



## QUALITY STANDARDS AND SAFETY PROFILE OF A UNANI FORMULATION, HABB-E-SURANJAN

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### ABSTRACT

When conventional therapies fail to treat chronic diseases efficaciously and without any adverse effects, many people seek unconventional including herbal formulations. Herbal medicines are easily accessible, low cost and free from severe side effects. Habb-e-Suranjan is a common unani formulation which is used for treatment of gout and cough. The aim of study deals to standardization of the formulation, Habb-e-Suranjan by using physico-chemical, microscopical and safety profile parameters. The standardisation of Habb-e-Suranjan was carried out as per WHO guidelines.

**KEY WORDS:** Habb-e-Suranjan, safety profile, WHO guideline, microscopical, physico-chemical parameter, gout, cough.

### INTRODUCTION

Habb-e-Suranjan is a common unani formulation which is first time mentioned in Qurabaddin majeedi (Pharmacopoeia of Majeedia). It consist of following crude drugs - *Aloe vera* juice, *Pistacia lentiscus* resin (Mastagi), gum of *Commiphora mukul* (Guggul), *Colchicum luteum* corm (Suranjan sheerein), *Ipomoea hederaceae* seeds (Kaladana), *Ipomoea turpenthum* stem (Jalap) and *Anethum sowa* fruits<sup>1</sup>. All the plant drugs having different type of pharmacological activities such as *Colchicum luteum* is used for the treatment of gout<sup>2</sup> and arthritis<sup>3</sup>, *Aloe* is having anti- bacterial<sup>4</sup>, antiinflammatory<sup>5</sup> and wound healing activity<sup>6</sup>, *Mastagi* is used in treatment of arthritis<sup>7</sup>, antibacterial<sup>8</sup> and antioxidant effect<sup>9</sup>, *Commiphora mukul* have antiarthritic<sup>10</sup>, anti-inflammatory<sup>11</sup>, antibacterial<sup>12</sup> and antifungal activity<sup>13</sup>. *Anethum sowa* is used as antimicrobial<sup>14</sup>, antiarthritic and anti-inflammatory agent<sup>15</sup>. Both *Ipomoea hederaceae* and *Ipomoea turpenthum* used in treatment of constipation<sup>16,17</sup> (as Purgative). But the formulation particularly used for the treatment of gout and cough<sup>1</sup>. The present study deals with the standardization of the formulation, Habb-e-Suranjan by using microscopical, physical, and safety profile parameters as per WHO guidelines.

### MATERIAL AND METHODS

#### Collection and authentication of crude drugs

*Aloe vera* juice, *Colchicum luteum* corm, *Commiphora mukul* gum, *Pistacia lentiscus* resin, *Anethum sowa* fruits, *Ipomoea hederaceae* seeds, *Ipomoea turpenthum* stem were bought from a local crude drug market (Khari Bowli) in Delhi and was authenticated from NISCAIR by taxonomist Dr. H.B. Singh (NISCARE/RHMD/Consult.-Ref no. NISCARE/RHMD/Consult.-2010-11/1589/187. A voucher specimen has been deposited for further reference.

#### Preparation of Habb-e-Suranjan

Habb-e-Suranjan consist of following herbal drugs such as *Colchicum luteum* corms (28 g), *Aloe barbedensis* gel (31 g), *Anethum sowa* fruits (31 g), *Pistacia lentiscus* resin (13 g), *Commiphora mukul* gum (13 g), *Ipomoea hederaceae* seeds (31 g), *Ipomoea turpenthum* stem (81 g) and prepared by method which is given in Qurabaddin Majeedi<sup>1</sup>.

### STANDARDIZATION OF HABB -E- SURANJAN

#### Organoleptic properties

Physical examination of the untreated sample of Habb-e-Suranjan was carried out under diffused sunlight and artificial source similar to day light.

#### Powder microscopy

Powdered formulation was taken and it was cleared with chloral hydrate solution and stained with Phlouroglucinol and conc. HCl. Powder is mounted with glycerine and observe under microscope<sup>18</sup>.

#### Physical parameter

Extractive value and ash value of formulation was carried out by following standard WHO techniques<sup>19</sup>. Fluorescence analysis was carried out by Chase and Pratt methods<sup>20</sup>. Qualitative phytochemical tests were carried out by standard methods of Kokate<sup>21</sup>, Trease & Evans<sup>18</sup> and Mohammad Ali<sup>22</sup>. pH and loss on drying determination of formulation was carried out according to Indian Pharmacopoeia<sup>23</sup>.

