



Research Article

PHYSICOCHEMICAL STUDY OF UNANI PHARMACOPEIAL OINTMENT 'MARHAM GULABI'

Abdullah^{1*}, Rajeev Kurele², Iqbal Ahmad Qasmi³

¹Production Unit, Unani Wing, IMPCL A Government of India Enterprise, Mohan, Via Ramnagar (244715), Distt. Almora, Uttarakhand, India.

²Manager Ayush-Dharwad plant, Karnataka Antibiotic & pharmaceutical Limited, Kotur, Dharwad, Karnataka.

³Professor and Chairman, Department of IlmulAdvia, Faculty of Unani Medicine, A.M.U., Aligarh.

ABSTRACT

In Unani medicine drugs derived from natural sources have been used since its origin in Greece about 2000 years ago. During the past decade there has been an ever increasing demand especially from developed countries for drugs from plant sources. This revival of interest is mainly due to the current widespread belief that Unani Medicine is safe and more dependable than synthetic drugs. The SOPs and standardization, which are essential for reproducing efficacy of any drug, have not yet been to be investigated in this formulation. Marahim (Ointments) are the important formulations of Unani System of Treatments, used as topical applicant for cuts, pains and abrasions etc. Most of the ointments contain mineral and/or plant products that vary from formulation to formulation. In the present paper the works on standardization and quality assurance of an ointment (Marhaam Gulabi) are reported. The parameters that are selected are those that are recommended by National Unani Pharmacopoea Committee. 'Marham Gulabi' is a Brick red, semisolid compound with smell of camphor. Its action is mentioned as 'Daf-e-Taffun', 'Mudammil' and 'Musakkin', in Unani literature and the mode of administration is topical (Anonymous, 1983). The parameters that are studied are Loss on drying (3.98%), pH 1% & 10% (6.6&6.4), Total Fatty Matter 68.40% and Passed the test of Rancidity, Thermal Stability and Spread ability Test. The heavy metals with in limit, Aflotoxins and Pesticidal residue are also estimated and reported which are absent.

KEYWORDS: Marham Gulabi; Standardization; quality control; Ointment.

INTRODUCTION

The use of herbs and their formulations to treat diseases has stood the test of time. The chemical constituents present in them are a part of the physiological functions of living flora and hence they are believed to have better compatibility with the human body [1]. That is why herbs and their products are now the centre of gravity for researches and application of it in treating the diseases. Plants and their products are composed of many constituents and are therefore, capable of variation. The variability of the plant material is due to different conditions of growth, harvesting, drying, and storage. The polarity of the solvent, the mode of extraction, and the instability of constituents may also influence the composition and quality of the extracts. In olden times, Hakims used to treat patients on individual basis and prepare drug according to the requirements of the patient. Today herbal medicines however, are manufactured on a large scale in mechanical units, where manufacturers come across many problems such as non availability of good quality raw materials and proper methodology for standardization, etc. [2]. Marahim (Ointments) are the important preparation of Unani Medicine, used as topical applicant for cuts, pains and abrasions etc. Most

of the ointments contain mineral and/or plant products that vary from formulation to formulation. No work on standardization of such type of drugs has been done till date, therefore, a series of work has been initiated to standardize the ointments for maintaining the quality and efficacy. For the present study 'Marham Gulabi' is selected and standardization is made. The work on others ointments will be reported elsewhere. The parameters that are selected are those which are recommended by National Unani Pharmacopoea Committee.

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^[3,4,5,6]. For those attributes that are not mentioned in the Unani Pharmacopoeia and/or WHO bulletin the standard methods mentioned in different Journals or books for standardization of Single as well

as compound formulations are used or developed in the lab. The commercial sample of, Sendur, Shingraf, Guncha-e-Anar and Raughan-e-Zaitoon were standardized and their standards are quoted here.

Sendur: Chemical Name: Lead Oxide Red; Red Lead; **Colour:** Red, Chemical Formulae: Pb_3O_4 ; Decomposition Point: $500^\circ C$; Solubility: Insoluble in Alcohol; Insoluble in Water; Soluble in strong acid; Total Ash: 99.00%, Water soluble ash: Negligible; Acid insoluble ash: Negligible

Shingraf: Chemical Name: Mercuric 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 $250^\circ C$ 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.

Gunch-e-Anar: 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%.

Raw Materials

The formulation contains the ingredients (Table 1) that are mentioned in part 1st of National Formulary of Unani Medicine [6]. The raw materials were purchased from the market and their identity, purity and strength were checked as per reference, given in table 1.

