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STANDARDIZATION OF GOMUTRA HARITAKI VATI: AN AYURVEDIC FORMULATION

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ABSTRACT

Newer guidelines, for standardization, manufacturing, quality control and scientifically rigorous research will be necessary for traditional system. *Gomutra haritaki* is an ayurvedic formulation prescribed for the mouth disease. Information on the qualitative and quantitative parameters of *Gomutra haritaki* to guarantee the quality and the safety of the product to the consumer is less; many of these parameters were vary according to the method of preparations. With this aim in the recent study an attempt has been made to develop standardization methods of *Gomutra haritaki vati*. A comparative study has been made between in-house preparation and the two marketed formulation. These all formulations were standardized for various qualitative and quantitative parameters according to WHO guidelines. The set parameters were found to be sufficient to evaluate the vati and can be used as reference standards for the said formulation which will be part of the quality assurance for these formulations.

KEYWORDS ; Ayurvedic formulations, Gomutra haritaki vati, Quality, Standardization,

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INTRODUCTION

Ayurveda is a time-tested, trusted worldwide plant based system of medicines and consists of various Ayurvedic formulations such as Asava, Arishta, Ghruta, Taila, Churna, Vati, Gutika, Kwatha and much more. A variety of herbal medicine has been used in ayurvedic system of medicine from ancient time [1]. In olden times, vaidyas used to treat patients on individual basis, and prepare drug according to the requirement of the patient. But the scenario has changed now; herbal medicines are being manufactured on the large scale in Pharmaceutical units, where manufacturers come across many problems such as availability of good quality raw material, authentication of raw material, availability of standards, proper standardization methodology of single drugs and formulation, quality control parameters [2]. The side effects of herbal products are due to the failure of good manufacturing practice in preparation which includes misidentification of plants, lack of standardization, contamination, substitution and adulteration of plants and incorrect preparations and/or dosages. The subject of herbal drug standardization is massively wide and deep. India can emerge as the major country and play the lead role in production of standardized, therapeutically effective Ayurvedic formulations [3]. India needs to explore the medicinally important plants. This can be achieved only if the herbal products are evaluated and analyzed using sophisticated modern techniques of standardization. The World Health Organization has appreciated the importance of medicinal plants for public health care in developing nations and has evolved guidelines to support the member states in their efforts to formulate national policies on traditional medicine and to study their potential usefulness including evaluation, safety, and efficacy [4]. Gomutra Haritaki is official in Ayurvedic formulary of India (AFI, Part I, 7:8) [5]. The basic Ayurvedic and the scientific concept of giving *Bhavana* to single or complex herbal formulations is to potentiate the herb or herbs by increasing the active principle contents of such processed herb or herbs, which is also beneficial in providing an optimum, balanced and reduced dosage as a herbal medicine [6]. Ayurveda describes Gomutra as a very holy Rasayana (health tonic) that is capable of balancing all three dosha (Vata, Pitta and Kapha). As per recent scientific research findings it contains variety of many useful bio-active substances like essential amino acids, enzymes, proteins, vitamins, hormones and minerals. During various scientific studies, it has shown very strong anti bacterial, anti viral, immuno-stimulator and adaptogenic properties. It has an ability to enhance original properties of respective medicinal substance or formula with which it is processed [7]. Various marketed formulation shows dose variation, content variation and lack of standardization which affect its therapeutic activity as well as there was little effort to documents on variations occurring due to different techniques of preparations, therefore it is essential to establishment of quality control parameters for ayurvedic formulations which will be in alignment with modern technology. With this aim the current project was designed to prepare and standardized the Gomutra haritaki vati in accordance with the WHO guidelines and make the comparative account of the same with the marketed formulation [8].

MATERIALS AND METHODS

Procurements of Plant material

The crude drugs used in preparation were purchased from the local Market, Pune and were identified and Authenticated by Department of Pharmacognosy, Marathwada Mitra Mandal's College of Pharmacy; Pune by correlating their morphological and microscopical characters with those given in literatures [9].

Method of preparation of Gomutra haritaki vati

Standard laboratory reference sample of Gomutra haritaki vati was prepared as per the procedure mentioned in Ayurvedic formulary of India. All the herbal ingredients of Pharmacopoeial quality present in the formulation were mentioned in Table no.1[5].

