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Research Article

STANDARDIZATION OF A UNANI PHARMACOPOEIAL TABLET 'QURS-E-NUQRA'

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KEYWORDS: Standardization, quality control, Qurs and NFUM.

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ABSTRACT

There is a global demand for natural plant based products including Unani medicines for various health problems. As such the standardization is burning topic in Unani as well as Ayurvedic drugs manufacturer today. Standardization is an essential measurement for ensuring the quality control. The three steps of standardization during the manufacturing of the drug i.e. raw material, in process and final product standardization. Like any other system of medicine the efficacy of Unani formulations depends on potential and purity of the drugs used. To develop a mechanism for quality assurance of plants products and to ensure the purity of crude drugs and its standardization is essential. Standardization and quality control are the key factors in regulating the therapeutic efficacy because organoleptic parameters are insufficient for quality assessment. The present study deal with compound Unani formulation of 'Qurs-e-Nuqra' a tablet formulated on the formullae mentioned in National Formulary of Unani Medicine Part I. For standardization of drugs, investigation of the tablets were made on the basis of the parameters approved by the Unani Pharmacopoea Committe, along with the analysis of pesticidal residue, microbial load, heavy metals and aflotoxin analysis. The Thin layer chromatography (TLC) finger printing was made to check the standard of future batch.

INTRODUCTION

In present era plant derived products are gaining importance as medicinal products, nutraceuticals and cosmetics. Herbal Medicines are widely used in health care in developed and developing countries. According to an estimate of the World Health Organization about 80% of the world population still uses herbs abd other traditional medicines for their primary health care needs. The interest of peoples increse day by day about Unani System of Medicine. The issue of quality, efficacy and safety of Unani Herbal Drugs have attained renewed attention of scientist, and there is need of sufficient scientific data in order to enforce acceptance of Unani Herbal medicines on large scale in India and abroad. One Unani formulation "Qurs-e-Nuqra" 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 (Unani Pharmacopoeia/WHO guidelines [1,2] 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."Qurs-e-Nuqra" is used in treatment of *La qwa, Zaheer, Ishal, Sua*l and *Nazla* [3].

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 and Indian 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 [2,4]. 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 [5] for standardization of Single as well as compound formulations are used or developed in the lab. The commercial sample of Shigraf was 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% Practically insoluble, In Alcohol Commercial sample approximately 8% soluble in alcohol.

Processing of raw materials

All the ingredients mentioned in table 1 of the tablet "Qurs-e-Nuqra" was powdered at 80 meshes sepratly. Frequent checking of particle size of powder was made. The drug passed through the 80 number sieves and if any parts are remains then powdered further and nothing was discarded.

Preparation of "Qurs-e-Nuqra" (Tablet)

"Qurs-e-Nuqra" (Tablet) is prepared according to the composition of the formulation (Table 1) in the following manner while maintaining the proportion of the ingredients for the present batch size. The powder was added in juice of the lemon to make paste (lubdi). The Lubdi was dried and passed through a granulator to get the grains. The granule was pressed through a tablet making machine using a die that gives 500 mg tablets. The tablets were dried in a hot air oven at 60°C + 5°C. Then Stored in air tight container and further studies were made.

Table 1: Formulae of Qurs Nuqra

S.No.	Unani Name	Botanical / English Name	Part Used	Reference	Quantity
1	Beesh-e-mudabbar	*Aconitum nepellus* Linn	Root	UPI, Part1, Vol. 4, P. 19-20	100 g
2	Shingraf	Murcuric sulphide	Mineral	*	100 g
3	Filfil-daraz	*Piper longum* Linn	Catkin	API, art1, Vol.4, P.91-92	100g
4	Tankar biryan	Sodium Borate	Mineral	IP, 1970, p. 82	100g
5	Filfil-e-siyah	*Piper nigrum* Linn.	Fruit	UPI, Part1, Vol. 4, P. 38	100 g
6	Aab-e-lemo	*Citrus limon* Linn.	Juice	API, Part1, Vol.4, P. 75	750 ml

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. 3. API: The Ayurvedic Pharmacopoeia of India. 4. IP: Indian Pharmacopeia

Determination of the weight and diameter of the "Qurs-e-Nuqra"

The weight of ten tablets was taken using electronic balance. The average weight of the tablets was calculated and considered as the weight of the tablet in grams. The diameter of five tablets was taken using Vernier Caliper. The mean of the reading gives the value of the diameter of the tablets.

