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Research Article

STANDARDIZATION OF A COMPOUND UNANI FORMULATION *'AL-AHMAR'*

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ABSTRACT

In Unani System of Medicine the drugs derived from natural sources are used, the majority of them are plant origin 85 %, animal origin 10% and mineral origin 5% but like any other system of medicine the efficacy of Unani System of Medicine also depends on potential and purity of the drugs used. To develop a mechanism for quality assurance of mineral compound to ensure the purity of crude drugs material and its standardization is essential. Standardization and quality control are the key factors in regulating the therapeutic efficacy of Unani Herbal drugs. Organoleptic parameters are often insufficient in the quality assessment of Unani Herbal Drugs. The present study deal with compound Unani formulation of 'Al-Ahmar' is compound formulation of National Formulary of Unani Medicine Part 5. 'Al-Ahmar' is a red colour powder therpeutically used in Zoof-e Bah and Qillat Shahwat Ba-sabab Broodat-e- Mizaj. 'Al-Ahmar' is a natural product and is absolutely safe as it does not produce any side effects. In standardization of drugs, the drugs investigation through different chemical method, their active principale are being worked out, their percentage composition are as follow Alcohol soluble matter 0.70 %, Water soluble matter 3.60%, Bulk Density 4.88-5.00, Water content negligible, Mercury not more than 50 ppm and pH 10%: 8.28 & 1%: 8.51 is being determined and purity is confirmed. In addition analysis of Microbial Load, Aflatoxin and Pesticidal residue were also done but not detected.

KEYWORDS: Al-Ahmar, Standardization, quality control and NFUM.

INTRODUCTION

In Unani medicine drugs derived from natural sources have been used since its origin in Greece about 2000 years ago. During the past decade there has been an ever increasing demand especially from developed countries for drugs from natural sources. This revival of interest is mainly due to the current widespread belief that Unani medicine is safe and more dependable than synthetic drugs. One Unani formulation "Alahmar" is taken in order to standardize it for quality assurance and to help manufacturers to produce standard products. The methods of preparations that are evolved after many experiments are finalized and mentioned in this communication. This Unani formulation are prepared after taking into consideration the best methods suitable in the Indian atmosphere. The standardization on the basis of the recommendations of attributes recommonded by authentic bodies[1], is made and three experiments for three different batches of compound preparations (nine experiments for one parameter) are done and the data were Statically finalized." Alahmar" is used in treatment of *Zoof-e Bah* and *Qillat Shahwat Ba-sabab Broodat-e- Mizaj*[2].

Material and Methods

The raw materials were procured or collected from local market or from the field as when required and subjected to the standardization based on the data provided in the Unani, Ayurvedic, Indian and/or British Pharmacopoeia and preceded accordingly. The standards of those raw materials that are not available were standardized in the laboratory based on the recommendations of the Indian Pharmacopoeia/WHO guidelines[1,3]. For those attributes that are not mentioned in the Unani Pharmacopoeia and/or WHO bulletin the standard methods mentioned in different Journals or CCRUM books[2] for standardization of Single as well as compound formulations are used or developed in the lab. The commercial sample of, Shingraf, Zamin Qand, Raugahn-e-Qurtum were standardized and their standards are quoted here.

Shingraf: Chemical Name: Murcuric Sulphide Red, Chemical Formulae: HgS; Composition: Mercury 86 %; Sulphur 14%; Colour: Bright Red; Texture: Powder or in solid pieces

Physico Chemical analysis: On heating: above 250^0 C Become brown but red again on cooling.