Table 1: Formulae of Marham Gulabi

| S. No. | Name of drugs | Scientific Name | Part Used | Reference | Quantity |
|--------|------------------------|-------------------------------|----------------------------|--------------------------------|----------|
| 1 | Kafoor | <i>Cinnamomum camphora</i> L. | Crystals from oil | IP. 1978, p. 99 | 60 g. |
| 2 | Kath Safaid | <i>Acacia leucophloea</i> | Dried extract of heartwood | UPI Part 1, Vol.6 p.40 | 30 g. |
| 3 | Kamila | <i>Mallotus philippinesis</i> | Gland & Hairs of fruits | UPI Part-1, Vol.1, p.44 | 30 g. |
| 4 | Murdar Sang | Lead Mono Oxide | Salt | IP, 1972, p. 272 | 30 g. |
| 5 | Mom Zard | Bees wax | Wax from honey comb | IP, 1978, p. 62 | 180 g. |
| 6 | Chob Chini | <i>Smilax china</i> | Tuberous root | UPI Part-1, Vol.5, p.23 | 30 g. |
| 7 | Damm-ul-Akhwain | <i>Dracaena cinnabari</i> | Dried secretion | API, 2008, paet-1, Vol.6.p.104 | 30 g. |
| 8 | Raal Safed | <i>Shorea robusta</i> | Resinous exudates | UPI Part-1, Vol.5, p.60 | 30 g. |
| 9 | Seemab | Mercury | Liquid | IP1978, p 447? | 30 g. |
| 10 | Safaida Kashghari | Zinc Oxide | Salt | IP; 1978, pp 550 | 30 g. |
| 11 | Sendur | Red lead/Minium | | * | 30 g. |
| 12 | Shingraf | Cinnabar | | * | 30 g. |
| 13 | Shibb-e-Yamani Biryani | Alum | Salt | IP, 1972, p. 38 | 30 g. |
| 14 | Ghunch-e-Anar | <i>Punica granatum</i> L. | Flower | * | 30 g. |
| 15 | Raughan Zard | Ghee | Liquid | API, 2008, paet-1, Vol.6.p.204 | 1 Kg. |
| 16 | Raughan-e-Zaitoon | <i>Olea europaea</i> | Liquid | | 500 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 Pharmacopoeia

Table: 2. Physicochemical Properties of Marham Gulabi

| Parameter* | Results | Limits |
|----------------------------|----------------------|-----------------------|
| Rancidity Test | Passes the test | Must pass the test |
| Thermal Stability | Passes the test | Must pass the test |
| Spreadability Test | Passes the test | Must pass the test |
| Total Fatty Matter (% w/w) | Not more than 68.40% | Not less than 60% w/w |
| Loss on dry | Not more than 3.98% | Not more than 10% w/w |
| pH 1% | 6.6 | 4-7 |
| pH 10% | 6.4 | 4-7 |

*Each sample done in triplicate

Table 3. Heavy Metals (a), Aflatoxin (b) and Microbial Load (c) of Marham Gulabi

(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 0.78 ppm | Not more than 10.0 ppm |
| 4 | Mercury | Less than 0.70 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 10 ⁵ /g |
| 2 | Total Fungal Count | Nil | Not more than 10 ³ /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 "Marham Gulabi"

| | | | |
|---|---|--|---|
|  |  |  |  |
| Mom Zard | ChobChini | Dam-ul-Akhwain | Raal Safed |
|  |  |  |  |
| Seemab | SafaidaKashghari | Sendoor | Shingraf |
| |  |  | |
| | Shibb-e-Yamani | Gunch-e-Anar | |

Preparation of Ointment

First of all Mom Zard (Bees wax) was put in a pan along with Raughan Zard and Raughan Zaitoon and kept on burner till melts then the pan was removed from the burner. In the content other ingredients after making fine powder were added except Semab. When all the ingredients mixed properly then lastly Seemab was added and mixed thoroughly to make a homogenous mixture and kept in air tight container.

Physicochemical Parameters

Physicochemical studies like loss on drying; total fatty matter and pH 1% and 10% were determined quantitatively and Passes the test of Rancidity, Thermal Stability and Spread ability Test according to methods recorded in Indian Pharmacopoeia, WHO guidelines and methods mentioned by Afaq et al [7, 8, 9]. The presence of Aflotoxins and Microbial load were studied as per revised recommendation of WHO mentioned in its bulletin^[8].

Results and Discussion

The present study is an attempt to ascertain the pharmacopoeial standards for the standardization of 'Marham Gulabi'. The parameters that are studied are Loss on drying (3.98%), pH 1% & 10% (6.6 & 6.4) Total Fatty Matter (68.40%) and Passed the test of Rancidity, Thermal Stability and Spread ability Test. These parameters are considered as tools of checking the quality, identity, purity and strength of the ointment. The heavy metals, aflotoxins, pesticidal residue and Microbial load were also studied and reported (Table 3a, 3b, 3c, 3d) No growth of any Fungi or Bacteria were observed in the cultural media and no aflotoxines (B1,B2,G1,G2) were detected. Pb, Hg, and As are detected in the formulation but present with in the limit. The presence of heavy metals is due to the presence of these metals in the Mercury and Cinnabar are ingredients of ointment but all are with in limits. No Aflotoxin, and Microb were detected hence passing all

the test for its clinical use. This semisolid is a Brick red, semisolid compound with smell of camphor and during preparation of one batch 5% loss is expected.

CONCLUSION

The outcome of the current study will be proved beneficial to pharmaceutical industries and research institutes for correct identification, purification and detection of adulteration for quality control and standardization of the compound Unani Formulation "Marham-e-Gulabi".

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*Address for correspondence

Dr Abdullah

Production Unit, Unani Wing, IMPCL A
Government of India Enterprise,
Mohan, Via Ramnagar (244715), Distt.
Almora, Uttarakhand, India.
Contact No.: 7055388826
E-mail: drabdullahalig@gmail.com

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