Physicochemical standardization of a Unani Pharmacopoeal Tablet ‘*Qurs-e- Mulayyan’*

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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- Mulayyan a tablet formulated on the formullae mentioned in National Formulary of Unani Medicine Part 5. 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 9.50 %, Acid insoluble ash 3.5 %, Water soluble ash 3.30, Alcohol soluble matter 19.30 %, Water soluble matter 16.80%, , Water content 3.6%, pH 10%: 6.32 & 1%: 7.16, Disintegration time in pure water 10.32 minutes, Disintegration time in acid media 12.36 minutes, weight of qurs 580 mg and Diameter of qurs 1.4 cm 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.

**Key Words**: Qurs, Standardization, quality control and NFUM

1. **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- Mulayyan” 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 (Anonymous, 1978(b), 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- Mulayyan*” is used in treatment of Qabz, Nazla, Qabz Sabab Ramad, Wajh-ul-uzn wa Anf, Mode of administration: oral and dose: 2-3 tablets (Anonymous, 2008).

1. **MATERIALS 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 (Anonymous, 1978(a);Anonymous, 1978(b). 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 (Anonymouse, 2008) for standardization of Single as well as compound formulations are used or developed in the lab. The commercial sample of Saqmonia, Arrowroot, and Magnesia Fahmi were standardized and their standards are quoted here.

## Saqmonia:

## This substance is all factious, and is said to be made in Surat; nevertheless it was for many years purchased by the Medical store Department in Bombay under the impression that it was genuine Scammony (PI) Appearance: in irregular fragments. Color: bright green colour; Texture: somewhat translucent at the edges, and having a resinous fracture. Solubility: Rectified spirit dissolves the resin, and leaves a residue of green colouring matter and gum. Green color residue: vegetable origin. Sometimes a black Saqmonia is met with; this is also spurious, and is resinous in taste and smell, but has a more solves out a quantity of resin, and leaves a black residue vegetable hairs, numerous small carbonaceous particles, and small irregular crystalline particles. Treat with dilute hydrochloric acid it effervesces feebly after a short time; with strong acid it effervesces strongly at once, and form a green solution.

## Physicochemical analysis of Saqmonia: Total Ash Value: not more than 3.41% , Acid insoluble ash: not more than 0.98% , Water soluble ash: Negligible, Alcohol Extract: Not less than 63.12%, Water Extract: Not less than 5.12%, NOTE: High Quantity of Pb is noted

## Past Arrowroot Starch

**Other name:** Maranta starch

**Microscopy:** The granules of maranta starch are ovoid with a few small tuberosities; the striations are concentric and rather indistinct; the hilum is usually at the border end of the granule and is represented in commercial starch by a split which usually has the form of two radiating, curved lines. They are 7 to 30 to 45 to 75 microns in diameter and are all simple.

**Colour Test:** With Iodine it gives blue colour

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## Sang-e-Jarahat: Unani Name: Sang-e-Jarahat

**Chemical Name:** Hydrated Magnesium Silicate

**Chemical Formulae**: Mg3O7Si2

**Physical Character:** White Monoclinic Crystals

**Solubility in water:** Insoluble in Water

**Solubility in HF:** Slightly soluble in HF (Hydrogen fluoride)

## Magnesia Fahmi

Unani Name: Magnesia Fahmi

Chemical Name: Magnesium Carbonate

Physical Characters: White Odorless, Bulky Powder

Chemical Formulae: MgCO3

Magnesium as Oxide: 45%

Solubility in Water: Less than 1%

Solubility in Alcohol: Insoluble

Soluble in Acetic Acid; approximately 99.90%

**Processing of raw materials**: It is prepared according to the composition of the formulation given under Table-1, in the following manner while maintaining the proportion of the ingredients for the present batch size.

**(a) Raw materials:** The raw materials were purchased from the market and their identity, purity and strength was checked as per reference.