Method for the determination of disintegration of tablets

The rate of disintegration was measured by Disintegration-testing apparatus using the two media, the aqueous as well as in the acidic medium. Simulated Gastric Fluid (pH about 1.2) was prepared without enzyme by dissolving 1 gm of NaCl in 500 ml of de-ionized water, adding 7 ml of concentrated HCl, and diluting the volume to 1000 ml with water. For measurement in aqueous medium Double distilled water was taken [1].

Friability and disintegration

Friability is the ability of tablets to withstand the movement of shipping and handling without breaking or chipping. A friabilator is a device use to test this ability by allowing a few tablets to roll and fall within the machine, and the change in weight of the tablets is measured.[6] The disintegration time were determined by using the disintegration equipment using the method mentioned in WHO Bulletin. [7]

Physicochemical Parameters

Physicochemical studies like total ash; acid insoluble ash; water soluble ash; alcohol and water soluble matter; water content; loss on drying according to methods recorded in Indian Pharmacopoeia, WHO guidelines and methods mentioned by Afaq *et al* [2, 6, 7, 8]. Thin Layer Chromatography was conducted taking the help of method mentioned by Harborne [9], using the standard methods by using a suitable solvent and pre-coated silica gel (60 F254) aluminum plates (layer thickness 0.25mm). The visualization 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. [7]

Table 2: Physicochemical Properties of Qurs Nuqra

Parameter	Qurs Zeabetus Sada*
Total ash Acid insoluble ash Water soluble ash	Not more than 14% Not more than 2% Not more than 0.068%
Alc. S. Matter Aq. S. Matter	Not less than 11% Not less than 20%
Water Content	Not more than 6%
pH of aq. Solution (i) pH of the 1% (ii) pH of the 10%	 8.33 8.22
Weight of Qurs in mg	500 mg
Disintegration time	In pure water: 17 sec Acid medium: 10 sec
Diameter of Qurs	10 mm

*Each sampal done in triplicate

Table 3: Heavy Metals (a), Aflatoxin (b) and Microbial Load (c) of Qurs-e-Nuqra

(a) Qualitative test for Heavy Metals

S.No.	Test Parameter	Results*	Limit
1	Arsenic	Less than 3 ppm	Not more than 3 ppm
2	Cadmium	Less than 0.3 ppm	Not more than 0.3 ppm
3	Lead	Less than 10.0 ppm	Not more than 10.0 ppm
4	Mercury	Less than 1 ppm	Not more than 1 ppm

*Each parameter is mean of three experiments

(b) Aflatoxin

S.No.	Test Parameter	Results*	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

*Each parameter is mean of three experiments

(c) Microbial Load

S.No.	Test Parameter	Results*	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

*Each parameter is mean of three experiments

Fig.1. Ingredients of "Qurs-e-Nuqra"

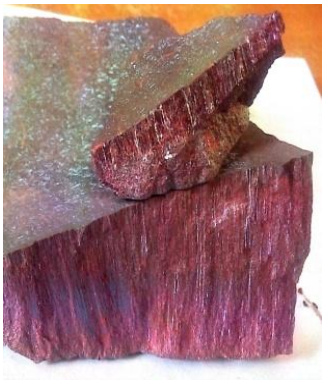
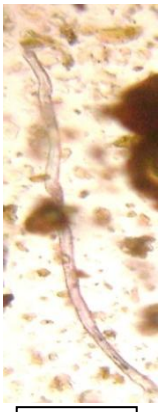
		