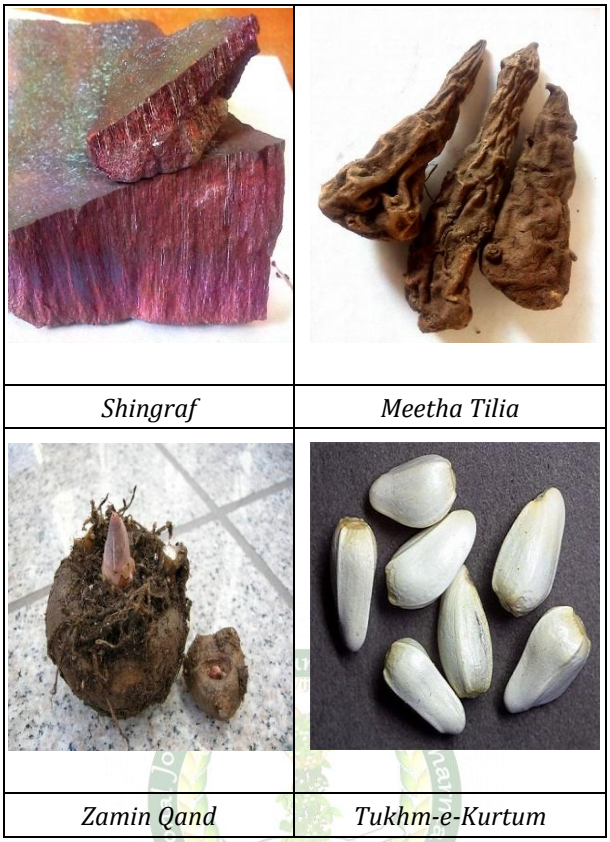
On heating (ignited): it burns and release Sulphur tri oxide; Solubility: Commercial sample is very less soluble in water; less than 3.5% Practicaly insoluble, In Alcohol Commercial sample approximately 8% soluble in alcohol.

Zamin Qand: Botanical Name: *Amorphophallus campanulatus* Blume**;** Family: Amorphophllacea, "A tuberous herb; tuber depressed-globose, 20-25 cm diameter, bulbiferous dark brown; leaves 1 or 2, appearing long after flowers, 30-90 cm broad ; segments spreading, simple or forked; leaflets 5-12.5 cm long of variable width, sessile, obovate or oblong strongly many-veined, with

green edges; petioles 60-90 cm long, stout, warted dark green with paler patches.

Physicochemical Analysis: Moisture: 74.8%; Ash: 0.73%; Fat (ether extract): 0.38%; Protein: 5.1%; Carbohydrates: 18.4%; Crude fibre: 0.6%. Chemical Analysis: Tuber contains an alkaloid, fat, protein and carbohydrates.

Fig.1. Ingridients of "Qurs Gulnar"



Shingraf | *Meetha Tilia*

Zamin Qand | *Tukhm-e-Kurtum*

Qurtum ka Tel: Botanical Name: *Carthamus tinctorius* Linn.; Family: Compositae; Source: Seeds; Physicochemical Property: Seeds contain: 30-35% oil; Appearance: oil is liquid at room temperature; Colour: colorless; Odour: flavorless; Taste: Oily; Density at 25°C: 918.8 kg/m; Refractive index: 918.8; Viscosity at 25°C, unrefined: 0.04914 kg/; Content of Oil: Palmitic acid : 4 - 9%; Stearic acid : 1 - 7%; Oleic acid : 14 - 10%; Linoleic acid : 48 - 74%.

Raw Materails: The formulation contains the ingridients (Table 1) that are mentioned in part Vth of National Formulary of Unani Medicine [4]. The raw materials were purchased from the market and their identity, purity and strength were checked as per reference, given in table 1.

Table 1. Ingredients of 'Alahmar'

S.No.	Unani Name	Botanical/English Name	Part Used	Quantity	Reference
1	*Shingraf*	Murcuric sulphide (HgS)	Mineral	100 g	*
2	*Metha Telia*	*Aconitum nepellus* Linn	Root	100 g	UPI, Part1, Vol. 4, P. 19-20
3	*Zammen Qand*	*Amorphophallus campanulatus* Blume	Root stock	1 No.	*
4	*Raugahn-e-Qurtum*	*Carthamus tinctorius* Linn	Seed Oil	500 ml	*
5	*Urad ka Aata*	*Phaseolus radialus* Linn	Flour	QS	*

Note:*1. Standardization of the raw material made in the laboratory and mentioned under the heading of material and method.

2. UPI: The Unani Pharmacopoeia of India

Method of preparation

Big size pieces of *Metha Telia* were cut and soak in water for whole night. When it becomes soft pits of moderate size was made and filled with small pieces of *Shingraf*. The opening of pit was covered with flacks and pieces of *Metha Telia* that was collected carefully while making the pits, and ties it with cotton thread. Then a deep grove was made in *Zamin Qand* of such a size that can accommodate all the pieces of *Metha Telia*. Then all the pieces of *Metha Telia* were placed in the groove in *Zamin Qand* and the opening was covered with the same *Zamin Qand* pieces that come out while making the deep grove. The *Zamin Qand* was covered with the paste of the flour of *Urud* made in water and then covered with cotton cloth carefully. In a separate fry pan the oil of *Qurtum* was boiled

and the prepared piece of *Zamin Qand* was placed and boil till the outer cover of *Zamin Qand* become red then the pan was removed from the burner and cooled. *Zamin Qand* was taken out and the covering was removed. Further all the pieces of *Metha Telia* containing *Shingraf* were taken out. All the pieces of *Meetha Telia* and *Zamn Qand* were discarded only *Shingraf* was collected that makes the drug.

