ACTA PHARMA REPORTS

Original Research Article | Journal homepage: https://pharma.researchfloor.org/ | ISSN: 3041-5381

# Clinical Validation of Unani Pharmacopoeial Formulation *Sharbat-e-Ejaz* in *Sual-e-Yabis* (Dry Cough)

**Irfan Ahmed[1], Nikhat Shaikh*[1], MD Manzar Alam[2], Shah Alam[1], Arjumand Shah[3], Mohammed Sheeraz[4], and Nighat Anjum[5]**

[1]*Regional Research Institute of Unani Medicine (RRIUM), Mumbai, Maharashtra, India*
[2]*Regional Research Institute of Unani Medicine (RRIUM), Patna, Bihar, India*
[3]*Regional Research Institute of Unani Medicine, Naseem Bagh, Habbak, Srinagar, 190006 Jammu & Kashmir, India*
[4]*Department of Moalajat, Regional Research Institute of Unani Medicine, Srinagar, Jammu & Kashmir, India*
[5]*Central Council for Research in Unani Medicine (CCRUM), New Delhi, India*

## ABSTRACT

***Background:*** *Sual-e-Yabis (dry cough) is a common respiratory ailment described in classical Unani texts as a condition primarily of Yabusiyat (dryness) affecting the respiratory tract. Sharbat-e-Ejaz is a compound Unani formulation included in the Unani Pharmacopoeia of India (UPI) with documented anti-tussive and mucolytic properties.*
***Objective:*** *To clinically validate the efficacy and safety of Sharbat-e-Ejaz in patients with Sual-e-Yabis through a multi-centre open-label clinical trial.*
***Methods:*** *A total of 128 patients (Male: 88, Female: 40) with confirmed diagnosis of Sual-e-Yabis were enrolled from four CCRUM research institutes. The formulation was administered orally for four weeks with assessments at baseline, 2nd week (1st follow-up) and 4th week (end of treatment). Primary outcome was assessed using the Visual Analogue Scale (VAS). Laboratory investigations including haematological and biochemical parameters were performed to assess safety.*
***Results:*** *Mean VAS score significantly decreased from 7.91 ± 1.35 at baseline to 2.69 ± 1.18 at end of treatment, reflecting a 65.9% reduction ($p < 0.001$). No clinically significant adverse changes were observed in laboratory parameters.*
***Conclusion:*** *Sharbat-e-Ejaz demonstrated significant clinical efficacy and acceptable safety profile in the management of Sual-e-Yabis, supporting its validation as a standard Unani therapeutic formulation.*

***Keywords****: Sharbat-e-Ejaz, Sual-e-Yabis, Dry Cough, Unani Medicine, Clinical Validation, VAS, CCRUM.*

## Introduction

Sual-e-Yabis, described in classical Unani literature as dry cough, represents one of the most prevalent respiratory conditions encountered in clinical practice. Unlike Sual-e-Ratab (productive cough), Sual-e-Yabis is characterised by absence of expectoration, persistent irritation of the respiratory mucosa, and predominance of Yabusiyat (dryness) in the Mizaj (temperament) of the affected organ.[1] In Unani medicine, cough (Sual) is understood as a reflex expulsive action of the lung aimed at expelling harmful materials or relieving irritation in the respiratory tract.

15 July 2022: Received
24 August 2022: Revised
02 September 2022: Accepted
25 September 2022: Available Online

**Citation:** Irfan Ahmed, Nikhat Shaikh, MD Manzar Alam, Shah Alam, Arjumand Shah, Mohammed Sheeraz, and Nighat Anjum (2022). Clinical Validation of Unani Pharmacopoeial Formulation *Sharbat-e-Ejaz* in *Sual-e-Yabis* (Dry Cough). *Acta Pharma Reports.*
**DOI: https://doi.org/10.51470/APR.2022.01.02.01**

*Corresponding Author: **Nikhat Shaikh**
Email Address: **drnikhat.unani@gmail.com**



