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Physico-chemical analysis of a Herbo-mineral compound *Mehamudgara vati* – A pilot study

Ila Tanna[1], S. M. S. Samarakoon[2], H. M. Chandola[3], V. J. Shukla[4]

[1]PhD Scholar, Roga Nidana and Vikriti Vijnana, Institute for Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurved University, Jamnagar, Gujarat, India, [2]Senior Lecturer, WGAI, University of Kelaniya, Sri Lanka, [3]Head, Department of Kaya Chikitsa, [4]Head, Pharmaceutical Chemistry Laboratory, Institute for Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurved University, Jamnagar, Gujarat, India

Abstract

Efforts have been made to lay down analytical standards for *Mehamudgara vati* (MMV), which were not found reported till date. Weight variation showed that 90% tablets of MV manufactured in the Gujarat Ayurved University Pharmacy were within acceptable range (323 mg ± 10%), pH 4.58, and disintegration time 17 min, whereas hardness was 1.25 kg/cm^2. Loss on drying was found to be 9.3% w/w, acid insoluble ash was 0.9 %w/w, water soluble extract was 24.06% w/w and methanol soluble extract 14.1% w/w. Determination of iron as Fe_2O_3 was done as *Lauha bhasma* being the major ingredient of MMV. The result showed that iron content was reduced in the formulation (28.67%) as compared to that in *Lauha bhasma* (61.19%). In TLC, 5 spots each at 254 nm and 366 nm were found.

Key words: *Lauha-bhasma, Mehamudgara vati,* standardization, thin layer chromatography

Introduction

Herbal medicines are at great demand globally for primary healthcare due to their higher safety margins and cost effectiveness. Quality control of herbal medicines generates a lot of problems. So first and foremost task is the selection of the right kind of plant material which is therapeutically efficacious compounds. Herbal medicines are being manufactured on large scale where manufacturers face many problems such as low-quality raw material, lack of authentication of raw material, non-availability of standards, lack of proper standardization methodologies of single drugs and formulations and lack of quality control parameters. Classical evaluation of herbal drugs is available based on *Rasa*, *Guna*, *Virya*, *Vipaka* and *Karma* etc. In the global view, there is shift towards the use of herbal medicine. At the same time consumers prefer to choose products with established standards. So it is a prime need to standardize Ayurvedic preparations to guarantee their purity, safety, potency and efficacy. Herbal products represent a number of unique problems related to quality which are further complicated by the use of combination of herbal ingredients being used in traditional practice. Therefore, in case of herbal drugs and products the standardization should encompass entire field of study from cultivation of medicinal plant to its clinical application. WHO involves in standardization and quality control of herbal crude drugs[1] to monitor the physicochemical evaluation of crude drugs covering the aspects of selection and handling of crude material, safety, efficacy, stability assessment of finished product, documentation of safety and risk based on experience, provision of product information to consumer and product promotion.

Mehamudgara vati (MMV) is used in the treatment of *Prameha*, *Mutraghata*, *Mutrakrichchha*, *Ashmari* and *Sthaulya* etc.[2] and by analyzing the properties of its ingredients it seems that its use may be justified in these clinical conditions. Till date, no standards are available for *Mehamudgara vati*. Hence, the present study has been carried out with aims and objectives to develop analytical profile of *Mehamudgara vati* and by assessing its physico-chemical parameters including weight variation, hardness, disintegration time, pH, loss on drying, ash value, acid insoluble ash, water soluble extract, methanol soluble extract, quantitative estimation of iron content (Fe_2O_3).

Address for correspondence: Dr. Ila Tanna,
Institute for Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurved University, Jamnagar, Gujarat, India.
E-mail: dr.ashka@yahoo.com

Materials and Methods

Before the raw materials used for the preparation of the finished product, proper identification of all plant materials is extremely necessary for its genuineness. This is done by evaluating their quality by various parameters. All ingredients were collected through the Pharmacy of Gujarat Ayurveda University, Jamnagar. Identification of raw drugs was done in Pharmacognosy Laboratory of Institute for Post Graduate Teaching and Research in Ayurveda, where they were proven authenticated as per the standards of Ayurvedic Pharmacopia of India. Firstly, *Triphala*

kwatha was made followed by dissolution of *Guggulu* and *Rasanjana* in the decoction. All the herbal ingredients were properly mixed with *Lauha bhasma*. After proper mixing of all the ingredients, they were levigated with *Triphala kwatha* in end runner and granules were made from the levigated material. After drying of granules, *vati* were made. *Mehamudgara vati* contains number of herbs and mineral constituents [Table 1].