**(b) Preparation of Tablet**

All the drugs except Mastagi, Sange Jarahat Sayeedah and Magnesium carbonate were grinded and filtered through the filter (80 meshes). Mastagi was grinded in a cold mortar and pestle till it changes in to fine powder then filtered, and added in the powder. To make granule powder mixed with the paste of Arraroot and Gelatin. After making the “lubdi” it was dried further and powdered and sieved through sieve number 16. After that paraffin liquid, Sange Jarahat Sayeedah and Magnesium Carbonate were added and finally tablets were prepared with the help of tablet making machine.

**(c) In Process Standardization**

Frequent checking of particle size of powder is necessary. The instruction may be issued that after passing through the mesh the remaining part should be powdered further and nothing should be discarded.

**(d) Production:** Net product is expected to be 95%.

**(e) Loss:** The net loss during processing is expected to be 5%.

**Determination of the weight and diameter of the “Qurs-e-Mulayyan”**

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 (Table-2).

**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 (Sodium Chloride) in 500 ml of de-ionized water, adding 7 ml of concentrated HCl (Hydrochloric acid), and diluting the volume to 1000 ml with water. For measurement in aqueous medium Double distilled water was taken (Anonymous, 1989)

**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 (Vijaya and Mishra, 2006). The disintegration time were determined by using the disintegration equipment using the method mentioned in WHO Bulletin.

1. **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* (Anonymous, 1978(a); Anonymous, 1978(b); Anonymous, 2005 and Afaq *et al*, 1994). Thin Layer Chromatography was conducted taking the help of method mentioned by Harborne (1973), 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 (Anonymous, 2005).

1. **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 petroleum ether extract of tablets was subjected to TLC studies (Fig. 3), and visualized under UV Long wave length; Two spots; Rf 0.9;0.7 Bluish florescence ; Short Wave length; Rf 0.9 (Yellow fluorescence);0.7 (Blue fluorescence) The plate was developed in the mixture of toluene and ethyl acetate (24:1).

The micrscopy of the powder of “*Qurs-e-Mulayyan*” show the trachieds, stone cells, vessels and fibers, epidermal cells of Senna are visible. The crystals and the starch granules of Arrowroot are abundant. The tablet is hard solid, brownish in color with Very astringent in taste and during preperation of one batch 5% loss is expected.

1. **CONCLUSION**

The compound Unani Formulation “Qurs-e-Mulayyan” 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.

**Table 1: Ingredients of Qurs-e-Mulayyan**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S N0.** | **Unani Name** | **Botanical Name** | **Part Used** | **Reference** | **Quantity** |
| 1 | Amla Khusk | *Emblica officinalis* Gaertn | Dried Fruit | UPI Part 1, Vol 1, p.5 | 25 g |
| 2 | Badyan | *Foeniculum vulgare* Mill | Fruit | UPI Part 1, Vol 1, p.13 | 50 g |
| 3 | Bahera | *Terminalia belerica Rosc* | Fruit | UPI Part 1, Vol 1, p.17 | 25 g |
| 4 | Post Halila Zard | *Terminalia chebula Retz* | Pericarp of Fruit | UPI Part 1, Vol 1, p.32 | 25 g |
| 5 | Turbud Safed | Operculina turpethum Linn | Root | UPI Part 1, Vol 5, p.105 | 100 g |
| 6 | Rewand Chini | *Rheum officinale* Baillon | Root | UPI Part 1, Vol 2, p.91 | 515 g |
| 7 | Saqmonia | *Convolvulus scammonia* Linn | Gum | \* | 375 g |
| 8 | Senna Makki | *Cassia angustifolia* Vahl | Leave | UPI Part 1, Vol 1, p.76 | 565 g |
| 9 | Gond | *Acacia nilotica* Linn | Gum | UPI Part 1, Vol 6, p.66 | 100 g |
| 10 | Mastagi | *Pistacia lentiscus* Linn | Oleo-gum-resin | UPI Part 1, Vol 5, p.50 | 50 g |
| 11 | Halila Siyah | *Terminalia chebula Retz* | Immature Fruit | Standardization of Single drugs Part1, P.86-90 | 25 g |
| 12 | Paste Arrowroot | *Maranta arvndinaceae* Linn | Starch obtained from root | \* | 300 g |
| 13 | Paste Gelatin | Gelatin |  | IP 1970 p.214 | 200 g |
| 14 | Shamaeen | Liquid Paraffin |  | IP 1970 p.354 | 15 g |
| 15 | Sang Jarahat Saeeda | Hydrated Magnesium Silicate | Hydrated Magnesium Silicate (Mineral) | \* | 50 g |
| 16 | Magnesia Fahmi | Magnesium Carbonate | Mg CO3 | \* | 10 g |

