Status-wise distribution of the patients

Dietary Habit	Number of Cases	Percentage (%)
Vegetarian	10	3.41
Non-vegetarian	283	96.59
Total	293	100.00

The dietary preferences of the sample were divided into "Vegetarian" and "Non-vegetarian." Non-vegetarians. The vast majority (around 97%) of the sample falls into the "non-vegetarian" category.

Fig 6: Dietary Habits Status-wise distribution of the patients

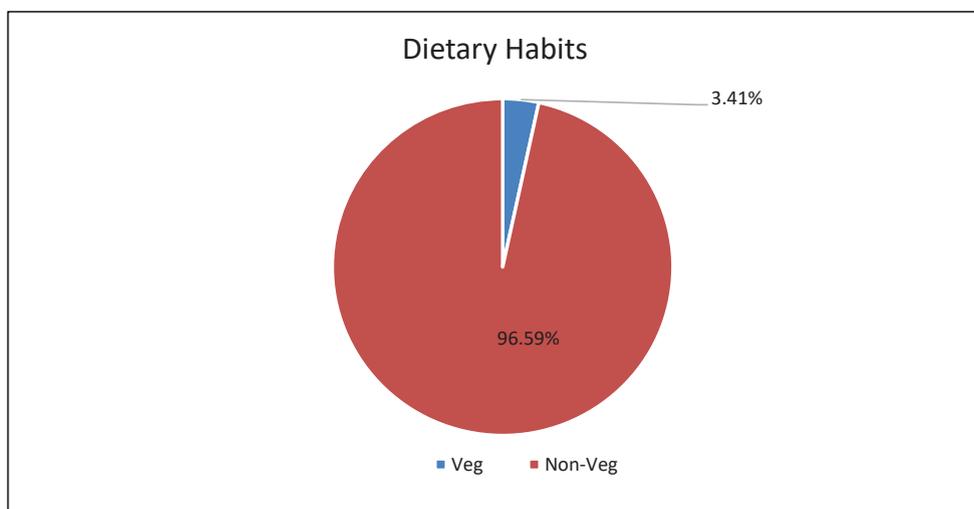


Table 8: Social Economic distribution of the patients

Socio-economic Status	Number of Cases	Percentage (%)
Lower	125	42.67%
Middle	165	56.31%
Higher	03	1.02%

Table 8 provides information about the socio-economic status of the sample, with most individuals falling into the "Middle" category.

Understanding the socio-economic distribution of the sample helps to analyze the socio-economic influence on disease factors. The details of this are discussed in the following sections.

Fig 7: Socio economic distribution of the patients

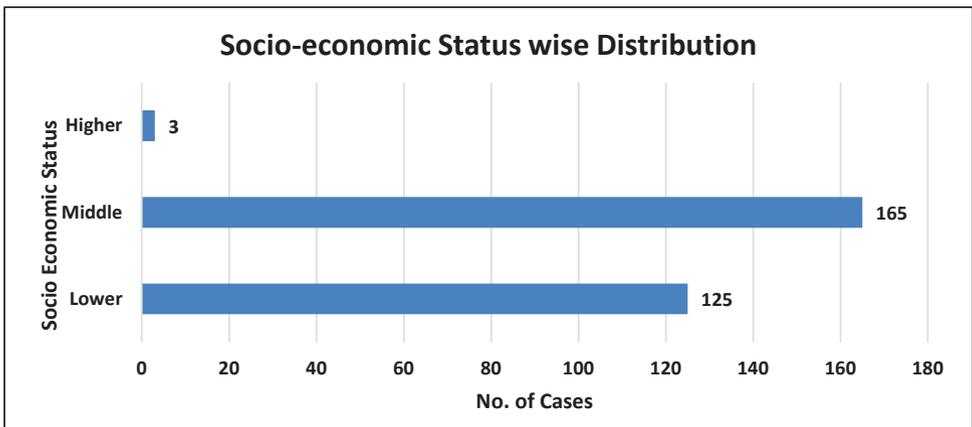
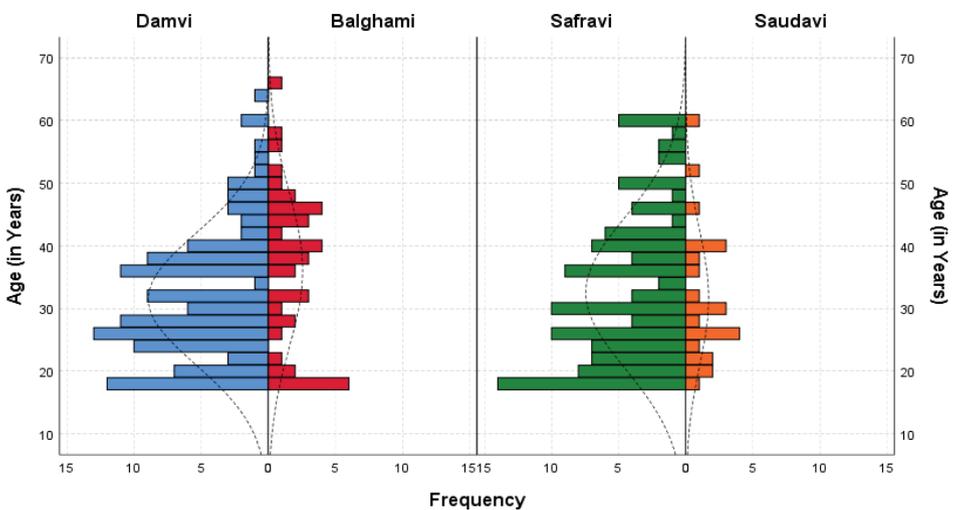


Table 9: Distribution of patients according to Temperament

Temperament	Number of Cases	Percentage (%)
<i>Damawī</i> (Sanguine)	117	39.93
<i>Balghamī</i> (Phlegmatic)	40	13.65
<i>Şafrawī</i> (Bilious)	113	38.57
<i>Sawdāwī</i> (Melancholic)	23	7.85
Total	293	100.00

The distribution of individuals according to temperament has been shown in Table 9 and Figure 8, with *Damawī* (Sanguine) (O-11.1) emerging as the most prevalent. It highlights the association between *Damawī* (Sanguine) (O-11.1) and *Şafrawī* (Bilious) (O-11.3) temperaments and their link with disease occurrence.

Figure 8: Distribution of patients according to Temperament



THERAPEUTIC RESPONSE BY DEMOGRAPHICS

The response to *Khamīra Banafsha* treatment varied according to age, sex, and temperament.

- **Age Group Response (Table 10):**

Patients in the 18–29 age group showed the highest rate of positive responses, with 15.04% achieving an "Excellent" response (90–100% improvement) and 26.31% showing a "Very Good" response (60–89% improvement). This highlights the influence of age-related factors such as immune resilience and anatomical efficiency.

Older age groups showed a progressively reduced response rate, with approximately 35 % of patients in the 50–60 years group achieving 'Very Good' or 'Excellent' outcomes

Table 10: Response in relation to the Age of the patients

Age Group (Years)	Number of Cases (n)	Excellent (90-100 %)	Very Good (60-89 %)	Good (30-59 %)	Poor (< 30 %)
18-29	133	20	35	46	32
30-39	79	10	24	11	34
40-49	50	10	8	16	16
50-60	31	3	8	9	11
Total	293	43	75	82	93

Table 10 provides a breakdown of the sample population by age and health status. A fair number of individuals in all age groups fall into the "Poor (31.7%)" health

status category, which indicates that a substantial portion (68.2%) of the sample responded positively to the treatment.

- **Gender Response (Table 11, Figure 9):**

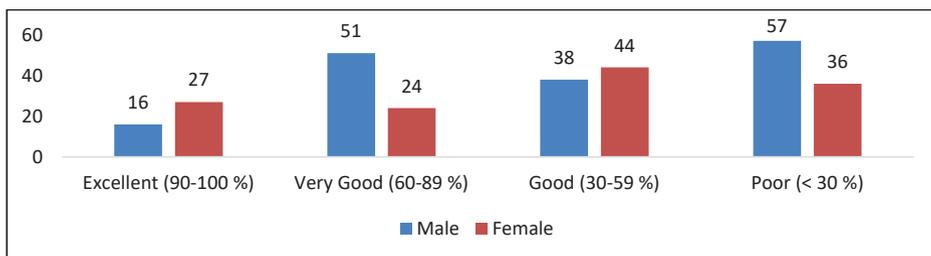
Male patients exhibited higher rates of "Very Good" responses (31.5%) compared to females (18.3%). However, females had a slightly higher percentage of "Excellent" responses (20.6%) compared to males (9.8%).