Analytical study of *Mehamudgara vati* was carried out in the pharmaceutical chemistry laboratory of I.P.G.T. and R.A., Jamnagar. Analytical parameters for finished drug were general appearance including size, shape; organoleptic properties; thickness, diameter, hardness,[3] weight variation and disintegration time[4] and physicochemical parameters including loss on drying,[5] ash value, acid insoluble ash,[6] water soluble extractive value and alcohol soluble extractive value[5] and pH[7] Estimation of iron content (Fe_2O_3)[8] was also done as *Lauha bhasma* being a major constituent of MMV.

Determination of Iron (Fe)

Preparation of sample solution- Required quantity of sample of MMV (in the presence of organic matter) ignited in a crucible in a Muffle furnace at 450-500 C° until the residue becomes free from organic matter. The residue was moistened with 5-10 ml of hydrochloric acid and boiled for 2 min followed by adding 30 ml of water and heating on the water bath for a few min. Then it was filtered and washed thoroughly with water and made up to a volume in a volumetric flask.

Solutions

Stannous chloride solution: Dissolve 5 g stannous chloride (A.R) in 25 ml conc. hydrochloric acid and dilute to 100 ml (5% solution). Mercuric chloride: saturated solution in water.

Sulfuric acid + orthophosphoric acid mixture: take 60 ml water, add 15 ml conc.

Sulfuric acid and 15 ml H_3PO_4, cool and dilute to 1000ml.

Diphenylamine barium sulfonate: Dissolve 0.25 g in 100 ml water.

N standard potassium dichromate solution: Dissolve 4.9035 g AR grade in water and dilute to 1000 ml.

Procedure

Sufficient aliquot from the stock solution was taken in 250 ml in duplicate, diluted it to about 100 ml with distilled water and added 1-2 drops of methyl red indicator. Then 1-2 g ammonium chloride was added followed by adding dil. ammonium solution till brown precipitate appeared. Then the solution was boiled with ppt. for 4-5 min and cooled the content and filtered through Whatman 41 numbered filter paper. The residue was washed with hot water 4-6 times and dissolved the residue in dil. HCl in a 250 ml beaker. The mixture was washed with hot water and made the volume to 100 ml approx followed by boiling the solution on burner. The Fe^{3+} was converted into Fe^{2+} by adding stannous chloride solution drop wise till solution become colorless. Then 1-2 drops of stannous chloride solution was added in excess, cooled the content in water and 10-15 ml 10% solution of mercuric chloride was added. A 25 ml acid mixture was taken and 2-3 drops of diphenylamine barium sulfonate indicator was added. Finally, distilled water was added if required and titrated against standard potassium dichromate solution. Appearance of violet color showed the endpoint. Each ml of 1N $K_2Cr_2O_7$ solution is equivalent to 0.05585 g iron; each ml of 1N $K_2Cr_2O_7$ solution is equivalent to 0.7985 g Fe_2O_3.

Observations and Results

Analytical study of *Mehamudgara vati* was carried out to establish suitable quality control parameters.

The data of uniformity of tablet shows that 90% tablets were within acceptable range of weight variation [Table 2]. The physico chemical parameters related to *Mehamudgara vati* and *Lauha bhasma* are given [Tables 3, 4].

Table 1: Ingredients of *Mehamudgara vati*

Drug	Latin name	Part used	Proportion
Lauha Bhasma	Fe_2O_3	Incinerated iron	15 parts
Guggulu	*Commiphora wightii* (Arnott) Wightii	Exudate	4 parts
Haritaki	*Terminalia chebula* (Gaerth.) Roxb.	Pericarp	1 part
Bibhitaki	*Terminelia bellerica* (Gaerth.) Roxb.	Pericarp	1 part
Amalaki	*Emblica officinalis* Gaerth.	Pericarp	1 part
Shunthi	*Zinziber officinalis* Rosc.	Rhizome	1 part
Marich	*Piper nigrum* Linn.	Fruit	1 part
Pippali	*Piper longum* Linn.	Fruit	1 part
Trivrita	*Operculina terpethum* (Linn) Silva Manso	Root	1 part
Pippalimula	*Piper longum* Linn.	Root	1 part
Bida lavana	–	–	1 part
Bilva	*Aegle marmelos* (Linn.) Correa	Fruit	1 part
Gokshura	*Tribulus terrestris* Linn.	Seed	1 part
Dadima	*Punica granatum* Linn.	Fruit bark	1 part
Devadaru	*Cedrus deodara* (Roxb. ex D. Don) G. *Don)*	Heart wood	1 part
Rasanjana	*Berberis aristata* DC var. aristata	Extrectum	1 part
Kiratatikta	*Swertia chirayita* (Roxb ex Flem) Karst	Whole plant	1 part
Triphala kwatha	–		Quantity sufficient for *Bhavana*