Marketed samples

The marketed sample of Gomutra haritaki vati was procured from Vagbhat pharmaceuticals, Dhule and Gomutra haritaki tablet was obtained from Vishal Ayurvedic Pharmacy, Dombivli were standardized based on their morphological description and physic-chemical parameters

Preformulation Study

The preformulation parameters like Appearance, taste, odor, bulk density, tap density, Carr's index, and Hausner's ratio of the granules used for the preparation of In house vati were done as per pharmacopoeial procedures. The physical characteristics like moisture content, pH, Bulk density, Tap density, Angle of repose and Carr's index indicates the flow properties as well as interparticulate resistance between the powders. The information collected from this evaluation was crucial to avoid ambiguous predictions of stability or solubility of formulation [10-11].

Pharmacognostic Standardization

Organoleptic Descriptions

Organoleptic evaluation was carried out to assess the color, odor and taste of In-house and marketed formulations [1, 9, 12].

Physicochemical Evaluation

Analysis of Physicochemical Constants In-house formulation and marketed formulation has been done to evaluate the quality and purity of the powder drug. In physicochemical evaluation moisture content, pH, ash value such as total ash, acid insoluble ash was evaluated. The ash value indicates the presence of inorganic salts present in the drug. The water soluble and alcohol soluble extractive values were determined [8, 12]. The information collected from this evaluation was useful for standardization and obtaining the quality standards for crude drugs as well as for formulations. Determinations of these physicochemical constants were done as per procedures mentioned in accordance with WHO guidelines [8, 13].

Phytochemical Evaluation

The qualitative chemical tests were carried out for the identification of nature of phyto-constituents present in the formulations [14].

Quantitative Parameters

Weight Variation Test

Twenty Vati/tablets were randomly selected and weighed to determine the average weight and were compared with individual Vati/Tablet weight. The percentage weight variation was calculated [10, 11].

Hardness test

Pfizer hardness tester was used for the determination of the hardness [15].

Disintegration test

Placed one tablet in each of the six tubes of the basket and operated the apparatus, using distilled water maintained at 37°C as the immersion fluid [16].

RESULT AND DISCUSSION

Preformulation studies of the intermediate granules produce during the preparation of formulation by using the ingredients mentioned in Table 1 were signify problems and identifying logical path in the preparation of formulations. It describes the process of optimizing the delivery of drug through determination of physical, chemical properties of granules.

Table 1
Composition of Gomutra haritaki vati

S.N.	Name of plant	Latin name	Part	Qauntity	USES
1	Gomutra	*Cow urine*	-------	4 part	Disease of mouth , eye
2	Hirada	*Terminalia chebula*	Powder	1 part	Relieving Stiffness, and Enhancing Immune Function
3	Jal kwath (Vala)	*Coleus vettiveroides*	Root	1 part	Used for skin diseases , rheumatism ,bronchitis and chronic allergies
4	Fennel	*Foeniculum vulgare*	Fruit	1 part	Carminative
5	Kushth	*Saussurea lappa*	Root	1 part	Anti-inflammatory

The observations of the preformulation study were reported in Table 2 which shows that appearance of In-house formulated Gomutra haritaki granules was smooth. Taste and odor of granules is Salty and Characteristic respectively. Bulk density and Tap density are used to measure a packing of particles or granules[10]. The bulk density and Tap density results obtained with the In-house formulated Gomutra haritaki granules was found to be 0.35 ± 0.003 and 0.42 ± 0.003 respectively. Angle of Repose has been used for quantifying powder flow ability; because of its relationship with interparticle cohesion. Angle of Repose for In-house formulated Gomutra haritaki granules was found to be 29 ^{0} 19'. Hausner's ratio is related to interparticle friction which can be used to predict the powder's flow properties. Powders with low interparticle friction such as coarse spheres have a ratio of approximately 1.2, whereas more cohesive, less flow able powders such as flakes have a Hausner's ratio greater than 1.6[11]. Hausner's ratio for In-house formulated Gomutra haritaki powder was found to be 1.18 ± 0.022 which was less than 1.2. Hence the In-house formulated Gomutra haritaki granule has low interparticle friction. Carr's index is another method for measuring the powder flow from bulk density[15]. Carr's index of In-house formulated Gomutra haritaki granules was found to be 0.18 ± 0.022.