Table 11: Response in relation to the Gender of the patients

Gender	Number of Cases (n)	Excellent (90-100 %)	Very Good (60-89 %)	Good (30-59 %)	Poor (< 30 %)
Male	162	16	51	38	57
Female	131	27	24	44	36
Total	293	43	75	82	93

Similar to age distribution, Table 11 categorizes individuals by gender and health status. A substantial number of patients (64.8% male and 72.8% females) responded positively to the treatment. Only 35.2% of the men and 27.5% females did not respond to treatment.

Figure 9: Response in relation to the Gender of the patients



• **Temperament Response (Table 12, Figure 10):**

Patients with *Damawī* (Sanguine) temperament (O-11.1) showed the most favorable response, with 79.5% achieving moderate-to-excellent improvement.

In contrast, patients with *Sawdāwī* (Melancholic) temperament (O-11.4) had the least favorable outcomes, with 60.9% showing "Poor" responses (<30% improvement).

Table 12: Response in relation to the Temperament of the Patients

Temperament	No. of Patients (n)	Excellent (90-100 %)	Very Good (60-89 %)	Good (30-59 %)	Poor (< 30 %)
<i>Damawī</i> (Sanguine)	117	24	34	35	24
<i>Balghamī</i> (Phlegmatic)	40	5	6	13	16
<i>Şafrāwī</i> (Bilious)	113	12	31	31	39
<i>Sawdāwī</i> (Melancholic)	23	2	4	3	14
Total	293	43	75	82	93

Table 12 provides insights into the relationship between temperament and health status. Different temperaments showed varying distributions across health status

categories. *Damawī* (sanguine) (O-11.1) achieved a maximum success rate of 79.5%.

Figure 10: Response in relation to the Temperament of the Patients

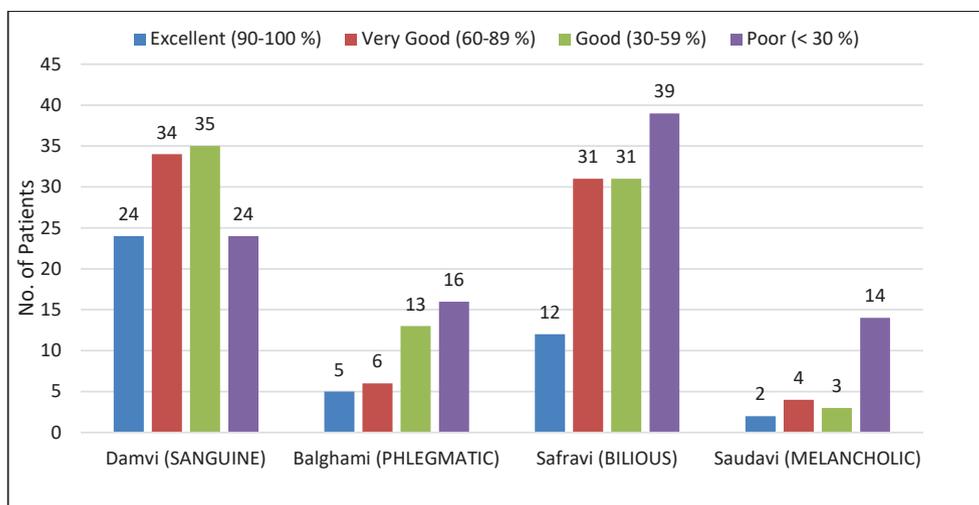
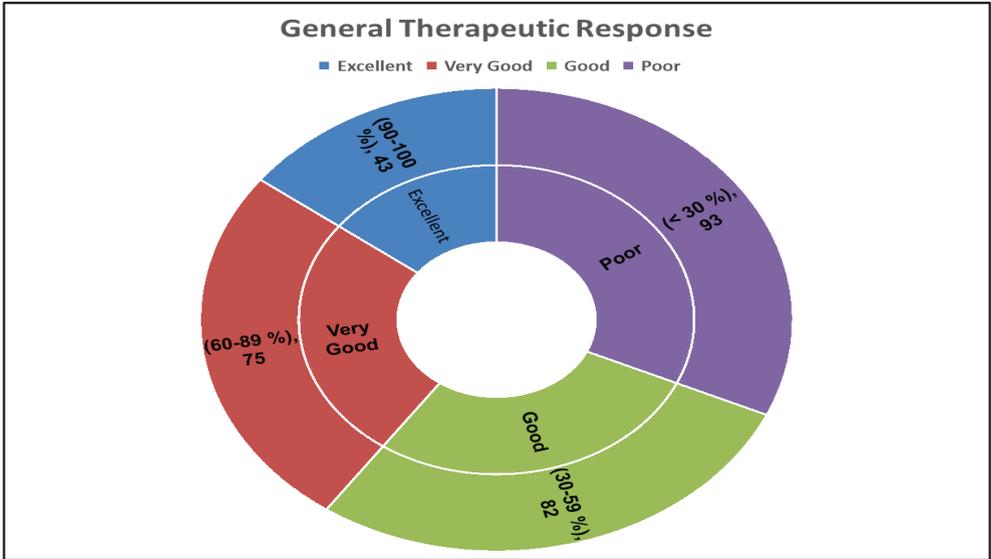


Table 13: General Therapeutic Response

	Total	Excellent (90-100 %)	Very Good (60-89 %)	Good (30-59 %)	Poor (< 30 %)
No. of Patients	293	43	75	82	93
Percentage (%)	100.00	14.68	25.60	27.99	31.74

Table 13 and the corresponding Figure 11 presents the percentage distribution of health statuses across the entire sample population. It's evident that a significant portion (68.2%) of the sample has responded positively whereas only (31.7%) are in the "Poor" health, making up only one-third of the population.

Fig 11: General Therapeutic Response



Clinical Efficacy

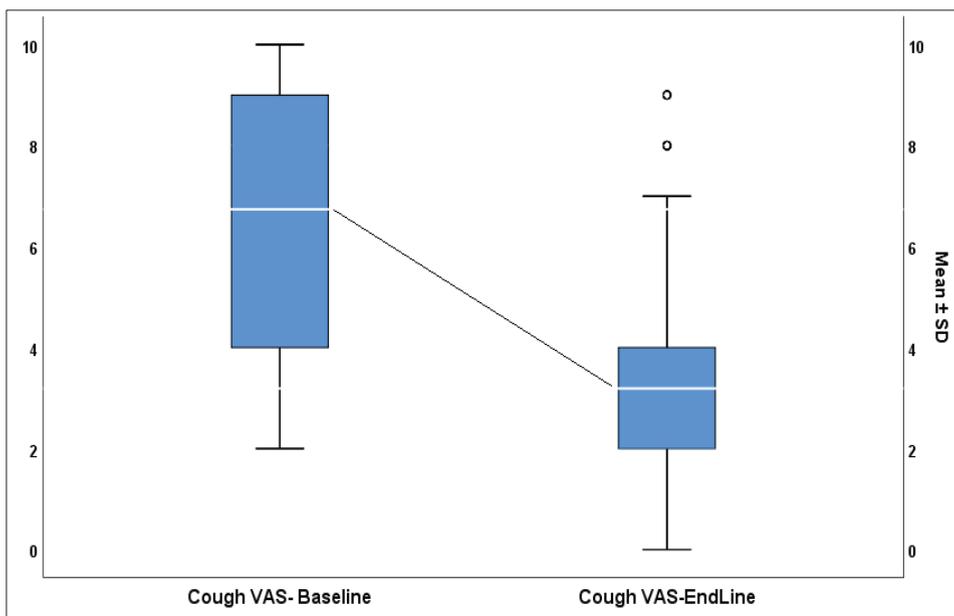
The efficacy of *Khamīra Banafsha* was evaluated using the Cough Visual Analogue Scale (VAS). At the end of the study, the baseline mean score was 6.74 ± 2.32 , which significantly reduced to 3.19 ± 2.27 at the end of the study. The mean improvement of 3.55 points was highly statistically significant ($p < 0.001$) (Table 14, Figure 12). This result highlights the substantial reduction in cough severity among the participants.

Table 14: Effect of drug on clinical Subjective parameters

Clinical Symptoms	Mean±SD		Mean Changes	
	Baseline	End of the Study	BL-EL	p-value
Cough (VAS)	6.74 ±2.32	3.19±2.27	3.55*	<0.001

Table 14 presents clinical symptom evaluation data, including the mean, standard deviation (S.D.), and mean changes. This demonstrates the efficacy of the treatment for all the parameters.