Table 2: Weight variation test

Tablet no.	Weight of individual tablet	% weight variation	Tablet no.	Weight of individual tablet	% weight variation
1.	295 mg	8.67	11.	322 mg	0.31
2.	348 mg	-7.74	12.	319 mg	1.24
3.	313 mg	3.10	13.	311 mg	3.72
4.	365 mg	-13	14.	296 mg	8.36
5.	317 mg	1.86	15.	366 mg	-13.31
6.	331 mg	-2.48	16.	323 mg	0.00
7.	302 mg	6.50	17.	319 mg	1.24
8.	314 mg	2.79	18.	316 mg	2.17
9.	320 mg	0.93	19.	350 mg	-8.36
10.	355 mg	-9.91	20.	312 mg	3.41

Table 3: Result on different quality control parameters

Parameter	Results	S.D.	S.E.
Average weight (uniformity)	Mean wt. = 324.7 mg; Max. wt= 366 mg; Min. wt= 295 mg	21.181	4.74
Hardness	1.25 kg/cm^2	0.38	0.09
Disintegration time (water)	17 min		
pH (5% solution)	4.58		
Loss on drying	9.3% w/w		
Ash value	45.65% w/w		
Acid insoluble ash	0.9 w/w		
Water soluble extract	24.06 w/v		
Methanol soluble extract	14.1 w/v		
Iron content (Fe_2O_3)	28.67%		

Table 4: Analytical study on *Lauha Bhasma*

Parameter	Result
Ash value	99.7% w/w
Acid insoluble ash	7.9% w/w
Iron content (Fe_2O_3)	61.19%

Table 5: Result of thin layer chromatography

Sample	Short UV – 254 nm		Long UV – 366 nm	
Mehamudgara Vati	Spot no.	R_f	Spot no.	R_f
	1.	0.22	1.	0.09
	2.	0.32	2.	0.12
	3.	0.67	3.	0.32
	4.	0.78	4.	0.58
	5.	0.87	5.	0.74
			6.	0.83

[Sample: Alcohol extract of MMV; Solvent system: Petroleum ether (60-80°): Ethyl acetate: Methanol (6:2:0.5); Development: Stepwise in Stahl chamber; Visualization: (under U.V. Radiation) Short U.V. 254 nm, Long U.V. 366 nm]

Discussion

In almost all traditional system of medicine, the quality control aspect has been covered by careful observation of skillful physicians. However, in modern concept, it requires necessary changes in their approach by way of quality control in terms of development of modern methodologies. Thus, today quality assurance is a thrust area for the evaluation of traditionally used medicinal plants and herbal formulations. Manufacturers who are doing some testing of their formulation have fixed their own parameter; most of them are only preliminary in nature. Combined and well-coordinated efforts from scientific workers of different disciplines are required for this purpose. Weight variation of tablet causes variation of active medicament which changes the bioavailability. This may be due to causes such as variation in granule size, poor flow, bridging, rat holing, punch variation and poor mixing.

MMV tablets were found to have (mean ± SD) 345.88 mg average weight. 90% tablets were within acceptable range of weight variation as for natural – herbal products, ±10% range of weight variation is acceptable. Both hardness and disintegration time interfere with the bioavailability of drug. MMV was found to have 1.25 kg/cm^2 hardness and 17 min disintegration time which was noticed with in accepted limits.[9] Moisture content should be minimum to prevent degradation of product. Excess of water in drug encourage microbial growth, presence of fungi or insects and deterioration following hydrolysis. MMV contained 9.3% w/w moisture showing that the tablet should be protected from humid atmosphere by keeping silica bag in it as climatic changes affect the tablet. The result shows that if it would not be protected in humid atmosphere, then water activity would be increased and it will cause degradation of the tablet. Ash values are the criteria to judge the identity and purity of crude drug, where total, water soluble and acid insoluble ashes are considered. *Mehamudgara vati* contained 45.65% w/w of total ash and 0.9% w/w acid insoluble ash. The result revealed that MMV is free from unwanted organic and inorganic compounds and production site was good enough keeping sample free from dust and other soil matters etc. The 24.06%w/w of water soluble and 14.10% w/w of methanol soluble extractive were present in MMV indicating that the drug is having good solubility in water. Though, *Mehamudgara vati* is prescribed for *prameha* (type-II

254 nm

Sample:

Alcohol extract of MMV

Solvent system:

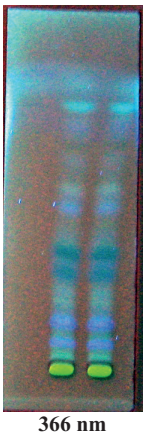
Petroleum ether (60-80°): Ethyl acetate: Methanol (6:2:0.5)

Development:

Stepwise in Stahl chamber

Visualization:

(under U.V. Radiation) Short U.V. 254 nm, Long U.V. 366 nm



366 nm

Figure 1: TLC Profile of *Mehamudgara vati* (MMV)

Diabetes) in classics, it is indicated in *pandu* (iron deficiency anemia) too which is proven in present study by revealing the fact that it contains 28.67% of Fe_2O_3 [Table 3] as *Lauha bhasma* is the main ingredient of MMV. In TLC of MMV, five spots at 254 nm and six spots at 366 nm were noticed [Table 5 and Figure 1] indicating its possible compounds of the matrix which may possess its therapeutic effect.

