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Research Article

### STANDARDIZATION OF *HABB-E-ASGAND*: A UNANI PHARMACOPOEIAL FORMULATION

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**Abstract:**

*Unani medicine is a component of Ayurveda, Yoga & Naturopathy, Unani, Homoeopathy (AYUSH) stream of non-conventional medical systems in India. Since centuries, these systems have been flourishing with the social and cultural acceptance of the general masses. However, standardization/quality control of herbal formulations belonging to these system have become the Achilles' heel. The national and international regulatory agencies have given guidelines for standardization/quality control of herbal formulations in terms of batch to batch quality control and quality assurance. The present study was an effort to prepare and standardize Habb-e-Asgand, a Unani polyherbal pharmacopoeial formulation, used as an anti-inflammatory drug, especially for arthritis/joint diseases. The various parameters performed for the finished products including organoleptic characteristics, physico-chemical analysis in order to establish its standardization.*

**Keywords:** Standardization, AYUSH, Habb-e-Asgand, anti inflammatory drug, arthritis.

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## INTRODUCTION:

Unani medicine is an age-old, time tested stream of medicine dating back 5000 years to the ancient Greece. The great Unani physician Buqrat / Hippocrates (460-377 BC) was the Greek philosopher-physician who freed medicine from the clutches of magic and superstition, and laid foundation of scientific medicine [1]. In Unani system of medicine, principally drugs of herbal origin and partly animal, mineral and metallic origin are used for cure or management of diseases.

Medicinal plants are being used therapeutically all around the world for treating diseases and it is probably the oldest existing method that humanity has used to try to cope with illness.

Polyherbal formulations dominate as the largest segment, capturing a significant share of the overall herbal supplements and remedies market worldwide. In the present advanced era, an increased demand of polyherbal formulations suggests a great need of standard criteria for the development and quality control of these herbal preparations. World Health Organization (WHO) has emphasized the need to ensure quality control of medicinal plant products by using modern techniques and by applying suitable parameters and standards. In order to overcome certain inevitable shortcomings of the pharmacopoeial monograph, other quality control measures must also be explored [2].

*Habb* meaning seed in Arabic relates to its round or oval shaped physical form which has been a pharmaceutical dosage form. Its equivalent is pill in modern pharmaceuticals. It is prepared by mixing of powder of one or more than one drugs with suitable binding agent. *Habb* can be taken by the patients easily as compared to *safoof* (powder) [3,4]. It is prepared manually as well as mechanically with the help of pills making machine.

A polyherbal formulation, *Habb-e-Asgand* described in the present study is a Unani pharmacopoeial formulation mentioned in *Bayaz-e-Kabeer*, Vol. 2, an official pharmacopoeia mentioned under Schedule-1 of Drugs & Cosmetics Act, 1940. The drug is used in the treatment of various ailments, especially the joint disorders like arthritis, backache and neurological disorders from a long time [3, 4, 5, 6].

In order to standardize the drug, the formulation has been prepared according to *Bayaz-e-Kabeer*, Vol. 2. The drug has been evaluated for various parameters like morphological and physico-chemical parameters like ash value, moisture content, pH of 1% and 10% solutions, disintegration time, pill friability. The present study may be used as a reference model for the preparation of the formulation and also described salient features of identification and safety evaluation of the product.

## MATERIALS AND METHODS:

All the individual crude drugs *Asgand* (*Withania somnifera*), *Filfil daraz* (*Piper longum*) *Bidhara* (*Gmelina asiatica*), *Satawar* (*Asparagus racemosus*), *Nankhah* (*Trachyspermum ammi*), *Filfil moya* (*Piper longum*), *Zanjabeel* (*Zingiber officinale*), *Musli Safed* (*Chlorophytum arundinaceum*) were procured from open market in Delhi.

### Processing of *Habb-e-Asgand*

*Habb-e-Asgand* was prepared according to *Bayaz-e-Kabeer*, vol. 2. *Asl/Shehad* (honey) was used as binding agent. All ingredients were identified by the experts, and cleaned thoroughly. They were weighed and powdered separately. Lubdi (dough) was made with honey manually. The round shape, pea size pills were made and thereafter left to dry.

### 1. Separation of foreign matter

All the foreign matter was inspected with the unaided eye and cleared from foreign matter.

### 2. Authentication of crude drugs:

All the drugs samples were separately examined by the departmental experts.

### 3. Powdering of drugs:

All drugs were taken individually, and each of the drugs was powdered one by one in the mixer grinder. Before powdering each sample, the grinder was properly washed and dried. Then, the powdered drugs were separately sieved with mesh (number 100).

### 4. Organoleptic characters

Appearance	: oval
Size	: 8mm
Color	: Light brown
Smell	: Medium note
Taste	: pungent

### Diameter of Pill

Uniformity of diameter was performed by picking three pills randomly and the diameter was measured individually by using a Vernier caliper and expressed in mm.