Fig 12: Response of therapy as per Cough VAS score



Laboratory Parameters

Baseline and post-treatment laboratory investigations showed minimal changes in most hematological and biochemical parameters, confirming the safety profile of the study drug. (Table 15, Fig 13)

- Haemoglobin (Hb) levels remained stable at 13.02 ± 1.87 g/dL before treatment and 12.95 ± 1.90 g/dL after treatment. The mean change in Hb was minimal (0.06 g/dL), with no statistically significant difference ($p =$

0.14). Likewise, there were negligible changes in the DLC and ESR, which were statistically insignificant. (Fig 13)

- Liver function tests (LFTs), including SGPT and SGOT, showed negligible changes, indicating no hepatic toxicity. ALP increased by 25.60 IU/L. This demonstrates the anti-inflammatory effects of the drug. (Fig 14)
- A significant reduction in total leukocyte count (TLC) was a significant reduction (mean change of 3034.43/mm³) was observed with a highly significant p-value (p < 0.001). (Fig 13)

Table 15: Effect of Drug on Laboratory Parameters

Name of Parameter		Mean ± SD		Mean change (B.L-AT)	Paired 't' test	
		Before Treatment	After Treatment		Statistic value	P-value
H A E M O G R A M	Hb(g/dL)	13.02±1.87	12.95±1.90	0.06	1.5	0.14
	TLC(/mm ³)	7246.65 ±1863.95	4212.21±3542.8 2	3034.43	12.91	<0.001
	N (%)	61.51±10.08	61.15±9.39	0.36	0.67	0.50
	L (%)	32.77±10.05	33.30±9.05	-0.53	-1.01	0.31
	E (%)	4.02±4.86	3.60±3.03	0.41	1.68	0.09
	M (%)	2.21±1.40	2.08±1.38	0.13	1.51	0.13
	B (%)	-	-	-	-	-
	ESR 1st Hr (mm)	24.15±16.50	22.69±17.25	1.46	1.68	0.09

	ESR 2nd Hr (mm)	39.58±28.51	38.74±38.91	0.84	0.30	0.76
L F T	S.Bilirubin (mg/dL)	0.71±0.31	0.73±0.34	-0.017	-1.02	0.31
	SGOT (IU/L)	24.53±17.13	23.87±10.79	0.66	0.65	0.52
	SGPT (IU/L)	25.94±16.68	25.79±15.05	0.15	0.21	0.84
	S.Alkaline Phosphatase	89.09±34.51	114.70±35.98	25.60	-1.08	.28
K F T	S.Creatinine (mg/dL)	0.875±0.381	0.932±0.232	-0.057	-1.11	0.27
	Blood Urea (mg/dL)	16.48±12.25	23.69±7.18	7.20	-9.54	<0.001
	Serum Uric Acid (mg/dL)	4.90±1.42	4.86±1.38	-0.04	-1.02	0.31

Fig 13: Response of Pathological (Haemograms)

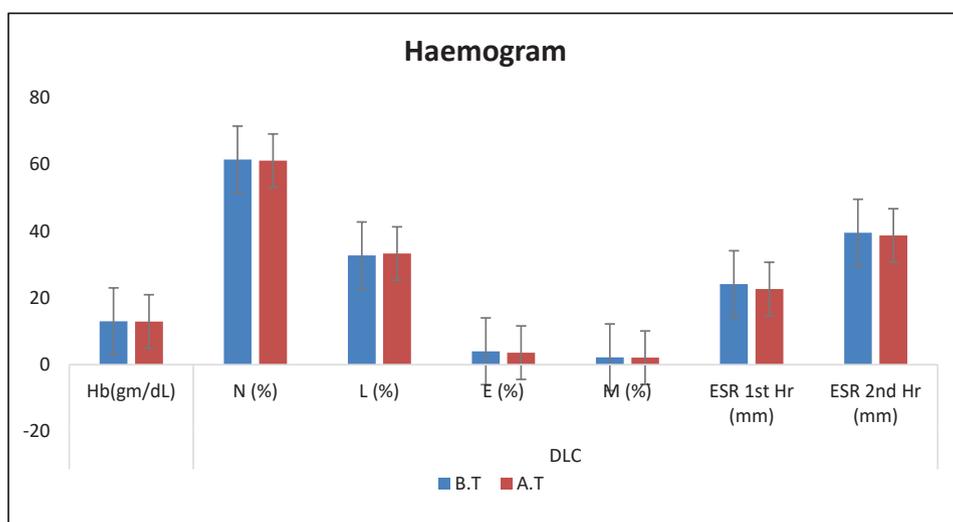


Fig 14: Response of Pathological (Liver Function Test)

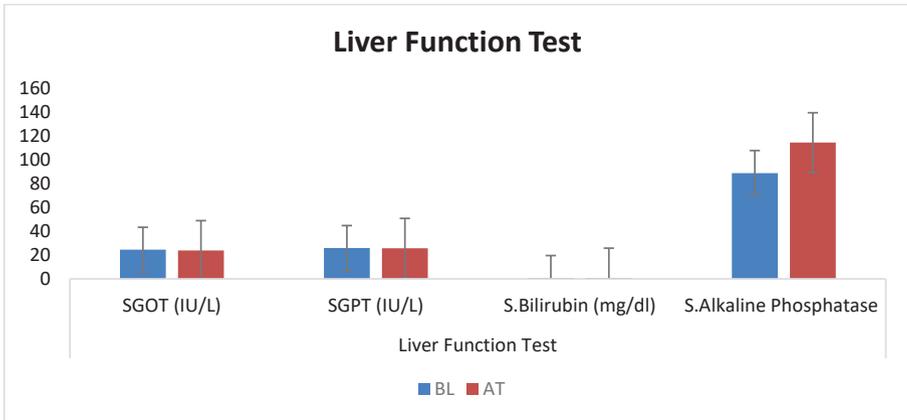
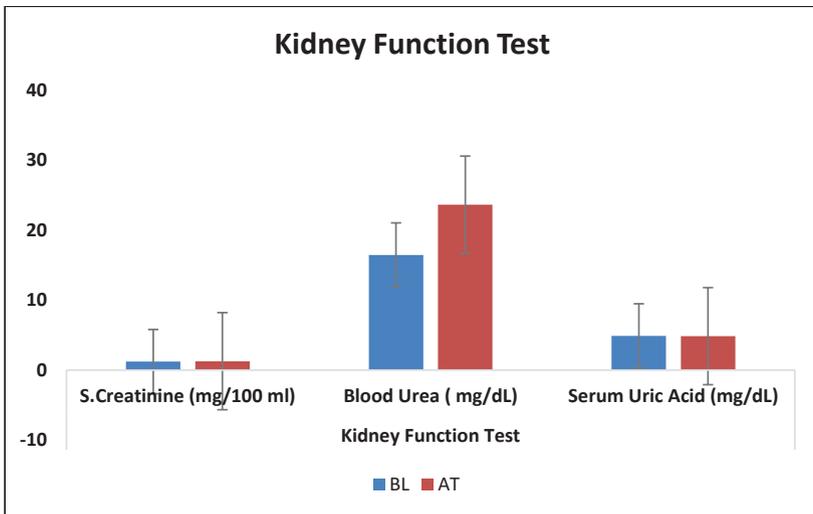


Fig 15: Response of Pathological (Kidney Function Test)



Safety analyses showed *Khamīra Banafsha* was well tolerated. Haemoglobin, differential leukocyte counts, ESR, and liver enzymes remained unchanged from baseline to endpoint, with no significant differences. The key changes were a decrease in total leukocyte count (TLC). TLC fell from 7246.65 ± 1863.95 to

4212.21 ± 3542.82 cells/mm³ (p < 0.001), compatible with reduced inflammatory activity; no patient developed leukopenia outside normal range (Table 15).

The reduction in TLC, is the most straightforward and compelling finding. It strongly suggests that *Viola odorata* possesses powerful anti-inflammatory or anti-infective properties. By reducing the overall white blood cell count, it is directly addressing the systemic cause of the illness.

General Therapeutic Outcomes

The overall therapeutic response to *Khamīra Banafsha* was as follows:

- 14.68% of patients achieved an "Excellent" response (90–100% improvement).
- 25.60% had a "Very Good" response (60–89% improvement).
- 27.99% showed a "Good" response (30–59% improvement).(Table 13)
- 31.74% fell into the "Poor" response category (<30% improvement) (Table 13, Figure 11).

These findings suggest that approximately 68.2% of patients experienced moderate to excellent improvement, emphasizing the efficacy of *Khamīra Banafsha* in managing *Su'āl Yābis / Surfa Yubsiyya* (Dry Cough) (D-7.6).

OBSERVATIONS

A total of 293 patients participated in this study, with ages ranging from 18 to 60 years and a mean age of 32.51 ± 11.36 years (Table 4).