Classical scholars such as Ibn Sina in his canonical text *Al-Qanoon fi al-Tibb* have classified Sual based on its aetiology, intensity and the nature of expectorated material. Sual-e-Yabis specifically arises due to accumulation of Khilt-e-Sawda (melancholic humour) or extreme Yabusiyat affecting the respiratory mucous membranes, leading to persistent dryness and tickling sensation [2][3]. The global burden of dry cough is substantial. Studies indicate that chronic or acute dry cough affects approximately 10-40% of the population at any given time, with significant impact on quality of life, sleep and social functioning.[4] In India, respiratory conditions including cough-variant presentations account for a significant proportion of outpatient consultations in both modern and traditional medicine settings [5]. Sharbat-e-Ejaz is a classical Unani compound syrup formulation included in the Unani Pharmacopoeia of India (UPI), Part-II. Its primary ingredients include drugs with established demulcent, anti-tussive and soothing properties such as *Unnab (Ziziphus jujuba)*, *Sapistan (Cordia myxa)*, and *Khatmi (Althaea officinalis)*. These ingredients possess established pharmacological actions including mucilaginous, anti-inflammatory, and antioxidant properties [6][7].

The Central Council for Research in Unani Medicine (CCRUM), Ministry of AYUSH, Government of India, has undertaken systematic clinical validation of pharmacopoeial Unani formulations through multi-centre clinical trials.

The present study was conducted under Protocol No. SY/DC/SECLNVAL/CCRUM 13-14 at four CCRUM research institutes: RRIUM-Srinagar, RRIUM-Mumbai, RRIUM-New Delhi, and CRU-Meerut. The objective was to validate the clinical efficacy and safety of Sharbat-e-Ejaz in patients diagnosed with Sual-e-Yabis, thereby generating scientific evidence for its therapeutic use [8].

## 2. Materials and Methods

### 2.1 Study Design

This was a multi-centre, open-label, single-arm clinical trial conducted at four CCRUM research institutes across India. The study followed the guidelines of the Indian Council of Medical Research (ICMR) for biomedical research on human participants and received ethical approval from respective Institutional Ethics Committees.

### 2.2 Study Population

Patients presenting with symptoms of Sual-e-Yabis (dry cough) to the outpatient departments of the participating centres were screened for eligibility. A total of 128 patients aged between 18 and 62 years (mean: 35.6 ± 10.1 years) were enrolled. Informed written consent was obtained from all participants prior to enrolment. Patients with severe underlying pulmonary pathology, pregnancy, or concurrent use of allopathic antitussive medications were excluded.

### 2.3 Diagnosis Criteria

Diagnosis of Sual-e-Yabis was established based on classical Unani diagnostic criteria including absence of expectoration, dry and harsh cough, tickling sensation in throat, signs of Yabusiyat in Mizaj assessment, and corroborated by conventional clinical examination. Nabz (pulse) examination and Mizaj assessment were performed at each visit.

### 2.4 Intervention

Sharbat-e-Ejaz was administered at the standard pharmacopoeial dose of 25 mL orally, twice daily (morning and evening), with water for a period of four weeks. The drug was procured from CCRUM-approved pharmaceutical units and quality tested as per UPI standards.

### 2.5 Outcome Assessment

The primary outcome measure was symptom severity assessed by Visual Analogue Scale (VAS) on a scale of 0–10, where 0 indicated no cough and 10 represented the most severe cough. Assessments were performed at three timepoints: Baseline (Week 0), 1st Follow-up (Week 2), and 2nd Follow-up/End of Treatment (Week 4). Safety was monitored through haematological parameters (Hb, TLC, DLC, ESR) and biochemical investigations (LFT, KFT, blood sugar) at baseline and end of treatment.

### 2.6 Statistical Analysis

Data were analysed using descriptive statistics (mean ± standard deviation). The significance of change in VAS scores was assessed using paired Student's t-test and Wilcoxon signed-rank test. A p-value of < 0.05 was considered statistically significant. SPSS v20.0 (IBM, USA) was used for statistical analysis.

## 3. Results

### 3.1 Demographic Profile

Of the 128 patients enrolled (147 registered; 19 excluded/dropped-out prior to first assessment), 88 were male (68.8%) and 40 were female (31.2%). The mean age was 35.6 ± 10.1 years (range: 18–62 years). The majority of patients belonged to middle socio-economic status (74.2%). The mean disease duration was approximately 10 days. Demographic distribution is illustrated in Figure 2.

