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Validation of Unani Pharmacopoeial formulation- *Sharbat Zūfā Murakkab* in patients of *Suāl Ratab* (Productive Cough)

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ABSTRACT

Background: *Suāl Ratab (Productive Cough) is a clinical entity characterised by excessive mucus production, cough, chest tightness, and sore throat, aligning with Unani concepts of Balgham (phlegmatic) predominance. Sharbat Zūfā Murakkab (SZM) is a classical compound formulation of hyssop and accessory drugs documented in Unani pharmacopoeia, purported to possess expectorant (Munaffis-e-Balgham), bronchospasmolytic, and anti-inflammatory properties.*

Objective: *To evaluate the clinical efficacy and safety of Sharbat Zūfā Murakkab in patients presenting with Suāl Ratab at a tertiary-level Unani institution.*

Methods: *A single-arm, open-label observational clinical trial was conducted at RRIUM Mumbai under the CCRUM protocol. One hundred and nine (109) consenting patients were enrolled; 92 completed the study. Standardised symptom scores (cough frequency, intensity, quantity of expectoration, sore throat, hoarseness, chest tightness) were recorded at baseline, 1st follow-up (approx. day 15), and 2nd follow-up/end of treatment (approx. day 30). Haematological parameters (Hb, TLC, ESR) and biochemical safety markers were assessed pre- and post-treatment. Outcome was categorised as Cured (CR), Relieved (RL), Partially Relieved (PRL), and Not Relieved (NRL). Wilcoxon signed-rank test was applied for within-group comparisons.*

Results: *Mean age was 41.3 ± 12.3 years (range 18–64); males predominated (87.9%). Balghami temperament (Mizaj) was present in 79.8% of cases. Among 92 evaluable patients, 41 (44.6%) were Cured, 29 (31.5%) Relieved, 15 (16.3%) Partially Relieved, and 7 (7.6%) Not Relieved — giving a combined positive response rate of 76.1% (CR+RL). All symptom scores showed statistically significant reduction from baseline to both follow-up visits ($p < 0.0001$). Mean cough frequency score fell from 2.37 to 0.74 (68.8% improvement). TLC declined significantly ($p = 0.002$) and ESR showed significant reduction ($p = 0.014$). No adverse events were recorded.*

Conclusion: *Sharbat Zūfā Murakkab demonstrated clinically meaningful and statistically significant benefit in Suāl Ratab, with a favourable safety profile. These findings support its validation as a pharmacopoeial Unani formulation for productive cough.*

Keywords*: Sharbat Zūfā Murakkab, Suāl Ratab, Productive Cough, Unani Medicine, CCRUM, Phytotherapy, Balghami Mizaj.*

1. Introduction

Cough (*Suāl*) is one of the most common presentations in clinical practice and serves as a primary defensive reflex of the respiratory system. It is triggered when irritants stimulate cough receptors distributed throughout the airways, initiating a sequence involving deep inspiration, forceful expiratory effort, brief glottic closure, and sudden release of air to expel offending material [1]. It represents the most violent of respiratory acts and is a hallmark symptom of both upper and lower respiratory tract infections [2]. Cough is broadly classified into non-productive (dry) and productive (*Suāl Ratab*) types, the latter being characterised by expectoration of mucus or sputum [3]. Productive cough, when persistent, significantly impairs quality of life and may indicate underlying mucosal inflammation or infection of the tracheobronchial tree [4]. In Unani medicine, *Suāl* is attributed to four principal aetiologies: *Su-e-Mizāj* (temperamental dyscrasia), inflammatory conditions including *Qurooh* and *Busoor* of the lungs, entry of foreign bodies (*Ajsām-e-Gharibā*) into the respiratory tract, and pathologies of neighbouring organs [5]. Classical Unani physicians described an elaborate pharmacopoeial repertoire of both *Mufrad* (single) and *Murakkab* (compound) preparations for its management, with particular emphasis on expectorant formulations for *Suāl Ratab* [6].