Demographic Distribution

The study population was predominantly male with a male-to-female ratio of 1.22:1 (Table 6, Figure 5). The largest age group was 18–29 years, comprising 45.39%

of the participants, followed by 26.96% in the 30–39 years group, 17.06% in the 40–49 years group, and 10.58% in the 50–60 years group (Table 5, Figure 5).

Dietary and Socioeconomic Characteristics

Most participants (96.59%) reported a non-vegetarian diet, whereas only 3.41% followed a vegetarian diet. This suggests a higher prevalence of the disease among the non-vegetarians (Table 7, Figure 6).

Regarding socioeconomic status, 56.31% belonged to the middle class, 42.67% were from the lower class, and only 1.02% were from the higher class (Table 8, Figure 7).

Temperament Distribution

Mizāj (temperament) analysis revealed that *Damawī* (Sanguine) (O-11.1) temperament was the most prevalent, observed in 39.93% of cases, followed closely by *Şafrāwī* (Bilious) (O-11.3) at 38.57%. *Balghamī* (phlegmatic) (O-11.2) and *Sawdāwī* (melancholic) (O-11.4) temperaments accounted for 13.65% and 7.85%, respectively (Table 9, Figure 8). This distribution suggests that temperamental factors may influence the occurrence and presentation of *Surfa Yubsiyya*.

DISCUSSION

This study analyzed the demographics, temperaments, and therapeutic outcomes of 293 patients diagnosed with *Su'āl Yābis* / *Surfa Yubsiyya* (Dry Cough) (D-7.6), providing valuable insights into the clinical efficacy and safety of *Khamīra Banafsha*.

The study revealed a mean patient age of 32.51 ± 11.36 years, with most patients in the 18–29 age group. Age significantly influences the etiology and physiology of coughs.

In infancy, cough often arises from infections, such as Bronchiolitis (J21), Respiratory Syncytial Virus (RSV), and Whooping cough (D-25). These conditions are caused by immature immunity and respiratory anatomy, making infants highly susceptible to respiratory ailments. Although coughing is critical for clearing the airway, the underdeveloped musculature in infants limits its efficiency.²⁹

Exposure to allergens, pollutants, and irritants contributes to conditions, such as allergic rhinitis (C-38) and asthma (D-4), in adolescents and young adults. This age group benefits from stronger respiratory and immune systems, which enables more effective airway clearance. The predominance of patients in this group may reflect higher rates of dry cough due to infections or environmental factors.

In older adults, cough pathology shifts due to physiological decline and chronic diseases, such as COAD, GERD, and Interstitial lung disease. A weakened cough reflex, diminished receptor sensitivity, and medication side effects such as *Su'āl Yābis / Surfa Yubsiyya* (Dry Cough) (D-7.6) induced by ACE inhibitors are common in this group.³³

Despite these differences, *Su'āl Yābis / Surfa Yubsiyya* (dry cough) (D-7.6) remains a universal concern across all ages owing to its prevalence, diverse causes, and significant impact on quality of life. Persistent dry cough can disrupt daily life, causing physical discomfort, social distress, and sleep disturbances.³³

Age and Gender Distribution

The mean age of participants was 32.51 ± 11.36 years, with the majority (45.39%) in the 18–29 years age group (Fig 5). This reflects a higher prevalence of dry cough in younger adults, likely influenced by environmental exposures, such as allergens, pollutants, and infections common in this demographic. Younger individuals benefited from stronger immune systems and more efficient airway clearance, possibly contributing to their dominance in the sample population.

Older adults, with a lower representation in the study (10.58% in the 50–60 age group), may exhibit cough patterns related to physiological decline and chronic conditions, such as CAPD, GERD, and interstitial lung disease. These conditions are often exacerbated by diminished cough reflex and medication side effects (e.g. ACE inhibitors).³⁴

In our study, the incidence of cough was higher in males (55%) (Table 6). This finding is noteworthy given the anatomical and physiological differences between male and female lungs. Males generally have larger lungs than females of similar height, along with greater lung capacity and flow rates. These structural differences form the basis for variations in lung health and disease susceptibility between sexes.

Certain lung conditions exhibit a clear gender predisposition. For instance, Bronchiectasis (D-32), Pulmonary arterial hypertension (PAH) (I27), and Lymphangioma (D18.1) are more commonly observed in females. Conversely, idiopathic pulmonary fibrosis (IPF) is predominantly observed in male patients. The underlying factors for these sex-specific tendencies may involve hormonal influences, immune responses, and genetic predispositions that interact with environmental exposure.³⁵

Dietary and Socioeconomic Factors

Non-vegetarian dietary habits were predominant among the participants (96.59%), possibly reflecting regional dietary preferences rather than a direct link to disease prevalence. Nonetheless, dietary habits can introduce confounding variables into respiratory health research.

Moreover, the study found that a significant proportion of patients (56.31%) were from middle-class socioeconomic strata. Socioeconomic factors significantly affect health outcomes, as individuals from different economic backgrounds may

experience varying levels of access to healthcare, exposure to environmental hazards, and lifestyle choices. Geographic data also revealed sex-based differences in the prevalence of lung diseases, with higher rates observed in high-income countries under certain conditions. These findings highlight the interplay between socioeconomic status and respiratory disease outcomes (Fig 7).

The study observed a higher incidence of cough among non-vegetarians, which may have been influenced by the uneven distribution of dietary habits within the sample.³⁵ This imbalance introduces a confounding factor that could affect the findings, potentially reflecting sampling bias rather than a direct link between diet and respiratory health. Although diet is known to affect overall health, its specific role in respiratory diseases requires further investigation. Properly addressing such confounding factors is crucial for ensuring an accurate interpretation of the findings and improving the reliability of future respiratory health studies.

The inclusion of primarily acute cases was intended to assess the effectiveness of the treatment during the early stages of the condition. This time frame allows the evaluation of the intervention's impact on symptom relief and disease progression before chronicity is set in.

Temperament and Disease Pathology

The data from our study revealed that most of the patients (39.93%) exhibited a *Damawī* (sanguine) temperament (O-11.1), followed by the *Şafrāwī* (bilious) temperament (O-11.3) (38.57%). There was a significant difference in the distribution of temperaments within the samples, with *Damawī* and *Şafrāwī* being the dominant types. This suggests that individuals with these temperaments were more prevalent in the studied population. The key characteristic of both *Damawī* (Sanguine) (O-11.1) and *Şafrāwī* (Bilious) temperaments (O-11.3) is heat, which likely contributed to the manifestation of *Sū'-i-Mizāj Hārr Sāda* (O-17.1.1.1), a condition associated with a disturbed balance of internal thermal regulation.

According to *Jurjānī*, three main causes of cough have been identified: disturbed temperament (*Sū'-i-Mizāj*), inflammation, pus, and abscesses in the lungs, or the presence of any irritant that reaches the lungs.³⁶ Both *Sū'-i-Mizāj Ḥārr Sāda* (heat-related morbid temperament) (O-17.1.1.1) and *Sū'-i-Mizāj Bārid Sāda* (cold-related morbid temperament) (O-17.1.1.2) can result in *Su'āl Yābis /Surfa Yubsiyya* (Dry Cough) (D-7.6). Ibn Sīnā (Avicenna) further suggested that the cause of such conditions, including cough, is often a (*Mizāj Ḥārr*) hot temperament or *Harārat* (external heat) (3.1.152),³⁴ which is the dominant feature in *Khilt-i-Dam* (3.1.23) and *Ṣafra'* (3.1.39) the two temperaments observed in our study.

Our findings indicate that the majority of patients in the study suffered from *Sū'-i-Mizāj Ḥārr Sāda* (O-17.1.1.1), with heat being the dominant factor in their condition. This heat imbalance likely contributes to coughing and discomfort. To counteract this heat, *Gul-i-Banafsha*, which has a *Bārid Raṭb Mizāj* (cold and moist temperament), was used. Its properties effectively neutralize excess heat and provide significant relief to patients. The cooling and moistening nature of *Gul-i-Banafsha* helped restore balance in the body's temperament, alleviating symptoms associated with heat-induced *Su'āl Yābis /Surfa Yubsiyya* (Dry Cough) (D-7.6).