Conclusion

The present effort to develop analytical profile of *Mehamudgara vati* deals with weight variation, hardness, Ph, disintegration time, loss on drying, acid insloluble ash, water soluble extract and methanol soluble extract with determination of iron content in the form of Fe_2O_3 in MMV as well as in lauha bhasma. In TLC, 5 spots at 254 nm and 6 spots at 366 nm were found. This piece of work is just a pilot study which can serve as a preliminary step towards standardization of a herbo-mineral drug *Mehamudgara vati*. Further study is necessary to explore other parameters related to standardization to be carried out in different batches to set the limit for the reference standards for the quality control and quality assurance of *Mehamudgara vati*.

References

1. Ritch R. Potential role for Ginkgo biloba extract in the treatment of glaucoma. Med Hypothesis 2000;54:221-35.
2. Bhaishajya Ratnavali 37 / 64 – 68 , Kaviraja Govind Das Sen edited with Siddhiprada Hindi Commentry by Prof. Siddhinandan Mishra. Varanasi: Chaukhambha Sanskrit Sansthan; 2007. p. 703
3. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy. Special indian edition. Bombay: Varghese Publishing House; 2009. p. 299.
4. Anonymus. The Ayurvedic Pharmacopia of India. Part-2, Vol-3, Appendix-3, 1st ed. New Delhi: Ministry of Health and Family Welfare, Goverment of India; 2010. p. 214 (3.18), 216 (3.19)
5. Anonymus. The Ayurvedic Pharmacopia of India. Part-2, Vol-1, Appendix -2, 1st ed. New Delhi: Ministry of Health and Family Welfare, Goverment of India; 2007. p. 141.
6. ibid, The Ayurvedic Pharmacopia of India, 2007. p. 140.
7. Anonymus. The Ayurvedic Pharmacopia of India. Part-2, Vol-1, Appendix -3, 1st ed. New Delhi: Ministry of Health and Family Welfare, Goverment of India; 2007. p. 191.
8. N. Howell Furman. Standard Methods of Chemical Analysis. Vol. 1. The Elements, Chap. 25th - Iron: Determination of Iron as Fe2O3, Gravimatric method. 6th ed. New York: Krieger Publishing Company, Huntington; 1962, Reprint – 1975. p. 535.
9. Gupta AK. Introduction to Pharmaceutics – I. 3rd ed. New Delhi: CBS Publishers and Distributors; 1994. p. 270.

हिन्दी सारांश

हर्बोमिनरल औषधि मेहमुद्गरवटी का भौतिक रासायनिकी विश्लेषण – एक प्रारम्भिक अध्ययन

इला तन्ना, एस. एम. एस. समरकून, एच. एम. चन्दोला, वी. जे. शुक्ला

भौतिक रासायनिकी विश्लेषण औषधि के मानकीकरण एवं गुणवत्ता नियंत्रण तथा उत्पादन की गुणवत्ता को सुनिश्चित करने की दिशा में एक महत्वपूर्ण कदम है। आयुर्वेदिक औषधियों का मानकीकरण औषध की प्राकृतावस्था तथा निर्मित कल्प के स्तर पर आधुनिक वैज्ञानिक गुणवत्ता नियंत्रण प्रक्रिया के माध्यम से किया जाता है। इस अध्ययन में एक शास्त्रीय योग मेहमुद्गरवटी का फार्मास्युटिकल विश्लेषण, भौतिक एवं रासायनिक मापदण्डों के आधार पर किया गया है। उक्त वटी का भार ३२३ मि.ग्रा. + १० %, पी.एच. ४.५८, विघटन दर १७ मिनट, कठोरता १.२५ कि.ग्रा. / से.मी.^{2}, शुष्क होने पर भार में कमी ९.३ % w/w, अम्ल घुलनशील राख ०.९ % w/w, जल घुलनशील सत्त्व २४.०६ % w/w तथा मिथेनोल घुलनशील सत्त्व १४.१ % w/w पाया गया। ग्रेवीमैट्रिक विधि से उक्त कल्प एवं लौह भस्म Fe_2O_3 के रूप में उपस्थित लौह की प्राप्त मात्रा से ज्ञात हुआ कि लौह की मात्रा कल्प में (२८.६७ %), लौहभस्म (६१.१९ %) की अपेक्षा कम हुई है। औषधि की TLC में २५४nm–३६६nm में ५ चिह्न प्राप्त हुए हैं।