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Sharbat Zūfā Murakkab, an officially listed Unani Pharmacopoeial compound, has been widely employed by traditional practitioners for productive cough with clinically promising responses [7]. Despite its traditional use, rigorous scientific validation of its efficacy and safety remains lacking. The present study, therefore, aims to evaluate the therapeutic efficacy and safety of Sharbat Zūfā Murakkab in patients of *Suāl Ratab* (productive cough) through an open clinical trial.

2. Methodology

2.1 Study Design

The present study was conducted as an open-label clinical trial to evaluate the efficacy and safety of the Unani Pharmacopoeial formulation Sharbat Zūfā Murakkab in patients of *Suāl Ratab* (productive cough). Open-label trials are considered appropriate in preliminary clinical validation of traditional medicine formulations where blinding is not feasible in early-phase evaluations [8].

2.2 Study Duration

The total duration of the study was one year. Each enrolled patient underwent protocol therapy for a period of two weeks (14 days), with follow-up assessments scheduled at day 7 and day 14 [9].

2.3 Patient Selection

Patients were recruited based on pre-defined inclusion and exclusion criteria in accordance with Good Clinical Practice (GCP) guidelines [10].

Inclusion Criteria: Patients of either sex aged between 18 and 65 years presenting with a complaint of productive cough (*Suāl Ratab*) of more than three days duration with associated expectoration were enrolled in the study.

Exclusion Criteria: Patients were excluded if they presented with non-productive (dry) cough, or were known cases of serious respiratory conditions requiring concomitant therapy, including pneumonia, bronchiectasis, bronchial asthma, pulmonary tuberculosis, or lung carcinoma. Patients with known renal, hepatic, or cardiac impairment, those requiring long-term therapy, and pregnant or lactating women were also excluded from the study [2].

2.4 Intervention

The study drug Sharbat Zūfā Murakkab, an officially listed formulation in the Unani Pharmacopoeia of India [7], was administered orally at a dose of 10 ml thrice daily (TDS) with lukewarm water for a period of 14 days. No concomitant or adjuvant medication was permitted during the study period. The pharmacopoeial standardisation of the formulation was ensured as per the specifications laid down in the Unani Pharmacopoeia of India [7].

2.5 Assessment of Efficacy

The primary outcome measure was the effect of the study drug on the frequency, intensity, and character (quantity and nature of expectoration) of productive cough. Secondary outcomes included improvement in associated symptoms namely *Khushūna al-Halaq* (sore throat), *Buhha al-Sawt* (hoarseness of voice), and chest tightness.

All parameters were scored on a standardised ordinal scale at baseline, day 7 (first follow-up), and day 14 (completion of protocol therapy) [3].

Cough Parameters:

- **Frequency:** Scored as 1 (mild – occasional), 2 (moderate – more than five episodes per day), or 3 (severe – constant throughout the day).
- **Intensity:** Scored as 1 (mild – not troublesome), 2 (moderate – affecting routine activities), or 3 (severe – compelling complete cessation of activity).
- **Quantity of expectoration:** Scored as 1 (scanty, 1–2 teaspoons per day), 2 (moderate, 3 teaspoons to half cup per day), or 3 (copious, half to one full cup per day).

Associated symptoms (*Khushūna al-Halaq*, *Buhha al-Sawt*, and chest tightness) were graded on a four-point scale: 0 (absent), 1 (mild), 2 (moderate), and 3 (severe).

Details of expectoration including colour (clear/watery, white/creamy, yellow, green, grey, or blood-tinged), consistency (watery, mucoid, thick, or frothy), and smell (agreeable or foul) were recorded at each assessment visit.

2.6 Assessment of Safety

Safety was assessed through clinical monitoring for adverse events and laboratory investigations performed at baseline and at the end of the study. Laboratory parameters included Complete Blood Count (Hb%, TLC, DLC, ESR), Liver Function Tests (serum bilirubin, SGOT, SGPT, serum alkaline phosphatase), Kidney Function Tests (serum urea, serum creatinine), and urine routine and microscopic examination along with classical gross urine examination. These investigations were selected in accordance with standard protocols for safety monitoring in traditional medicine trials [11].