Thus, the study supports the concept that specific temperaments can influence the manifestation of respiratory conditions and that temperamental imbalances, particularly heat, can be managed with therapeutic interventions that counteract these excesses. The use of *Gul-i-Banafsha* in this context demonstrated its effectiveness in treating patients with *Sū'-i-Mizāj Ḥārr Sāda* (O-17.1.1.1), which offers a valuable therapeutic approach grounded in traditional medical principles.^{36, 37}

Therapeutic Response and Efficacy

The therapeutic response varied by age, gender, and temperament. Younger patients (18–29 years) showed the best responses, with 46 achieving a "Good" outcome (30–59%), 35 showing "Very Good" improvement (60–89%), and 20 achieving "Excellent" outcomes (90–100%). This age group is likely to benefit from improved lung function and stronger immunity. Males had a higher "Very Good" response rate (31.5%) compared to females (18.3%), but females exhibited slightly better "Excellent" outcomes (20.6%).

Men in the age group of 18-29 years showed the best response to treatment, likely due to anatomical and physiological factors. The male lung tended to be larger and had better airflow capacity than females of similar height. This provides a structural advantage in terms of lung health and function, leading to a more efficient treatment response. Additionally, younger individuals generally have stronger immunity, known as *Quwwat-i-mudafiyat*, which helps in faster recovery and better management of respiratory conditions.³⁸ The combination of these factors likely contributed to the enhanced treatment outcomes observed in this age group, suggesting that age and sex can play a significant role in treatment efficacy.

This study demonstrated that the therapy was effective in a significant proportion of patients, with approximately 60% falling into the excellent, very good, and good response categories. This is a positive outcome, suggesting that most patients (68.2%) experienced at least a moderate response to treatment. These results highlight the overall effectiveness of this therapy in alleviating symptoms and improving patient outcomes. The response to cough alleviation was highly significant ($p < 0.001$).

One of the key ingredients in this treatment is *Khamīra Banafsha*, known for its *Taskīn-i Su'āl* (anti-tussive) and *Mulayyin* (laxative) properties.^{22,23} These effects contribute to the reduction of cough and other associated respiratory symptoms.

The primary drug used in *Khamīra Banafsha* is *Viola odorata*, which has multiple therapeutic properties. It acts as a *Moaddil* (moderator of temperament), *Mulattif* (demulcent), and *Mu'arriq* (diaphoretic), making it suitable for treating a variety of respiratory conditions, including *Su'āl* (cough), *Nazla-o-Zukam* (coryza and catarrh), *Dhāt-al-Janb* (pleurisy), and *Dhāt-al-Ri'a* (pneumonia). The versatility of *Viola odorata* in addressing such conditions underpins its efficacy in this study.²³

25 - 27

Several animal studies have demonstrated that *Viola odorata* possesses antibacterial properties, making it active against a range of bacterial species. This antimicrobial activity likely enhances its effectiveness in treating respiratory infections and related symptoms.³⁴ In clinical practice, the adjuvant use of *Viola odorata* syrup along with short-acting beta-agonists has shown to significantly suppress cough in children with intermittent asthma. This combination treatment provides a multi-faceted approach to managing cough symptoms, highlighting the importance of *Viola odorata* as a potent therapeutic agent.³⁵

Furthermore, Qasemzadeh et al. observed that the administration of *Viola odorata* syrup resulted in a considerable reduction in cough, further supporting its efficacy as a therapeutic agent for treating respiratory conditions.³⁶ These findings, combined with the results from our study, emphasize the potential of *Khamīra Banafsha* and its primary ingredient, *Viola odorata*, in managing and alleviating the symptoms of cough and other respiratory ailments. Thus, this treatment proved to be effective and beneficial in addressing the multifactorial nature of respiratory diseases.

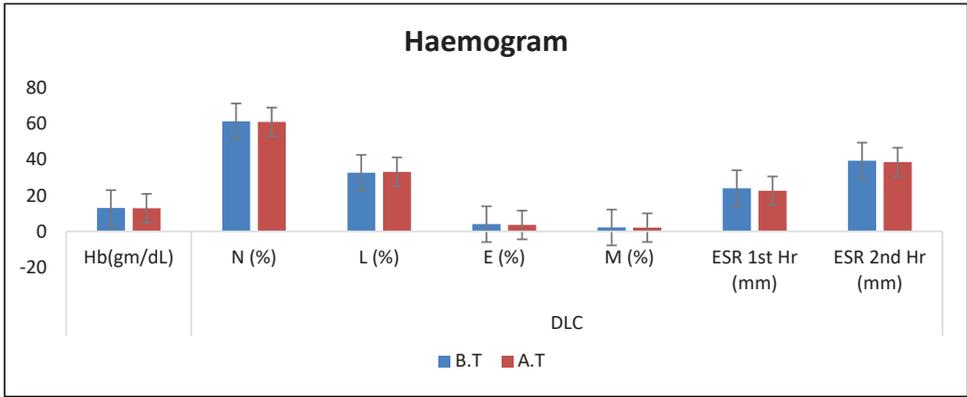
Damawī patients demonstrated the highest success rate, with 79.5% achieving moderate-to-excellent improvement. *Şafrawī* (O-11.3) patients also responded well, whereas *Balghamī* (O-11.2) and *Sawdāwī* (O-11.4) temperaments exhibited lower response rates.

The patients showed varying responses to the treatment. However, individuals with a *Ṣafrāwī* (bilious) disposition responded best, as *Banafsha*, being cold and moist in temperament, directly contrasts with the hot and dry nature of *Ṣafrā'* (bile). This combination effectively counteracts the excess heat associated with *Ṣafrāwī* temperament and provides relief. *Banafsha*'s cooling and moistening properties help balance excess heat and dryness, thereby aiding the treatment of *Ṣafrāwī* individuals. This principle of opposites (*'Illāj bi'l Ḍidd*), as per Unani medicine, proves beneficial for those with a *Ṣafrāwī* disposition, as it helps restore their internal balance.

The treatment led to a significant reduction in Cough VAS scores, with baseline scores decreasing from 6.74 ± 2.32 to 3.19 ± 2.27 (mean improvement: 3.55; $p < 0.001$). This statistically significant outcome highlights the efficacy of *Khamīra Banafsha* in alleviating cough.

The primary aim of this study was to assess the safety & efficacy of this treatment in reducing cough severity. The results showed a significant reduction in the mean cough severity score, from 6.74 at baseline (B.L) to 3.19 at the endpoint (E.L). This substantial decrease indicates a positive effect of the treatment on alleviating cough severity. The difference in mean scores suggests that the intervention was effective in managing the symptoms of cough in the majority of patients.

To understand the variation in cough severity within each condition, we analyzed the standard deviation (S.D) values. At baseline (B.L), the S.D was 2.32, and at the endpoint (E.L), it was 2.27. These relatively low values indicate that the data points were closely clustered around the mean, suggesting a consistent response to treatment across patients. The low S.D further supports the reliability of the sample data, indicating a minimal sampling error and reinforcing the validity of the observed outcomes.



The mean change in cough severity, calculated as 3.55, demonstrated a substantial improvement in the condition of most patients. This confirmed that the treatment had a meaningful impact on reducing cough severity, with a significant proportion of patients experiencing improvement.

A paired t-test was used to determine whether the reduction in cough severity after treatment was statistically significant. The results from the test indicated that the reduction was highly significant, with a p-value <0.001, confirming that the treatment effectively reduced cough severity in a statistically meaningful manner. This statistical significance underscores the therapeutic value of this intervention.

Overall, the data suggest that the treatment was effective in significantly reducing cough severity in most patients. The substantial improvement in cough severity, combined with the low variability in responses, indicates that the therapy is reliable and beneficial for managing cough symptoms. This highlights the potential of this treatment as a promising option for addressing cough-related respiratory issues.

Patients with *Şafrāwī* (bilious) temperament particularly benefited from the cooling and moistening effects of *Banafsha*, which counteracted the hot and dry nature of *Şafrā'* (bile). This principle of opposition (*'Ilāj bi'l Didd*), central to Unani medicine, underscores the importance of personalized treatment based on temperament.

Mechanism of Action and Broader Implications

The therapeutic effects of *Khamīra Banafsha* can be attributed to its primary ingredient, *Viola odorata*, which possesses anti-tussive, demulcent, and antimicrobial properties. The flavonoids, saponins, and essential oils of *Viola odorata* contribute to its cooling, moistening, and inflammation-modulating effects.³⁶

Several studies support its efficacy in managing respiratory conditions. *Viola odorata* has demonstrated antibacterial properties, enhancing its effectiveness in treating respiratory infections. In clinical settings, adjuvant use with beta-agonists has shown significant reduction in cough symptoms, further emphasizing its utility.

Efficacy of *Banafsha* in supporting immune health is attributed to its rich phytochemical composition, which includes flavonoids, saponins, alkaloids, and essential oils. These compounds have demonstrated potential for enhancing immune responses, promoting overall well-being, and offering protective effects against infections. Flavonoids are known for their antioxidant properties, whereas saponins can stimulate immune cell activity. Alkaloids and essential oils further contribute by modulating inflammation and supporting the body's defense mechanisms.