#### Safety profile

Microbial load, pesticidal residue, heavy metal analysis and aflatoxin determination was carried out according to Pharmacopoeia standards<sup>24</sup>.

### RESULTS AND DISCUSSIONS

#### Organoleptic properties

The organoleptic properties are dark brown in colour, round in shape, bitter in taste, pungent odour and smooth appearance of the formulation and all these parameters helpful to make the formulation more appealing.

#### Powder microscopy

Brownish green powder showed oil globules and minute starch grains scattered throughout and parenchyma of cotyledon with oil globules and starch grains, group of pitted lignified cell of testa was observed which was characteristic of seeds and Habb-e-Suranjan was consist only seed of *I. Hederaceae* Jacq. Powder also showed fragments of dark brown cork composed of thin-walled cells, polygonal and more or less isodiametric in surface view. Abundant starch granules which was simple and spherical in shape. Sclereids which was found singly and sometime it was associated with parenchyma also and these characteristics was present in *I. Turpenthum* L. Epidermis in surface view showing cells with more uniformly thickened walls, parenchyma and part of

spirally thickened vessels, fragments of vessels with spiral and annular thickening and these features was in corm of *Colchicum luteum* Baker. It also showed fragment of a vittae in surface view, sclereids of the wings, endosperm cells with microrosette crystals of calcium oxalate and oil globules and it was characteristic of umbelliferous fruits and this formulation was contain only one umbelliferous fruit *i.e* *A. sowa* Roxb (Figure 2). All the cellular content was identical for particular drugs so presence of these contents indicates presence of particular drugs and maintain genuinely standard of the formulation.

#### Physical parameter

All the phytochemical standards were established according to procedure laid down in WHO guidelines and Indian Pharmacopoeia<sup>18</sup>. The formulation was found to be total ash content of 18.90 % and the acid insoluble ash being of 1.5% and water soluble ash being of 8.6. The analysis of ash values suggested the presence of inorganic substances in considerably normal amounts which was indicated that adulterated materials (silica, sand, dust and soil) were not present in the formulation. pH of the formulation was found to be 6.1 in 1% and 5.75 in 10% solutions. The pH of the formulation was found neutral so it indicates that the formulation is safe to administer. Loss on drying value of formulation was found 6.8 and if it is in more amount then formulation are more prone for microbial infections (Table 1).

The hot extractive value of formulation was found highest 30.34% in hydro-alcoholic extract and lowest 3.7% in petroleum ether extract (Table 2) and in case of cold extractive value, only the extractive percentage is different (figure 1). Fluorescence analysis was carried out to check purity of formulation. The powder form of formulation was observed in visible light as brownish yellow in colour. The powder was treated with different type of reagents and observed in UV light (short and long wavelength) and it emit different colour fluorescence as shown in Table 3.

Qualitative analysis of formulation indicated the presence of protein, carbohydrates, tannin, resins, glycosides, alkaloids, steroids, phenolic compounds and flavonoids (Table 4).

#### Safety profile

To determine safety profile of drugs heavy metal analysis (lead, mercury, cadmium, and arsenic) and pesticidal residue analysis, aflatoxins and microbial load were find out. The formulation showed the results within prescribed limits (as per WHO guideline). So formulation was found to be free of lethal effect due to absence or under the limits of these safety parameters. The observation value of these safety parameters such as microbial load determination (Table 5), heavy metal (Table 6), aflatoxins (Table 7) and for pesticidal residue (Table 8) was indicate that Habb-e-Suranjan was safe to administer.

#### CONCLUSION

Powder microscopy of the formulation, Habb-e-Suranjan was performed to check the presence of genuine drugs by identifying cellular contents. Physico-chemical parameters like ash value, extractive value, fluorescence analysis, pH determination, loss on drying, qualitative estimation of phyto-constituents of this formulation was established and safety profile parameters (heavy metal analysis, aflatoxin, pesticidal residue and microbial load) of standardization were also determined and was found to be under the limits (as per WHO guidelines) which indicate that the formulation "Habb-e-Suranjan" was safe. The present study will be useful for the establishment of quality standards and may be useful for

further research on Habb-e-Suranjan for academicians and researchers.