2.7 Assessment of Results

The overall therapeutic response was graded based on percentage relief in symptoms and signs as follows [9]:

Grade	Interpretation
Complete Relief	90–100% relief in symptoms and signs
Relief	60–89% relief in symptoms and signs
Partial Relief	30–59% relief in symptoms and signs
Not Relieved	Less than 30% relief in symptoms

2.8 Statistical Analysis

Data collected on the Clinical Record Form (CRF) at baseline, first, and second follow-up visits were compiled and analysed using appropriate statistical methods. Paired comparisons of symptom scores before and after treatment were performed to determine the significance of therapeutic response, with a p-value of less than 0.05 considered statistically significant [12].

4. RESULTS

4.1 Patient Enrolment and Disposition

A total of 109 patients were enrolled during the study period (April 2013 – January 2016). Of these, 92 patients were evaluable for the primary outcome analysis, having completed the study per protocol and attended at least the end-of-treatment visit. Seventeen patients (15.6%) were lost to follow-up or withdrew consent and were excluded from the per-protocol analysis.

4.2 Demographic and Baseline Characteristics

Table 1: summarises the demographic and temperamental profile of the 109 enrolled patients

Characteristic	Category / Value	n (%) or Mean ± SD
Total enrolled	—	109
Evaluable patients	—	92 (84.4%)
Age (years)	Mean ± SD (range)	41.3 ± 12.3 (18–64)
Sex	Male	96 (88.1%)
	Female	13 (11.9%)
Mizāj (Temperament)	Balghami (Phlegmatic)	87 (79.8%)
	Safrawi (Bilious)	22 (20.2%)
Duration of disease (days)	Mean ± SD (range)	17.0 ± 7.2 (2–45)
Patient status	New cases	99 (90.8%)
Socioeconomic status	Lower-middle / Poor	82 (75.2%)

Table 1: Baseline demographic and clinical characteristics of enrolled patients (N = 109).

The majority of patients were male (88.1%), consistent with occupational exposure patterns in lower-income populations. The mean disease duration of 17 days indicates a predominantly acute or sub-acute presentation. Balghami Mizāj was present in nearly 80% of patients, underscoring the classical Unani pathophysiological basis of Suāl Ratab as a Balgham-predominant condition.

4.3 Treatment Outcomes

Among the 92 evaluable patients, treatment outcomes were distributed as follows: 41 patients (44.6%) were Cured, 29 (31.5%) Relieved, 15 (16.3%) Partially Relieved, and 7 (7.6%) Not Relieved. The combined positive response rate (Cured + Relieved) was 76.1%.

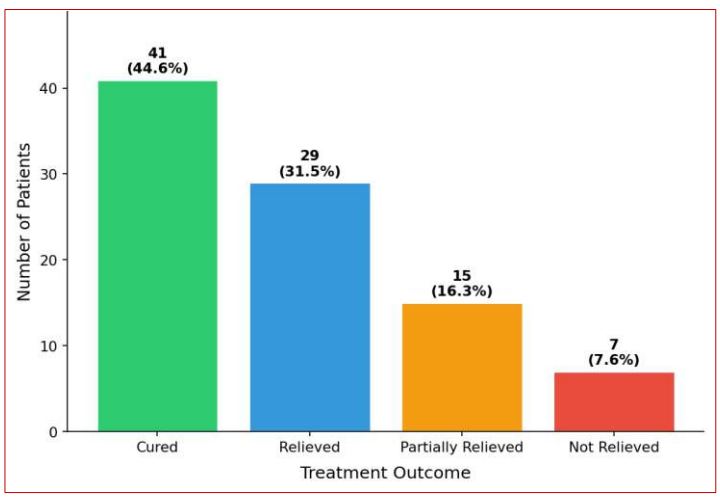

Figure 1: Treatment outcome distribution, Distribution of treatment outcomes in 92 evaluable patients treated with Sharbat Zūfā Murakkab for Suāl Ratab. CR = Cured; RL = Relieved; PRL = Partially Relieved; NRL = Not Relieved.

4.4 Symptom Score Analysis

All three primary symptom domains — cough (frequency/intensity), sore throat, and chest tightness — showed progressive and statistically significant reductions across the two follow-up assessments. Mean cough frequency scores declined from 2.37 ± 0.67 at baseline to 1.42 ± 0.72 at 1st follow-up and further to 0.74 ± 0.82 at 2nd follow-up (68.8% reduction; Wilcoxon $p < 0.0001$). Sore throat scores reduced from 2.04 to 0.44 (78.4% reduction) and chest tightness from 1.70 to 0.25 (85.3% reduction) by end of treatment.