Given the immune-enhancing and anti-inflammatory effects of *Banafsha*, it may help mitigate respiratory symptoms such as cough, which are common in viral infections such as COVID-19 and other respiratory conditions.²⁴ Although not directly aimed at treating COVID-19, its properties suggest potential benefits in managing symptoms associated with respiratory illness, warranting further exploration through clinical trials. The study was extended owing to the COVID-19 pandemic, although COVID-19 patients were excluded through RT-PCR testing. Despite this, the general tonic and immune-boosting properties of *Banafsha* (*Viola*

odorata) make it a potentially valuable option for managing symptoms including COVID-19-related cough. These properties could serve both as a preventive measure (prophylactic) and part of a therapeutic regimen.

The ingredients of *Khamīra Banafsha*, particularly *Viola odorata*, have been shown to enhance immune cell function, modulate inflammatory responses, and strengthen respiratory defences. Active compounds in *Viola odorata* stimulate the production and activity of immune cells, such as macrophages and lymphocytes, which are crucial for fighting infections. By balancing pro and anti-inflammatory cytokines, *Banafsha* can help prevent excessive inflammation, often associated with severe COVID-19 cases (cytokine storm). Mucolytic and anti-inflammatory properties help maintain the integrity of the respiratory tract, which is a primary site of viral infection. These immune-enhancing effects can reduce the susceptibility to viral infections, including SARS-CoV-2, and may aid in faster recovery.

The tonic properties of the formulation contribute to overall vitality and resilience, which are crucial during illness. These effects included improved energy levels, enhanced respiratory function, and detoxification. The adaptogenic properties of *Banafsha* help counter fatigue and weakness, which are common in COVID-19 and other post-viral syndromes. By supporting lung health and reducing congestion, *Khamīra Banafsha* ensures better oxygenation and respiratory efficiency. Diaphoretic and hepatoprotective actions help eliminate toxins from the body, supporting recovery from viral infections.

The symptoms addressed by *Khamīra Banafsha*, such as cough, fever, and throat irritation, overlap significantly with those seen in COVID-19. Additionally, its potential to mitigate inflammation and oxidative stress may help alleviate respiratory symptoms, prevent severe complications, and accelerate recovery. Its antitussive and *Munaffith-i-Balgham* (expectorant) properties help manage dry and productive coughs, a hallmark of COVID-19.

Vascular protective and anti-inflammatory effects may reduce the risk of complications such as pneumonia or acute respiratory distress syndrome (ARDS). Its hepatoprotective and antioxidant properties can aid recovery by reducing organ stress and promoting tissue repair.

Laboratory Efficacy

The data indicated that some clinical parameters showed changes after treatment, while others remained relatively stable. For example, parameters related to kidney function (blood urea and serum creatinine levels) exhibited significant changes (Figure 15). Hemoglobin, TLC, and various components of DLC showed minimal changes after treatment; Serum Bilirubin values were consistent before and after treatment; and ESR values, both at the 1st and 2nd hour, showed limited changes after treatment, possibly indicating that the treatment did not have a significant impact on inflammation levels.

Safety analyses showed *Khamīra Banafsha* was well tolerated. Haemoglobin, differential leukocyte counts, ESR, and liver enzymes remained unchanged from baseline to endpoint, with no significant differences (Table 15). The key changes were a decrease in total leukocyte count (TLC). TLC fell from 7246.65 ± 1863.95 to 4212.21 ± 3542.82 cells/mm³ ($p < 0.001$), demonstrating an anti-inflammatory activity (Table 15).

The reduction in TLC, is the most straightforward and compelling finding. It strongly suggests that *Viola odorata* possesses powerful anti-inflammatory or anti-infective properties. By reducing the overall white blood cell count, it is directly addressing the systemic cause of the illness. This is consistent with its traditional use and some modern studies that show its anti-inflammatory effects.

This study demonstrates the efficacy and safety of *Khamīra Banafsha* in managing *Su'āl Yābis /Surfa Yubsiyya*, with significant symptom relief observed in 68.2% of

the patients. The results highlight the relevance of Unani principles in addressing temperamental imbalances and their role in respiratory health.

Future research should explore the long-term benefits of *Khamīra Banafsha*, its role in managing chronic respiratory conditions, and its potential integration into broader health care practices. Addressing confounding factors, such as dietary habits and socioeconomic status, in future studies will further enhance the reliability of the findings.

SUMMARY

This study investigated the prevalence and treatment efficacy of *Su'āl Yābis /Surfa Yubsiyya* (Dry Cough) (D-7.6) in a patient population and revealed several key findings. The mean age of the patients was 32.51 years, with a higher incidence in the 18-29 age group, showcasing the age-related nature of cough. Despite age-related variations in cough-inducing factors, dry cough remains a common reason for medical consultations across different age groups.

The study observed a higher incidence of cough in males (55%), potentially related to lung size and physiological differences between the sexes. Dietary habits were confounding factors that affected the study's results.

Most patients belonged to the middle class of the socioeconomic strata (56.31%) (Table 8), highlighting regional differences in lung disease prevalence.

This study primarily focused on uncomplicated cases of dry cough (*Su'āl Yābis /Surfa Yubsiyya*), emphasizing the importance of timely management to prevent persistence of symptoms. The distribution of temperaments among the patients showed a significant dominance of *Damawī* (O-11.1) and *Şafrāwī* (O-11.3) temperaments, highlighting the role of *Hararat* (heat) in dry cough.

Therapeutic outcomes indicated that younger males (18–29 years) responded most effectively to treatment, likely due to their stronger immunity and favourable lung anatomy. Overall, 68.2% of the patients experienced moderate to very good improvement following treatment with *Khamīra Banafsha*, a Unani formulation containing *Viola odorata*. The anti-tussive, demulcent, and antimicrobial properties of the formulation significantly contributed to reducing cough severity.

The study reported a mean reduction in Cough VAS scores of 3.55, with a high level of statistical significance ($p < 0.001$). This consistent response across patients underscores the reliability and effectiveness of the treatment. Additionally, adenosine phosphate (AP) has been noted for its role in regulating immune responses and reducing inflammation, potentially enhancing the therapeutic impact of *Khamīra Banafsha*.

In conclusion, this study provides compelling evidence for the efficacy of *Khamīra Banafsha* in managing dry cough, particularly in younger male patients. This underscores the importance of incorporating demographic, temperamental, and lifestyle factors into personalized treatment approaches for respiratory conditions, reinforcing the value of Unani medicine in addressing complex health issues.

CONCLUSION

This study provides significant insights into the prevalence and treatment outcomes of *Su'āl Yābis / Surfa Yubsiyya* (Dry Cough) (D-7.6) in a diverse patient population, emphasizing the multifaceted nature of cough-related conditions.

The age-related patterns observed in this study highlight the importance of considering age as a critical factor in the diagnosis and management of cough. The majority of cases were concentrated in the 18–29 years age group, reflecting the heightened susceptibility of this demographic to dry cough. This may be

attributed to their exposure to environmental factors such as allergens and pollutants, along with a robust immune system capable of mounting rapid responses. Despite its age-related distribution, dry cough remains a prevalent clinical complaint across all age groups, underscoring its universal relevance in medical practice.

The higher incidence of cough in males (55%) than in females highlights the potential influence of anatomical and physiological differences, including larger lung volumes and higher airflow capacities in males. These findings suggest the need for a gender-specific approach to understand and address cough-related conditions. Additionally, the study identified dietary habits as a confounding variable, with the predominance of non-vegetarian patients potentially reflecting sampling bias rather than a direct relationship with respiratory health.

Socioeconomic factors were another important consideration, with a significant proportion of the patients (56.31%) belonging to the middle socioeconomic class. Limited access to health care, greater exposure to environmental pollutants, and lifestyle factors likely contributed to the prevalence of cough in this group. Suggesting that other factors, such as environmental and occupational exposure, may play a more significant role in this population.

This study focused on uncomplicated cases of dry cough (*Su'āl Yābis / Surfa Yubsiyya*), emphasizing the importance of early management to prevent symptom persistence. The dominance of specific temperaments (*Damawī* and *Şafrāwī*) among patients provides historical and theoretical insights, aligning with the Unani principles that associate heat-related imbalances (*Sū'-i-Mizāj Hārr Sāda*) with dry cough.