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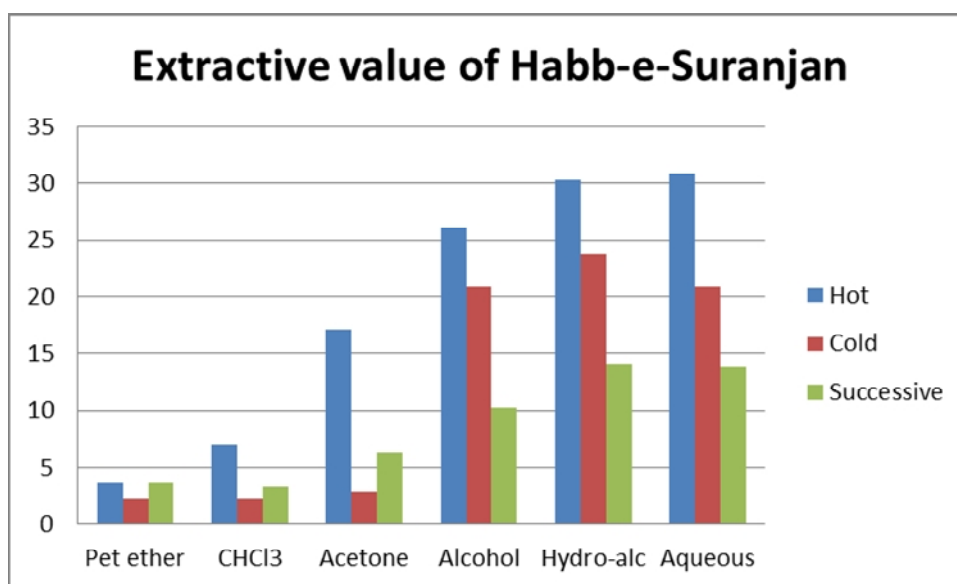
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**Table 1. Ash value, Loss on drying and pH of Habb-e-Suranjan**

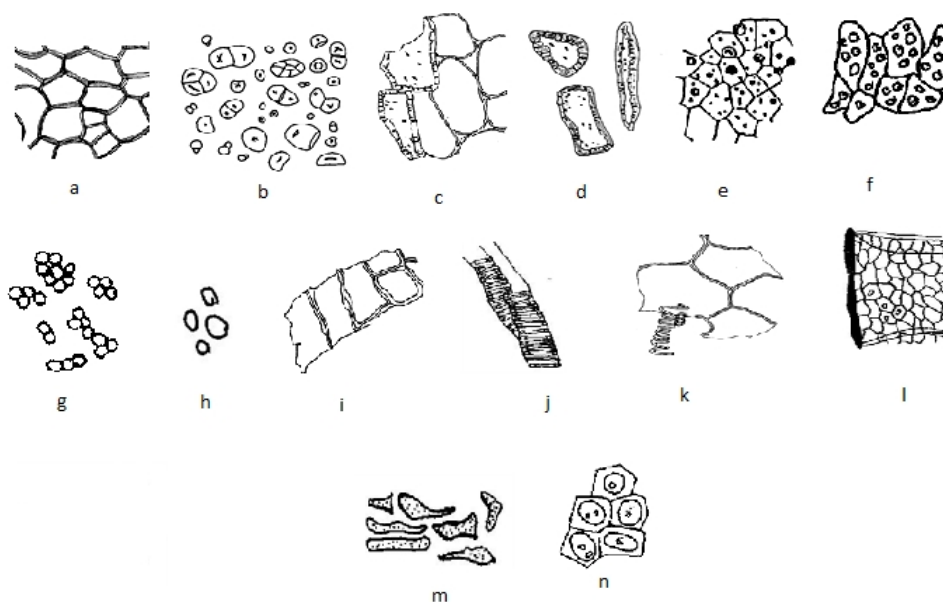
Habb-e-Suranjan		% mean
Ash value (% w/w)		
Total ash (%)		20.96
Acid insoluble ash (%)		1.5
Water soluble ash (%)		8.6
pH		
pH of 1 % solution		6.10
pH of 10 % solution		5.75
Loss on drying		6.8

**Table 2. Extractive value of Habb-e-Suranjan**

Extract	Pet Ether %	Chloroform %	Acetone %	Alcohol %	Hydro-Alcoholic %	Aqueous %
Hot	3.7	6.94	17.14	26.13	30.34	30.90
Cold	2.2	2.27	2.9	20.9	23.8	20.9
Successive	3.7	3.42	6.25	10.20	14.08	13.91



**Fig 1. Extractive value of Habb-e-Suranjan**



**Fig 2. Powder microscopy of Habb-e-Suranjan**

**Fig 2.** (a) cork; (b) Starch grains (c) Sclereids; (d) Group of Sclereids; (e) Parenchyma of cotyledon with oil globules and starch grains; (f) pitted lignified cell of testa; (g) Starch Grains; (h) oil globules; (i) Epidermis with more uniformly thickened walls; (j) parenchyma with spirally thickened vessels; (k) Fragments of vessels; (l) Fragment of a vittae; (m) sclereids of the wings; (n) Endosperm cells.