*Table 1: Demographic Characteristics of Study Participants (n=128)*

| Parameter | Category / Value | n (%) |
|---|---|---|
| Total Patients | — | 128 |
| Age (years) | Mean ± SD | 35.6 ± 10.1 |
| Age Range | 18–62 years | — |
| Sex – Male | Male | 88 (68.8%) |
| Sex – Female | Female | 40 (31.2%) |
| Socio-economic Status | Middle (MD) | 95 (74.2%) |
| Socio-economic Status | Lower (LW) | 33 (25.8%) |
| Disease Duration (Most Common) | 10 Days | 91 (71.1%) |

### 3.2 Effect on VAS Score

The mean VAS score at baseline was 7.91 ± 1.35, which declined to 5.10 ± 1.37 at the 1st follow-up (Week 2), and further reduced to 2.69 ± 1.18 at the end of treatment (Week 4). This corresponds to a total reduction of 65.9% in symptom severity from baseline to end of treatment. The improvement was statistically highly significant (paired t-test: $t = 21.35$, $p < 0.001$; Wilcoxon test: $p < 0.001$). The progressive reduction in VAS scores across all timepoints is shown in Figure 1.

*Table 2: Changes in VAS Score at Different Assessment Timepoints*

| Timepoint | Mean VAS | ± SD | % Reduction |
|---|---|---|---|
| Baseline (Week 0) | 7.91 | 1.35 | — |
| 1st Follow-up (Week 2) | 5.10 | 1.37 | 35.5% |
| End of Treatment (Week 4) | 2.69 | 1.18 | 65.9% |
| *p < 0.001 (Paired t-test and Wilcoxon signed-rank test)* | | | Significant |

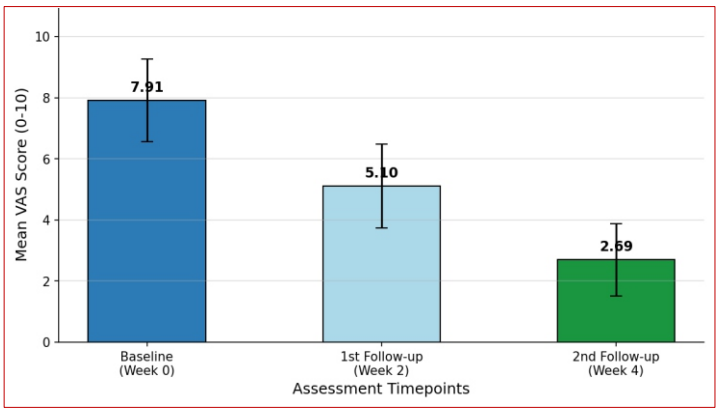


*Figure 1: Mean VAS Scores at Baseline, 1st Follow-up and End of Treatment with Sharbat-e-Ejaz*

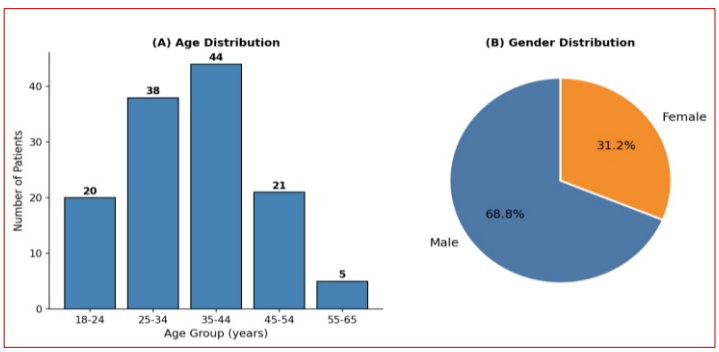


*Figure 2: Age Distribution (A) and Gender Distribution (B) of Study Participants*

### 3.5 Safety Parameters

Haematological and biochemical parameters showed no clinically significant changes following four weeks of treatment. Mean haemoglobin levels remained stable (baseline: 13.69 ± 1.72 g/dL; end of treatment: 13.67 ± 1.58 g/dL). ESR values were within acceptable ranges at both timepoints (baseline: 19.25 ± 12.34 mm/hr; end of treatment: 19.87 ± 12.33 mm/hr). No serious adverse events were reported during the trial period, confirming the safety profile of the formulation.