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. PI: Pharmacopoeia of India

**Table 2: Physicochemical Properties of Qurs-e-Mulayyan**

|  |  |
| --- | --- |
| **Parameter** | **Qurs-e-Mulayyan \*** |
| Total ash  Acid insoluble ash  Water soluble ash | Not more than 9.50 %  Not more than 3.5 %  Not more than 3.3 % |
| Alcohol Soluble Matter  Aqueous Soluble Matter | Not less than 19.30 %  Not less than 16.80 % |
| Water Content | Not more than 3.6 % |
| pH of aq. Solution  (i) pH of the 1%  (ii) pH of the 10% | 6.32  7.16 |
| Disintegration time:   1. In distilled water 2. In simulated gastric fluid | 10.08-10.32 minutes  10.08-10.32 minutes |
| Diameter of Qurs | 1.40 cm |
| Thickness | 0.4 cm |
| Weight of Qurs in mg | 580-600 mg |

Note: \* Each sample done in triplicate

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

1. Qualitative test for Heavy Metals

|  |  |  |  |
| --- | --- | --- | --- |
| S.No. | Test Parameter | Results\* | Limit |
| 1 | Arsenic | 0.064 ppm | Not more than 3 ppm |
| 2 | Cadmium | 0.441 ppm | Not more than 0.3 ppm |
| 3 | Lead | 0.064 ppm | Not more than 10.0 ppm |
| 4 | Mercury | Not detected | Not more than 1 ppm |

\*Each parameter is mean of three experiments, ppm: stand for part per million

(b) Aflatoxin

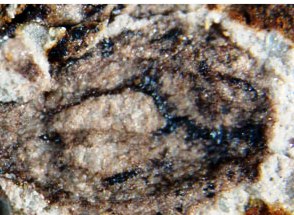
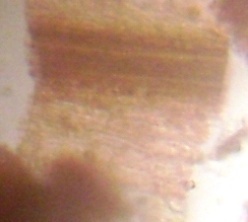
|  |  |  |  |
| --- | --- | --- | --- |
| **S.No.** | **Test Parameter** | **Results\*** | **Limit** |
| 1 | B1 | Not detected | Not more than 0.50 ppm |
| 2 | B2 | Not detected | Not more than 0.10 ppm |
| 3 | G1 | Not detected | Not more than 0.15 ppm |
| 4 | G2 | Not detected | Not more than 0.10 ppm |

\*Each parameter is mean of three experiments.

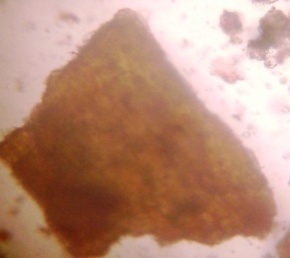
(c) Microbial Load

|  |  |  |  |
| --- | --- | --- | --- |
| **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 |

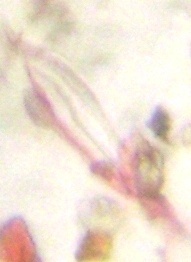
\*Each parameter is mean of three experiments.

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**Parasitic stomata of Senna Crystals, starch grains and stone cells A portion of epidermis**

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**Trachieds Vessels Portion of Post Halila**



**Vessels Crystals, Starch & Stone cells Stone Cell**

## Image 1: Microscopy Qurs Mullayan

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**Short Wave UV Long wave UV**

## Image 2: TLC of Qurs Mullayan

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