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Research Article

PHYSICOCHEMICAL STUDY OF A *UNANI* PHARMACOPOEAL TABLET '*QURS-E-GULNAR*'

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ABSTRACT

In the Unani System of Medicine the drugs derived from natural sources are used, the majority of them are from plant origin. These single drugs are formulated in different dosage forms i.e. Tablets, Pills and Semisolids (Lauq, Khamira, Majoon etc.). 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-Gulnar 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. their percentage composition are as follow Total ash 22,89 %, Acid insoluble ash 21.72 %, Water soluble ash 1.39, Alcohol soluble matter 17.68 %, Water soluble matter 31.11%, , Water content 4.53%, pH 10%: 3.91 & 1%: 4.05, Disintegration time in pure water 30 second, Disintegration time in acid media 25 second, weight of qurs 500 mg and Diameter of qurs 10 mm is being determined and purity is confirmed. In addition analysis of Microbial Load, Aflatoxin and Pesticidal residue were also done but not detected The Thin layer chromatography (TLC) finger printing was made to check the standard of future batch.

INTRODUCTION

In present scenerio the interest of peoples increse day by day about traditional medicine and drugs of Unani System of Medicine are included in the list. 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-Gulnar" 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." Qurs-e-Gulnar" is used in treatment of Ishal-e-Muzmin, Ishal-e-Damwi and Nazf-ud-Dam [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 [4] for standardization of Single as well as compound formulations are used or developed in the lab. The commercial sample of Aqaqia, Gile-e-Armani, and Gulnar were standardized and their standards are quoted here.

Aqaqia: Botanical name: Acacia nilotica (L) Willd (Leguminosae); The black colored tablets (disk like) of around 2 cm diameter and around 4 mm thick, Irregular margin hard in texture and astringent in taste. Some time the mark of the company or numbers are also encrypted. The drug is prepared by boiling the crushed pods of Acacia Arabica in water and drying the extract in shade or in oven under low temperature black particles in the powder are visible under microscope. % of Alcohol soluble matter: not less than 37%, Water soluble matter: not less than 60%, Total Ash: not more than 8 %, Water soluble ash: not more than 3.6%, Acid insoluble ash: not more than 1.6%.

Gil-e-Armani: Armenian Bole; It occurs in powder or irregular pieces of favorable brown color soft and somewhat heavy. It is granular and sprinkled with white particles, when put into the mouth it stick firmly to tongue. % of alcohol soluble matter: not less than 0.5%, Water soluble matter: not less than 1.6%, Total Ash: not more than 94.5%, Acid insoluble ash: not less than 78.5 %, Water soluble ash: not more than 2.0% Chemical Test: Iron positive.

Gulnar: Botanical name: *Punica granatum* Linn. (Lythraceae); Flowers 3.8-5 cm long and as much across, mostly solitary, sometime 2-4 together, terminating short shoots, sometimes apparently axillary, sessile or nearly so. % of Alcohol soluble matter: not less than 42%, Water soluble matter: not less than 50%, Total Ash: not more than 55 %, Water soluble ash: not more than 3%, Acid insoluble ash: not more than 1.2%.

Processing of raw materials:

All the ingredients except Aab-e-gulnar mentioned in table 1 of the tablet "Qurs-e-Gulnar" were 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. The Juice of the fresh flowers of Gulnar was obtained by using an electrical juicer.

Method of preparation

"Qurs-e-Gulnar" (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 "Gulnar" 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.

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

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 [5]. 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 (2005) and methods mentioned by Afaq *et al* [1,3,7,8]. 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: 1. Formullae of "Qurs Gulnar"

S. No.	Unani Name	Botanical / English Name	Part Used	Quantity	Reference
1	Gulnar	*Punica granatum* Linn.	Flower	40 g	*
2	Aqaqiya	*Acacia nilotica* (L) Willd	Dried extract of Pods	30g	*
3	Gil-e-Armani	Armenian Bole	Bole	40 g	*
4	Gul-e-surkh	*Rosa damascena* Mill.	Flower	30 g	UPI, Part 1, Vol. 3, pp.31
5	Samagh-e-Arabi	*Acacia nilotica* (L) Willd	Gum	40 g	UPI, Part 1, Vol. 6, pp.66
6	Kateera	*Cochlospermum religiosum* Linn.	Gum	20 g	UPI Part 1, Vol. 6 pp.38
7	Aab-e-gulnar	*Malus sylvestris* Mill.	Juice	Q.S.	

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

Table: 2.Physicochemical Properties of "Qurs Gulnar"

Parameter	"Qurs Gulnar"*
Total ash Acid insoluble ash Water soluble ash	Not more than 23% Not more than 22% Not more than 1.5%
Alc. S. Matter Aq. S. Matter	Not less than 17% Not less than 30%
Water Content	Not more than 5%
pH of aq. Solution (i) pH of the 1% (ii) pH of the 10%	 4.03-4.07 3.90-3.98
Weight of Qurs in mg	500 mg
Disintegration time	30-31min. 24-25min.
Diameter of Qurs	10 mm

Note:*Each sample done in triplicate

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

(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.

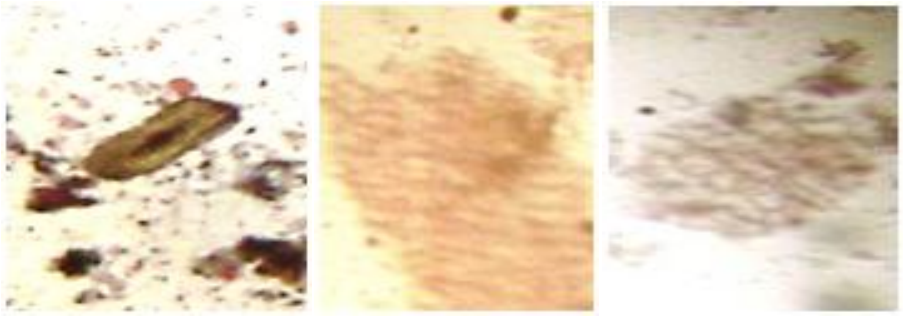
(c) Microbial Load

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. Ingridients of "Qurs Gulnar"

Fig.2. Microscopy of "Qurs Gulnar"



The stone cells | Petal parts | Petal parts

Fig.3. Thin Layer Chromatography Profile of "Qurs Gulnar"

Results and Discussion

The physicochemical studies of the average 500 mg tablets not less than revealed the total ash not more than 23%, acid insoluble ash not more than 22% and water soluble ash not more than 1.5%. The alcohol soluble matter not less than 17% and water soluble matter was not less than 30%. The water content was recorded as not more than 5%. The pH of 1% aqueous solution was 4.05 and 10% aqueous solution was 3.91. 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 15 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. The methonolic extract of tablets was subjected to TLC studies (Fig. 3) and four spots were observed (Rf. 0.14 (dark purple), 0.32 (pink), 0.43 (Dark purple), 0.46 (dark purple) after spraying the plate with vanillin sulphuric acid reagent. The plate was developed in the mixture of toluene and ethyl acetate (9:1).

The micrscopy of flower petals of Gul-e-surkh and Gulnar, along with the small tracheids and fibers are visible. The soil Particles of Gil-e-Armani and the particles of gums of Kateera and Samagh-e-arabi are also present. Small stone cells of Gulnar are also visible at many places.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-Gulnar" 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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