Beesh-e-mudabbar	**Shingraf**	**Filfil-daraz**
		
Tankar biryan	**Filfil-e-siyah**	**Lemo (for Aab-e-lemo)**

Fig.2. Thin Layer Chromatography Profile of "Qurs-e-Nuqra

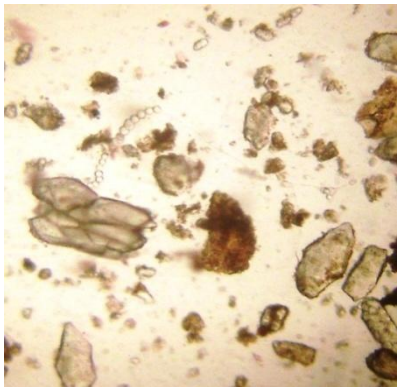
Qurs-e-Nuqra

Fig.3. Microscopy of Qurs-e-Nuqra

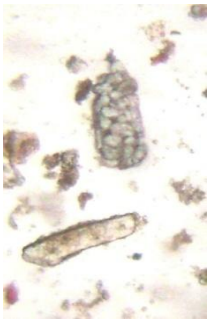
Sclerenchyma of Aconite



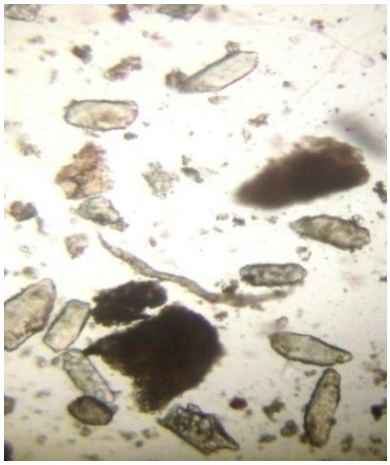
Fibers



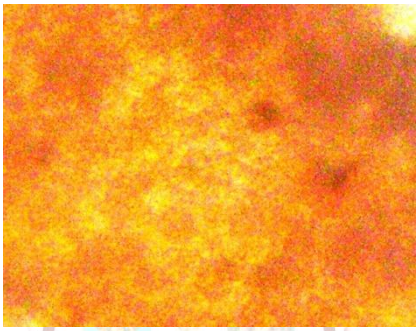
Parenchyma of Filfil-e-Draz and Siyah



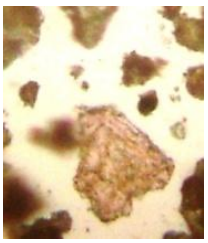
Vessel

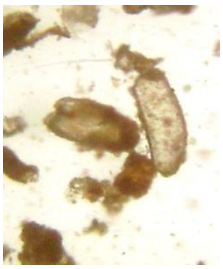


Parenchyma of Filfil-e-Draz & Siyah



Epicarp of Filfil-e-Siyah





Stone cell and Parenchyma of Filfil-e-Siyah

Results and Discussion

The physicochemical studies of the average 500 mg tablets not less than revealed the total ash not more than 14%, acid insoluble ash not more than 2% and water soluble ash not more than 0.068% (negligible). The alcohol soluble matter not less than 11% and water soluble matter was not less than 20%. The water content was recorded as not more than 6%. The pH of 1% aqueous solution was 8.33 and 10% aqueous solution was 8.22. The average 10 mm size of the tablets stands for 2 hours with a minimum loss of 1% in friability test. The maximum disintegration time of the tablets in the water was 17 second showing that the tablet can be disintegration in stomach quickly making the drug available to the body for its designated activities. The atomic absorption analysis of the tablets shows absence of all the heavy metals (As, Cd, Pb and Hg). While no bacteria or fungus was noted, even after keeping the tablets for about two years. The zero hours no aflatoxin (B1, B2, G1, G2) were recorded and also not recorded after two years. No pesticide (Chloropyriphos, DDT, Endosulphan, Malathion and Parathion) were detected.

The methonolic extract of tablets was subjected to TLC studies (Fig. 1) and 6 major spots were observed (Rf. 0.2 (Yellow), 0.38 (purple), 0.47 (Dark purple), 0.62 (Light brown), 0.8 (Light brown), 0.98 (Light brown) after spraying the plate with vanillin sulphuric acid reagent. The plate was developed in the mixture of toluene and ethyl acetate (9:1). The tablet is hard solid, blackish in colour with Very astringent in taste and during preperation of one batch 2% loss is expected.

CONCLUSION

The compound Unani Formulation "Qurs-e-Nuqra" 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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