**Table 3. Fluorescence analysis of Habb-e-Suranjan**

S.No	Treatment	Day light	UV light (254 nm)	UV light (366 nm)
1	Powder as such	Greenish brown	Yellowish green	Yellowish green
2	Powder treated with dist. water	Greenish yellow	-	Pinkish yellow
3	Powder treated with 1N aq. NaOH	Yellow	Light green	Purple
4	Powder treated with H <sub>2</sub> SO <sub>4</sub>	Brown	black	Greenish yellow
5	Powder treated with conc. HCl	Yellow	Light green	Purple
7	Powder treated with FeCl <sub>3</sub>	Reddish	Greenish yellow	Dark purple
8	Pet ether	Yellowish brown	-	Creamish white

**Table 4. Qualitative test of formulation Habb-e-Suranjan**

Extract constituents	Pet. ether	Acetone	Chloroform	Alcoholic	Hydroalcoholic	Aqueous
Alkaloids	-	+	+	+	+	+
Carbohydrates	-	-	-	+	+	+
Glycosides	-	-	++	+	+	+
Phenolics	-	-	-	+	+	+
Flavonoids	+	+	++	+	+	+
Proteins & A.A	-	-	+	+	+	+
Steroids	+	+	+	+	+	++
Resins	+	++	+	-	-	-
Tannins	-	-	-	+	+	+

**Table 5. Microbial load determination of the Habb-e-Suranjan (with naked eye)**

S.No	Dilution of stock solution	No. of colonies		Colonies characteristics
		Formulation	Control	
1.	1:1	00	Nil	Not appeared
2.	1:10	00	Nil	Not appeared
3.	1:100	00	Nil	Not appeared

**Table 6. Heavy Metal of Habb-e-Suranjan**

S. No.	Test Parameter	Test Method	Result	MDL
1	Cadmium (Cd)	ICP-OES	Not detected	1 ppm
2	Lead (Pb)	ICP-OES	Not detected	1 ppm
3	Arsenic (As)	ICP-OES	Not detected	1 ppm
4	Mercury (Hg)	ICP-OES	Not detected	1 ppm

**Table 7. Aflatoxine determinatio of Habb-e-Suranjan**

S.No.	Test Parameter	Test Method	Result	MDL
1	Aflatoxin B1	AOAC 990.33/LCMSMS	Not Detected	1.0µg/kg
2	Aflatoxin B2	AOAC 990.33/LCMSMS	Not Detected	1.0µg/kg
3	Aflatoxin G1	AOAC 990.33/LCMSMS	Not Detected	1.0µg/kg
4	Aflatoxin G2	AOAC 990.33/LCMSMS	Not Detected	1.0µg/kg

**Table 8. Pesticidal residue by GC-MS of Habb-e-Suranjan**

S. No.	Pesticides	Test Method	Result	MDL
1	$\alpha$ -BHC	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
2	$\beta$ -BHC	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
3	$\gamma$ -BHC(Lindane)	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
4	$\delta$ -BHC	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
5	Heptachlor	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
7	$\alpha$ -Chlordane	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
8	$\alpha$ -Endoulfan	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
9	$\beta$ -Chlordance	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
10	Endrin	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
11	Total DDE	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
12	Total DDD	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
13	Total DDT	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
14	$\beta$ -Endoulfan	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
15	Endrin	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
16	Aldrin	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
17	Methoxychlor	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
18	Dieldrin	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
19	Butachlor	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
20	Mevinphos	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
21	Malathion	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
22	Methyl-parathion	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
23	Ethion	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
24	Atrazine	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
25	Diazinon	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
26	Fenthion	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
27	Parathion	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
28	Malaoxon	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
29	Dichlorvos	ACQ method(GC-MS)	Not Detected	0.01 mg/kg
30	2,4-D	ACQ method(GC-MS)	Not Detected	0.01 mg/kg

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