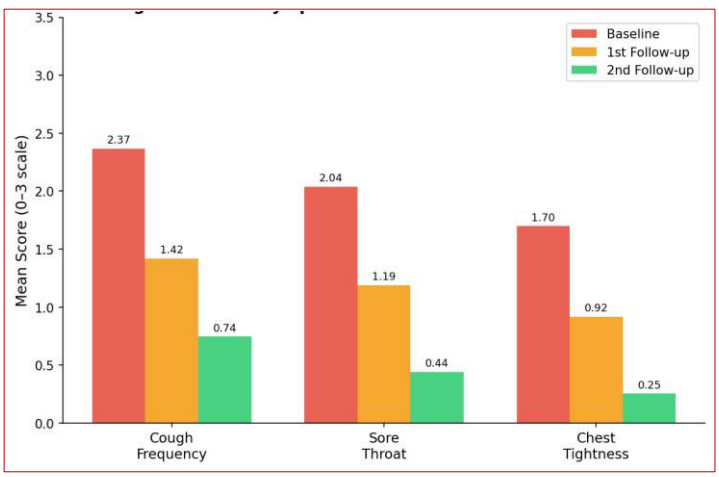

Figure 2: Mean symptom scores across treatment phases. Mean symptom scores at baseline, 1st follow-up (day ~15), and 2nd follow-up/end of treatment (day ~30) for cough frequency, sore throat, and chest tightness (0–3 scale; 0 = absent, 3 = severe). All comparisons baseline vs. 2nd follow-up: $p < 0.0001$ (Wilcoxon signed-rank test).

Table 2: presents detailed symptom score statistics

Symptom	Baseline Mean ± SD	1st F/U Mean ± SD	2nd F/U Mean ± SD	% Improvement (p-value)
Cough Frequency	2.37 ± 0.67	1.42 ± 0.72	0.74 ± 0.82	68.8% ($p < 0.0001$)
Cough Intensity	2.07 ± 0.65	1.30 ± 0.70	0.55 ± 0.76	73.4% ($p < 0.0001$)
Quantity of Expectoration	1.93 ± 0.71	1.15 ± 0.73	0.47 ± 0.68	75.6% ($p < 0.0001$)
Sore Throat	2.04 ± 0.88	1.19 ± 0.87	0.44 ± 0.71	78.4% ($p < 0.0001$)
Hoarseness of Voice	1.58 ± 1.02	0.99 ± 0.95	0.33 ± 0.62	79.1% ($p < 0.0001$)
Chest Tightness	1.70 ± 0.97	0.92 ± 0.91	0.25 ± 0.57	85.3% ($p < 0.0001$)

Table 2: Within-group comparison of symptom scores before and after treatment with Sharbat Zūfā Murakkab (n = 92 evaluable patients). F/U = Follow-up.

4.5 Laboratory Parameters

Haematological and biochemical investigations are presented in Table 3. Haemoglobin levels remained essentially stable (14.2 ± 1.5 vs 14.0 ± 1.4 g/dL; p = 0.062), confirming no haematinic toxicity. Total leucocyte count showed a statistically significant decline from 8049 ± 1715 to 7627 ± 1658 cells/mm^3 (p = 0.002), consistent with resolution of the underlying infective or inflammatory process. ESR also declined significantly from 21.1 ± 13.1 to 20.5 mm/hr at 1st hour (p = 0.014). Serum creatinine and blood urea remained within normal limits throughout, indicating no nephrotoxicity. Liver function tests showed no clinically meaningful changes.