### Hardness of pill

Hardness of pills was evaluated by Monsanto hardness tester. Three pills were selected randomly. The tester consists of a barrel containing a compressible spring held between two plungers. The lower plunger was placed in contact with a pill, and a zero reading is taken. The upper plunger was then forced against a spring by turning a threaded bolt until the pill fractures. As the spring compressed, a pointer rides along a gauge in the barrel to indicate the force. The force of fracture was recorded, and the zero reading was deducted from it. Hardness was performed on three tablets in all instances, and the average values were recorded.

**Friability Test**

Friability of the pills was determined using Friability test apparatus. This device subjects the pills to the combined effect of abrasions and shock in a plastic chamber revolving at 25 rpm and dropping the pill at a height of 6 inches in each revolution. Pre-weighed sample of pills was placed in the friabilator and were subjected to 100 revolutions. Pills were dedusted using a soft muslin cloth and reweighed. The friability ( $f$ ) is calculated by the formula:

$$f = [1 - w/w_0] \times 100$$

Where,  $W$  is the weight of the pills before the test and  $W_0$  is the weight of the pills after the test. The procedure was repeated three times and the mean value was calculated.

**Determination of pH****(a) The pH value of 1% solution**

An accurately weighed one gm of powdered drug was dissolved in accurately measured 100 ml of distilled water, filtered and pH was measured with a pH meter.

**(b) The pH value of 10% solution**

An accurately weighed 10gm of powder drug was dissolved in accurately measured 100 ml of distilled water, filtered and pH was measured with a pH meter

**Loss of Weight on drying**

5 gm of drug was taken, spread uniformly and thinly in a shallow petri dish. It was heated at a regulated temperature of  $105 \pm 1^\circ\text{C}$ , cooled in a desiccator and weighed. The process was repeated many times till two consecutive weights were constant. The percent loss in weight was calculated with respect to initial weight. The readings were carried out in triplicate and average value was noted.

**Ash values Determination****Total Ash:**

A sample of 2 gm of air dried powdered drug was incinerated in a silica dish at a temperature not exceeding  $450^\circ\text{C}$  until free from Carbon, cooled and weighed and the percentage was calculated with reference to air dried drug [7].

**Determination of Disintegration Time**

Disintegration rate was measured by a double six-cylinder basket rack assembly 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 1gm of NaCl in 500 ml of deionized 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. The USP device to test disintegration uses 6 glass tubes that are 3 inches long, open at the top, and held against a 10 mesh screen at the end of basket rack assembly. To test for disintegration time, one pill was placed in each tube, and the basket rack is positioned in a 1L beaker of water, simulated gastric fluid at  $37^\circ\text{C} \pm 2^\circ\text{C}$ , such that the pills remain 2.5 cm below the surface of liquid on their upward movement and descend not closer than 2.5 cm from the bottom of beaker. A standard motor driven device was used to move the basket assembly containing the tablets up and down through a distance of 5 to 6 cm at a frequency of 28 to 32 cycles per minute. The pills must disintegrate and all particles must pass through the 10 mesh screen. If any residue remains it must have a soft mass with no palpably firm core. The readings were carried out in triplicate and average values were noted [8].

**RESULTS AND DISCUSSION:**

The standardization of *Habb-e-Asgand* has become possible by considering various pharmaceutical parameters concerning the quality protocol, keeping intact procedures following the Unani pharmaceutical procedures and methods. For the quality control analysis, a battery of parameters, such as ash content, acid insoluble ash, moisture content, pH, soluble extractives were performed. The values retrieve for each of these parameters was found to be consistent for four months. So, the preparation method and value obtained for above parameters might be considered for laying down new standards while preparing *Habb-e-Asgand* according to traditional methods. The fact that the finished product was found to be stable over up to 4 months is more than indicative that the medicine continues to retain its therapeutic value. The outcomes obtained could be used as a standard reference for the preparation of *Habb-e-Asgand* for getting optimal efficacy of the medicine.

**Table: Physicochemical Parameters**

Physicochemical Parameters	Results
Appearance	oval
size	8mm
Color	Light brown
Smell	Medium note
Taste	pungent
pH in (1% sol)	6.32
pH in (10 % sol)	6.05
Total Ash	6.09%
Friability (in 30 minutes)	0.53%
Hardness	5 Kg/cm
Disintegration	47 min.
Mean weight	0.33grams
LOD	6.7%

**CONCLUSION:**

There are no standard operating procedures (SOPs) available so far. Hence, an effort has been made to standardize *Habb-e-Asgand*, a popular Unani compound formulation. In the present study, *Habb-e-Asgand* was prepared according to Bayaz-e-Kabir, Vol. 2. The formulation under study was subjected to physico-chemical analysis in order to establish the standards by using a battery of physical parameters, such as pH determination (1% and 10%), Friability test, Ash value, Disintegration time, Dissolution test, Moisture content, Thin layer chromatography (TLC) etc. This study will be helpful in the quality assurance of pharmacopoeial formulations prescribed in the Unani system of medicine and in the development of standard parameters.

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