## 4. Discussion

The present multi-centre clinical trial provides robust evidence for the therapeutic efficacy of Sharbat-e-Ejaz in Sual-e-Yabis. The highly significant reduction in VAS scores (65.9%; $p < 0.001$) across the four-week treatment period indicates a consistent and progressive anti-tussive effect of this compound Unani formulation. These findings are concordant with the classical Unani understanding of the formulation's mechanism — primarily through its Muqawwi and Mulayyin (soothing and moistening) actions on the respiratory mucosa [9]. The predominance of male patients (68.8%) in our cohort may reflect greater occupational exposure to environmental irritants, dust and pollutants, which are known precipitants of Sual-e-Yabis [10]. The mean age of 35.6 years indicates that working-age adults are the most vulnerable demographic, consistent with patterns reported in other studies on cough disorders in South Asian populations [11]. The ingredient profile of Sharbat-e-Ejaz offers pharmacological plausibility for the observed outcomes. *Cordia myxa* (Sapistan) has documented mucoprotective and anti-inflammatory properties, while *Althaea officinalis* (Khatmi) contains mucilaginous polysaccharides that coat and soothe inflamed mucous membranes [12][13]. Modern phytochemical research supports these mechanisms, providing scientific basis for the classical Unani pharmacological claims regarding this formulation. The stable laboratory parameters across the treatment period confirm the safety and tolerability of Sharbat-e-Ejaz, which is particularly relevant given its use in diverse patient populations including varying age groups and socio-economic backgrounds. The absence of hepatotoxic or nephrotoxic effects strengthens confidence in its long-term administration safety, aligning with findings from similar validation studies on compound Unani formulations [14].

## 5. Conclusion

Sharbat-e-Ejaz demonstrated statistically significant ($p < 0.001$) and clinically meaningful reduction in dry cough severity (65.9% VAS reduction) over four weeks of treatment in patients with Sual-e-Yabis. The formulation exhibited an excellent safety profile with no adverse effects on haematological or biochemical parameters. These findings provide scientific validation of this Unani Pharmacopoeial formulation, supporting its inclusion as a standard therapeutic option for Sual-e-Yabis in evidence-based Unani clinical practice. Larger randomised controlled trials with a comparator arm are recommended to further substantiate these findings.

## Acknowledgment

The authors sincerely acknowledge Director General, Central Council for Research in Unani Medicine (CCRUM), Ministry of Ayush, Government of India, for his constant support and for providing the financial assistance and necessary facilities to carry out this validation study.

His guidance and encouragement have been invaluable in enabling us to complete this work and publish it in a peer-reviewed journal.

## References

1. Ibn Sina. Al-Qanoon fi al-Tibb (The Canon of Medicine). Lucknow: Munshi Nawal Kishore Press; 1906. Vol. II, pp. 312-318.
2. Kabiruddin M. Al-Makhzan-ul-Mufradat (Khawas-ul-Advia). New Delhi: CCRUM; 1985. pp. 220-225.
3. Jurjani AH. Zakhira-e-Khawarzam Shahi. Tehran: Nashr-e-Ketab; 1976. Vol. 5, pp. 45-52.
4. Morice AH, Millqvist E, Bieksiene K, et al. ERS guidelines on the diagnosis and treatment of chronic cough in adults and children. Eur Respir J. 2020;55(1):1901136.
5. Prasad R, Garg R, Singhal S. Pattern of respiratory diseases: A hospital-based study from Northern India. Lung India. 2012;29(1):10-14.
6. Anonymous. Unani Pharmacopoeia of India, Part-II. Vol. 1. New Delhi: Ministry of Health and Family Welfare, Govt. of India; 2007. pp. 71-72.
7. Beg S, Swain S, Ibrahim M, et al. Review on phytochemistry and pharmacology of Cordia myxa Roxb. Anc Sci Life. 2011;31(1):32-37.
8. CCRUM. Guidelines for Clinical Validation of Unani Formulations. New Delhi: Central Council for Research in Unani Medicine, Ministry of AYUSH; 2013.
9. Khare CP. Indian Herbal Remedies: Rational Western Therapy, Ayurvedic and Other Traditional Usage, Botany. Berlin: Springer-Verlag; 2004.
10. Morice AH, Jakes AD, Faruqi S, et al. A worldwide survey of chronic cough: a manifestation of enhanced somatosensory response. Eur Respir J. 2014;44(5):1149-1155.
11. Song WJ, Chang YS, Faruqi S, et al. The global epidemiology of chronic cough in adults: a systematic review and meta-analysis. Eur Respir J. 2015;45(5):1479-1481.
12. Dewick PM. Medicinal Natural Products: A Biosynthetic Approach. 3rd ed. Chichester: Wiley; 2009.
13. Al-Snafi AE. Therapeutic properties of medicinal plants: a review of plants with anti-inflammatory, antipyretic and analgesic activity. Int J Pharmacol. 2015;12(2):148-162.
14. Khan IA, Khanum A. Role of Biotechnology in Medicinal and Aromatic Plants. Vol. XIII. New Delhi: Ukaaz Publications; 2005.