Preparation of powder: The *Shingraf* was powdered in a Mortal and Pistil till the shine of the *Shingraf* defatted. Complete the powdering process till the grains passes the 100 mesh sieve.

Production: Net production is expected to be 95g /100 g *Shingraf*.

Loss: The net loss during processing is expected to be 5g/100g *Shingraf.*

Physicochemical Parameters

Physicochemical studies like alcohol and water soluble matter; water content; loss on drying according to methods recorded in Indian Pharmacopoeia, WHO guidelines (2005) and methods mentioned by Afaq *et al* [1,3,6]. Thin Layer Chromatography was conducted taking the help of method mentioned by Harborne[7], using the standard methods by using a suitable solvent and pre-coated silica gel (60 F254) aluminum plates (layer thickness 0.25mm). The visuali-zation of spots were made by giving the different spray treatment of developed plates or observing the colour under UV light. The atomic absorption method for heavy metals determination was used. The drug was ignited in to ash that dissolved in suitable solvent and proceeded accordingly. The presence of aflotoxins and microbial load were studied as per revised recomendation of WHO mentioned in its bulletin [5].

Table 2. Heavy Metals (a), Microbial Load (b), Aflatoxin (c) and Pesticide residue (d) of 'Marham Quba'

(a) Qualitative Analysis for Heavy Metals

S. No.	Test Parameters	Results	Limits
1	Lead as Pb	5.219 ppm	NMT 10.ppm
2	Mercury as Hg	46.418 ppm	*
3	Arsenic as As	3.185 pm	NMT 3.0 ppm
4	Cadmium as Cd	Not Detected	NMT 0.3 ppm

***Note** Limit of Mercury is not applicable. The drug comprises only processes *Shingraf*. The Market sample of *Shingraf* contains Hg, Pb. and As.; hence the limit of heavy metals did not apply as a whole.

(b) Microbial Load (for three samples)

S. No.	Microbes	Result*	Limit
1	Total Bacterial Count	Nil	Not more than 105 /g
2	Total Fungal Count	Nil	Not more than 103/g
3	*Enterobacteriaceae*	Nil	Nil
4	*Salmonella*	Nil	Nil
5	*Staphylococcus aureus*	Nil	Nil

(c) Aflatoxin (for three samples)

S. No.	Aflatoxin	Result*	Limit
1	B1	Not detected	Not more than 0.50 ppm
2	B2	Not Detected	Not more than 0.10 ppm
3	G1	Not Detected	Not more than 0.15 ppm
4	G2	Not Detected	Not more than 0.10 ppm

(d) Pesticide residue (for three samples)

S. No.	Pesticide	Result*	Limit
1	Chlorpyrifos	Not detected	Not more than 0.2 mg/kg
2	DDT	Not detected	Not more than 1.0 mg/kg
3	Endosulfan	Not detected	Not more than 3.0 mg/kg
4	Malathion	Not detected	Not more than 1.0 mg/kg
5	Parathion	Not detected	Not more than 0.5 mg/kg

Note. *All result based on three experiments.

Results and Discussion

The alcohol soluble matter not less than 0.70% and water soluble matter was not less than 3.60%. Bulk density was 4.88-5.00. The water content was recorded as Negligible. The pH of 1% aqueous solution was 8.51 and 10% aqueous solution was 8.28. The methonolic extract of powder was subjected to TLC studies but no any spot observed after spraying the plate with vanillin sulphuric acid reagent. The plate was developed in the mixture of toluene and ethyl acetate (9:1). The heavy metals, aflotoxins, pesticidal residue and Microbial load were also studied and reported (Table 3a, 3b, 3c, 3d) No growth of any Fingi or Bacteria were observed in the cultural media

and no aflotoxines (B1,B2,G1,G2) were detected. Hg, and As are detected in the formulation due to such type of compound which is containg with mercury and arsenic.

CONCLUSION

The compound Unani Formulation "*Alahmar*" used in the current study is of the standard parameter as given in Ayurevedic and Unani Pharmacopoeia. The above standards can be used for correct identification of market samples of drug.

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