The treatment demonstrated notable efficacy, with 68.2% of the patients experiencing moderate to very good improvement. Younger males in the 18–29

years age group responded most favourably, likely due to their stronger immunity and advantageous lung anatomy. The use of *Khamīra Banafsha*, a formulation containing *Viola odorata*, was instrumental in achieving these outcomes. Its anti-tussive, antimicrobial, and demulcent properties effectively alleviated the symptoms and reduced Cough VAS scores by a statistically significant margin (mean reduction: 3.55, $p < 0.001$).

These findings underscore the importance of integrating demographic, temperamental, and lifestyle factors into personalized treatment strategies for cough-related conditions. By aligning modern clinical approaches with traditional Unani principles, this study highlights the potential of evidence-based herbal therapies to address complex respiratory disorders.

LIMITATIONS

While the study yielded promising results, several limitations must be acknowledged:

1. **Confounding Factors:**
2. Although the majority of participants were non-smokers and non-tobacco users, residual confounders, such as environmental exposures or undetected smoking habits, may have influenced the outcomes. Future studies should implement stricter exclusion criteria or control for these behaviours to minimize bias.
3. **Patient Communication and Counselling:**
A relatively high percentage of patients fell into the "Poor" response category, indicating dissatisfaction or limited efficacy of the treatment in certain cases. This underscores the need for improved patient counselling to manage expectations, address concerns, and explore alternative therapeutic strategies for non-responders.
4. **Sample Size and Statistical Robustness:**

The "Excellent" response category had the smallest number of patients, making it challenging to draw definitive conclusions for this group. Future research should aim for larger and more balanced sample sizes across all response categories to ensure greater statistical power and reliability.

5. Treatment Protocol Optimization:

The variability in patient responses suggests that further refinement of the treatment protocol is required. Detailed analyses of poor responders should be conducted to identify potential areas of improvement, such as dosage adjustments or complementary therapies.

Future Research

Building on these findings, future studies should explore the long-term efficacy of *Khamīra Banafsha*, its potential for managing chronic respiratory conditions, and its application across diverse populations. Investigations incorporating advanced diagnostics, such as imaging and biomarker analysis, could provide deeper insights into the mechanisms of action. Furthermore, randomized controlled trials with robust controls for confounders are essential to strengthen the evidence base for this Unani therapeutic intervention.

In conclusion, this study highlights the clinical relevance of *Khamīra Banafsha* in managing *Su'āl Yābis / Surfa Yubsiyya*, providing a foundation for its broader application in respiratory health. By addressing the identified limitations and adopting a comprehensive research approach, future studies can advance the understanding and treatment of cough-related disorders.

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SCREENING FORM

**Clinical Validation of Unani Pharmacopoeial formulation *Khamīra Banafsha*
for symptomatic relief in patients of *Su'āl Yābis* (Dry Cough)**

Protocol No: SY/DC/KB/CLNVAL/CCRUM 16-17

Version No: 01

Centre Code:

Code No.

1. Trial code:
2. Screening No.:
3. Date of Birth:
4. Age (in years):
5. Gender: Male/ Female
6. Caste: SC/ ST/ BC/ OC
7. Address:

Phone:

8. Marital Status Married/ Unmarried
9. Social Status Poor/ Average/ Good
10. Occupation
11. Dietary Pattern Veg / Non-Veg
12. Height (cm.):
13. Weight (kg.):
14. B.P.: Pulse:

15. Is the patient on any other treatment including use of alternative medicine
Yes/ No

16. Previous treatment taken for *Su‘āl Yābis* (Dry Cough)

Treatment	Duration	Response
Allopathy		
Ayurvedic		
Unani		
Homeopathy		

17. Presence of Dry Cough < 3 weeks Duration Yes/ No
18. Is the patient suffering from any acute or chronic Yes/ No
lower respiratory tract infection like pneumonia, Bronchitis,
Asthma and Bronchiectasis.
19. Obstructive airway disease (COAD) including chronic Yes/ No
bronchitis and emphysema. Yes/ No
20. Bronchiectasis, pulmonary tuberculosis, pulmonary
oedema, interstitial pulmonary fibrosis Tumours of larynx,
bronchi, and lungs
21. Drug-induced Cough (e.g., ACE Inhibitors) Yes/ No
22. Is the patient taking long term treatment for any Yes/ No
chronic ailment Yes/ No
23. History of long-term use of any other drugs, alcohol, narcotics
or smoking Yes/ No
24. Is the patient Pregnant or lactating Yes/ No
25. Written Informed Consent obtained: Yes/ No
26. Eligible for inclusion: Yes/ No

Name & Signature of the Investigator	Counter Signature of the Incharge

* If the Answer to Q No 18 is YES and Answer to Q. No 19-25 is NO then include the patient.

Annexure-II

CASE RECORD FORM

**Clinical Validation of Unani Pharmacopoeial formulation *Khamīra Banafsha*
for symptomatic relief in patients of *Su'āl Yābis* (Dry Cough)**

Protocol No. SY/DC/KB/CLNVAL/CCRUM 16-17

Center Name:

Reg. No.

Date of Registration:

Date of Completion

PATIENT'S PARTICULARS

Patient's Name: _____

Age: _____ Years Sex: _____

Male/Female

Father's/Guardian's/Husband's

Name:

Address:

Occupation: _____

Income Group: Lower Middle Higher

Patient's Status: New Known Case

Duration of Disease:

CLINICAL OBSERVATIONS

Chief complaints with duration:

1. _____
2. _____
3. _____

History of Presenting/Current illness:

Past Medical History:

Personal History:

Family History:

Treatment History:

Lymphatic system

EXAMINATION OF NABZ (Pulse):

(Please record the characteristics of *Nabz* present)

S. No.	<i>Adilla al-Nabz</i>	<i>Characters</i>			<i>At Baseline</i>
		A	B	C	
1.	Miqdār al-Inbisāt	'Azīm	<i>Saghīr</i>	<i>Mu'tadil</i>	
		Ghalīz	<i>Raqīq</i>	<i>Mu'tadil</i>	
2.	Kayfiya al-Qar'	Qawī	<i>Za'if</i>	<i>Mu'tadil</i>	
3.	Zamāna-i-Harakat	Sarī	<i>Batī</i>	<i>Mu'tadil</i>	
4.	Zamāna-i-Sukūn	Mutawātir	<i>Mutafāwit</i>	<i>Mu'tadil</i>	
5.	Qiwām-i-Āla	Sulb	<i>Layyin</i>	<i>Mu'tadil</i>	
6.	Khalā-o-Imtilā'	Mumtalī	<i>Khālī</i>	<i>Mu'tadil</i>	
7.	Malmas	Hārr	<i>Bārid</i>	<i>Mu'tadil</i>	
8.	Istiwā'-o-Ikhtilāf	Mustawī	<i>Mukhtalif</i>	<i>Mu'tadil</i>	
9.	Nizām-o-'Adm-i-Nizām	<i>A Muntazim</i>		<i>B Ghayr Muntazim</i>	
10.	Wazn	<i>A Jayyid-al-Wazn</i>		<i>B Radī-al-Wazn</i>	

CLINICAL ASSESSMENT:

Base line scores of sign/symptoms present except fever will be recorded as per VAS in the following table:

S.No.	Presenting complaints	Base Line
1	Cough VAS score	

LABORATORY EXAMINATIONS:

(Please record findings of the investigations)

S.No.	Laboratory Investigations	At Base line	
1	CBC	Hb%	
		TLC	
		DLC	N
			L
			E
			M
			B
ESR			
2	LFT	S. Bilirubin	
		SGOT	
		SGPT	
		S. Alkaline phosphatase	
3	KFT	Blood Urea	
		S. Creatinine	
4	Urine R/M		
5	Blood Sugar (Fasting)		

Drug	Dosage	Route	Duration	Quantity of medicine given
<i>Khamīra Banafsha</i>	7g BD	Oral	7 days	

Date of Next follow up

Name & Signature of the Investigator	Counter Signature of the Incharge

FOLLOW – UP SHEET

**Clinical Validation of Unani Pharmacopoeial formulation *Khamīra Banafsha*
for symptomatic relief in patients of *Su'āl Yābis* (Dry Cough)**

Protocol No. SY/DC/KB/CLNVAL/CCRUM 16-17

Version

No:01

Centre Name:

Reg. No.:

Date of Follow-Up:

Date of Completion:

Date of last visit: _____

Compliance

Quantity of medicine returned _____

Were any doses missed? Yes

No

If yes, how many

Reasons for missed doses:

Over all compliance: 1. Excellent

2.