Table 3: Effect of Treatment on Hematological, Inflammatory, and Renal Function Parameters

Parameter	Baseline Mean ± SD	End of Treatment Mean ± SD	p-value
Haemoglobin (g/dL)	14.2 ± 1.5	14.0 ± 1.4	0.062 (NS)
Total Leucocyte Count (/mm^3)	8049 ± 1715	7627 ± 1658	0.002*
ESR — 1st hr (mm)	21.1 ± 13.1	20.5 ± 12.8	0.014*
Serum Creatinine (mg/dL)	1.28 ± 0.41	1.07 ± 0.28	< 0.05*
Blood Urea (mg/dL)	21.6 ± 9.8	20.7 ± 9.3	NS

*Table 3: Haematological and biochemical parameters before and after treatment. * Statistically significant (p < 0.05, Wilcoxon signed-rank test). NS = Not significant.*

4.6 Safety

No adverse drug reactions or serious adverse events were reported during the study period. Routine monitoring of hepatic and renal function tests revealed no clinically significant abnormalities attributable to the study drug. The formulation was well tolerated by all participants across the full treatment duration.

5. DISCUSSION

This study demonstrates that Sharbat Zūfā Murakkab produced clinically significant and statistically robust improvements across all measured symptom domains in patients with Suāl Ratab. A combined positive response rate of 76.1% (CR+RL) at end of treatment is a meaningful clinical result for a condition that, particularly in the lower-income demographic served by this institution, often goes undertreated or is managed only with symptomatic conventional medicines. The predominance of Balghami Mizāj (79.8%) in the study population is consistent with classical Unani diagnostic criteria for Suāl Ratab: cold and moist humoral excess predisposes to mucus hypersecretion, bronchial hyperresponsiveness, and ciliary dysfunction. The pharmacological logic of SZM aligns precisely with this pathophysiology. Zūfā (Hyssopus officinalis) is documented in Unani and contemporary pharmacognostic literature for its antispasmodic, expectorant, and antimicrobial properties, attributable to rosmarinic acid, flavonoids, and volatile oils including pinocamphone and isopinocamphone. Asl-us-Sūs (Glycyrrhiza glabra) contributes anti-inflammatory (glycyrrhizin) and demulcent effects; Unnāb and Sapistān provide soothing mucilaginous action on the irritated tracheobronchial mucosa; and Tukhm-e-Khatmī adds further expectorant and emollient activity. The significant decline in TLC (p = 0.002) reflects reduction of the acute inflammatory-infective process driving productive cough, and is consistent with the anti-inflammatory and antimicrobial pharmacological profile of SZM ingredients. The decline in ESR (p = 0.014) corroborates systemic anti-inflammatory activity. Importantly, haemoglobin stability throughout treatment confirms the absence of haemolytic or bone marrow adverse effects, while renal and hepatic safety data provide evidence that SZM does not produce organ toxicity at the prescribed doses.

The progressive improvement observed at both follow-up visits — rather than a plateau after the first assessment — supports the hypothesis that the therapeutic effects of SZM accumulate over the treatment period, consistent with the classical Unani concept of progressive Islāh-e-Mizāj (temperamental correction) rather than simple symptom suppression.

The particularly large improvement in chest tightness (85.3%) may reflect the bronchospasmolytic component of Zūfā's volatile oil fraction, which has been compared in preclinical models to beta-adrenergic agents. Study limitations include the single-arm design without a placebo control group, the single-centre setting, and the absence of spirometric or radiological assessment. The observational nature means that regression to the mean cannot be excluded as a contributor to symptomatic improvement. Future work should include randomised controlled trials comparing SZM with both placebo and a standard-of-care comparator (e.g., ambroxol or guaifenesin), with objective respiratory function endpoints.

6. CONCLUSION

Sharbat Zūfā Murakkab demonstrated statistically significant and clinically meaningful efficacy in the management of Suāl Ratab (Productive Cough), with a 76.1% positive response rate (Cured or Relieved) and substantial improvement across all symptom domains in 92 evaluable patients. The drug was well tolerated without any adverse events, and laboratory safety parameters remained within acceptable limits. The significant reduction in TLC and ESR additionally supports an objective anti-inflammatory effect. These findings provide clinical validation for the pharmacopoeial status of Sharbat Zūfā Murakkab and justify its continued inclusion in the Unani Pharmacopoeia of India as a formulation for productive cough. Randomized controlled trials with objective endpoints are recommended to establish its efficacy against placebo and conventional therapy.

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