Good

3. Poor

Adverse events

Whether the patient experienced any of the following:

Yes

No

Nausea

Vomiting

Abdominal Discomfort/ Pain

Anorexia

2.	Kayfiya al-Qar'	Qawī	Za'īf	Mu'tadil	
3.	Zamāna-i-Harakat	Sarī	Batī	Mu'tadil	
4.	Zamāna-i-Sukūn	Mutawātir	Mutafāwīt	Mu'tadil	
5.	Qiwām-i-Āla	Sulb	Layyin	Mu'tadil	
6.	Khalā-o-Imtilā'	Mumtalī	Khālī	Mu'tadil	
7.	Malmas	Hārr	Bārid	Mu'tadil	
8.	Istiwā'-o-Ikhtilāf	Mustawī	Mukhtalif	Mu'tadil	
9.	Nizām-o-'Adm-i-Nizām	A Muntazim		B Ghayr Muntazim	
10.	Wazn	A Jayyid-al-Wazn		B Radī-al-Wazn	

CLINICAL ASSESSMENT:

Base line Scores of sign/symptoms present except fever will be recorded as per VAS in the following table:

S.No.	Presenting complaints	1 st follow up
1	Cough VAS score	

LABORATORY EXAMINATION:

(Please record findings of the investigations in concerned column)

S.No.	Laboratory Investigations	1 st follow up (7 th day)	
1	CBC	Hb%	
		TLC	
		DLC	N
		L	
		E	

			M	
			B	
		ESR		
2	LFT	S. Bilirubin		
		SGOT		
		SGPT		
		S. Alkaline phosphatase		
3	KFT	Blood Urea		
		S. Creatinine		
5.	Urine R/M			

Name & Signature of the Investigator	Counter Signature of the Incharge

GLOBAL EVALUATION

Patient Global Assessment of Response to Therapy (PGART):

Poor Satisfactory Good Excellent

Investigator Global Assessment of Response to Therapy (IGART):

Not Effective Effective Very Effective

Patient completed study: Yes No

If No: Reason for drop out / Discontinuation

1. Poor Compliance
2. Lost to follow up
3. Adverse event
4. Abnormal Lab parameter
5. Poor efficacy
6. Concurrent illness
7. Any other reason: Give details:

Name & Signature of the Investigator	Counter Signature of the Incharge

ASSESSMENT OF RESULTS

S. No.: _____ Reg. No.: _____

Date of Registration: _____

Name: _____ Age: _____ Years

Sex: M / F _____

S. No.	Presenting complaints	Baseline	End of Treatment
1	Cough VAS Score		

Reduction in Score:

Change in fever (If Any)

RESULT:

Percentage Efficacy: _____

SUMMARY

CONCLUSION

Name & Signature of the Investigator	Counter Signature of the Incharge

PARTICIPANT INFORMATION SHEET (PIS)

Study Title: Clinical Validation of Unani Pharmacopoeial formulation *Khamīra Banafsha* for Symptomatic relief in patients of *Su'āl Yābis* (Dry Cough)

Name of the Investigator:

.....

Phone/ Mobile No.:

.....

You are invited to participate in a research study on *Su'āl Yābis* (Dry Cough). The study is part of a multi-centric study sponsored by Director General, CCRUM, Ministry of AYUSH, Government of India. The study doctor or study staff will provide answers to any queries you may have regarding this form or the study. This form may contain words or information that you may not understand; in which case you could seek clarification from the study doctor or designated study staff. After going through the content you will be asked to sign the form or give your thumb impression. You will be provided with a copy of the signed consent form to take home and keep for your records.

Before you decide whether or not to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. What is the purpose of this study?

The purpose is to investigate whether the drug *Khamīra Banafsha* used for the management of *Su'āl Yābis* (Dry Cough) is useful and to study the safety of *Su'āl Yābis* (Dry Cough) in human subjects.

2. Why have I been invited to participate in this study?

You are eligible to participate in this study because you are suffering from *Su'āl Yābis* (Dry Cough)

3. What if I don't want to take part in this study, or if I want to withdraw later?

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

New information about the treatment being studied may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to continue in the study.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

4. What does this study involve?

If you agree to participate in this study, you will be asked to sign the informed consent form (ICF). This study will be conducted for 8 weeks. There will be tests to be done during this period.

5. How is this study being funded by?

The study is being sponsored and funded by CCRUM.

6. Are there risks to me in taking part in this study?

All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study.

7. What happens if I suffer injury or complications as a result of the study?

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate medical treatment.

8. Will I benefit from the study?

This study aims to further medical knowledge and may improve future treatment of *Sual-e-Yabis* (Dry Cough) and as a personal gain you may not go into chronic state and result in complications.

9. What will happen to my blood sample after it has been used?

The blood sample you provide during the study will be destroyed after use.

10. How will my confidentiality be protected?

Of the people treating you only will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission or except as required by law. Only the researchers named above will have access to your details and results that will be held secretly at institution.

11. What happen with the results?

If you give us your permission by signing the consent document, we plan to discuss/publish the results (State the possible persons to whom the information will be disclosed, the nature of the information disclosed and the purpose of the disclosure e.g. the sponsor (DG, CCRUM) and the IEC for monitoring purposes, publication of the data in peer-reviewed journals and presentations at various conferences or other professional forums). In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.

12. What happens to my treatment when the study is finished?

The procedure will be available after the study finishes. You may be able to continue procedure following completion of this study if found to be of benefit to you. This decision will be made in consultation between you and your treating doctor about the most appropriate treatment for you at that time.

13. What should I do if I want to discuss this study further before I decide?

When you have read this information, the researcher will discuss it with you and any queries which you may have will be answered. If you would like to know more at any stage, please do not hesitate to contact him/her.

14. Who should I contact if I have concerns about the conduct of this study?

For further information / questions, you can contact one of our following researchers:

Principal Investigator

Name _____

Institute _____

Address _____

Telephone/ E-mail _____

Co-Investigator

Name _____

Institute _____

Address _____

Telephone/ E-mail : _____

Thank you for taking the time to consider this study. If you wish to take part in it, please sign the attached consent form. This information sheet is for you to keep.

CENTRAL COUNCIL FOR RESEARCH IN UNANI MEDICINE

(Ministry of AYUSH, Govt. of India)

61-65, Institutional Area, Opposite "D" Block, Janakpuri, New Delhi-110058

CONSENT FORM

**Clinical Validation of Unani Pharmacopoeial formulation *Khamīra Banafsha*
for symptomatic relief in patients of *Su'āl Yābis* (Dry Cough)**

Protocol No.: SY/DC/KB/CLNVAL/CCRUM 16-17

Patient Identification Number for this Study:

1. I acknowledge that I have read the participant information sheet, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation and the information sheet has been explained to me to my satisfaction.
2. Before signing this consent form, I have been given the opportunity of asking any question relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.
3. I understand that I can withdraw from the study at any time without prejudice to my relationship to the (insert if applicable) University (name) and the Hospital, Research Institute)
4. Confidentiality: I understand that my information can be accessed by the Ethics committee members and institutional/regulatory authorities, if required
5. I agree that research data gathered from the result of the study may be published, provided that I cannot be identified.

6. I understand that if I have any question relating to my participation in this research, I may contacton telephone.....
7. I acknowledge receipt of a copy of this consent form and the participant information sheet.

Complaints may be directed to the research office, (Details of office).

Signature of Participant

Name

Date

Signature of Witness

Name

Date

Signature of Investigator

Name

Date

Annexure-IV

ASSESSMENT OF THE TEMPERAMENT

	SANGUINE	PHLEGMATIC	BILIOUS	MELANCHOLIC
COMPLEXION	Ruddy (Reddish/Wheatish Brown)	Chalky (Whitish)	Pale (Yellowish)	Purple (Blackish)
BUILT	Muscular & Broad	Fatty & Broad	Muscular & Thin	Skeleton
TOUCH	Hot & Soft	Cold & Soft	Hot & Dry	Cold & Dry
HAIR	Black & Lustrous Thick, Rapid Growth	Black & Thin Slow Growth	Brown & Thin Rapid Growth	Brown & Thin Slow Growth
MOVEMENT	Active	Dull	Hyperactive	Less Active
DIET (MOST LIKED)	Cold & Dry	Hot & Dry	Cold & Moist	Hot & Moist
WEATHER (MOST SUITABLE)	Spring	Summer	Winter	Autumn
SLEEP	Normal (6-8 hours)	In excess	Inadequate	Insomnia
PULSE	Normal in Rate (70-80/min) Large in Volume	Slow in Rate (60-70min) Normal in Volume	Rapid in Rate (80-100/min) Normal in Volume	Slow in Rate (60-70/min) Less in Volume
EMOTIONS	Normal	Calm & Quiet	Angry	Nervous

(Maximum no. of ticks in a particular column denote the dominant temperament)



Central Council for Research in Unani Medicine

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unanimedicine@gmail.com