Table 2
Pre-formulation study of in house Gomutra haritaki Granules

S. N.	Parameters	IN HOUSE
1	Appearance	Smooth
2	Taste and odour	Salty and Characteristic
3	Bulk density gm/cm3	0.35 ± 0.003
4	Tapped density	0.42 ± 0.003
5	Hausner's ratio	1.18 ± 0.022
6	Carr's index	0.18 ± 0.022
7	Angle of repose	29 ^{0} 19'

Values are expressed as mean ± SEM

The observations for the organoleptic evaluations and physicochemical evaluations of the In-house and marketed formulations were reported in Table 3 and Table 4 respectively; where it was found that all type of formulations were Blackish brown in color, with a characteristic odor and Salty taste. The physicochemical parameters play important role in the standardization of formulation. The total ash is particularly important in the evaluation of purity of drugs, i.e. the presence or absence of foreign matter such as metallic salts or silica[12-14]. Analytical results showed total ash values for In-house vati, Marketed vati and Marketed tablet were 2.66 ±0.33, 7.1 ± 0.60, 2.66 ± 0.66 % respectively. The amount of acid-insoluble siliceous matter present in In-house vati, Marketed vati and Marketed tablet was 1.5 ± 0.288, 4 ± 0.288 and 1.5 ± 0.288 respectively. Hence the results of ash values signify that the crude drugs used for preparation of in-house formulations were of good quality while the change in type of formulation like tablets instead of vati can also change these physicochemical values. The water soluble extractive values indicated the presence of sugar, acids and inorganic compounds[1,9]. Analytical results showed water soluble extractive values for In-house vati, Marketed vati and Marketed tablet were 18.00 ± 2.30, 14.33 ± 0.66, 12.66 ± 2.02 respectively. The alcohol soluble extractive values indicated the presence of polar constituents like phenols, alkaloids, steroids, glycosides, flavonoids. [12] The alcohol soluble extractive values In-house vati, Marketed vati and Marketed tablet were 14.66 ± 2.40, 12.66 ± 1.85, 8.66 ± 0.88 respectively which signify the superiority of in-house formulation which was prepared by using traditional method of preparation over the marketed formulation. It also gives the outcomes of new technology transfer and their advantages along with their disadvantages. Deterioration time of the plant material depends upon the amount of water present in plant material. If the water content is high, the plant can be easily deteriorated due to fungus.[8] The loss on drying at 105°C In-house vati, Marketed vati and Marketed tablet were 1.83 ± 0.16, 2 ± 0.28, 2.66 ± 0.16 respectively. The pH from 10% w/v solution revealed that pH of all the formulations were comparable and was slightly acidic for all formulations. [9] This may be because of acidic salts present in the crude drugs used for preparation of formulations.

Table 3
Organoleptic properties of Gomutra haritaki vati and Marketed formulations

S. N.	Parameters	IN HOUSE	STANDARD VATI	STANDARD TABLET
1	Appearance	Smooth	Smooth	Smooth
2	Color	Blackish brown	Blackish brown	Brown
3	Odour	Characteristic	Characteristic	Characteristic
4	Taste	Salty	Salty	Salty

Table 4
Physical and Chemical evaluation of samples of Gomutra haritaki vati

S.N	Parameters	In house	Standard VATI	Standard TABLET
1	Total ash (% w/w)	02.66 ±0.33	07.1 0± 0.60	2.66 ± 0.66
2	Acid insoluble ash (% w/w)	01.50 ± 0.28	04.00±0.28	1.50 ± 0.28
3	Alcohol soluble extractive value (% w/w)	14.66 ± 2.40	12.66 ± 1.85	8.66 ± 0.88
4	Water soluble extractive value (% w/w)	18 ± 2.30	14.33 ± 0.66	12.66 ± 2.02
5	Loss on drying (% w/w)	1.83 ± 0.16	2 ± 0.28	2.66 ± 0.16
6	pH 10 % solution (% w/v)	3	2	2

Values are expressed as mean ± SEM

Phytochemical analysis gives the information about phytoconstituents present in the crude drug are tabulated in Table 5 which shows the presence of glycosides and tannins as a major secondary metabolites.

Table 5
Phytochemical screening of samples of Gomutra haritaki vati

S. N.	Parameters	In house	Standard VATI	Standard TABLET
1	Carbohydrates	+	+	+
2	Amino acids	+	+	+
3	Glycosides	+	+	+
4	Flavonoids	-	-	-
5	Alkaloids	-	-	-
6	Tannins	+	+	+
7	Steroids	-	-	-

+ indicates presence; - indicates absence

The results of Quantitative Parameters used for comparative account in between the In-house vati, Marketed vati and Marketed tablet were reported in table no 6. The weight variation of a tablet/vati is used to determine the uniformity of dosage unit. [15] The weight variation of In-house vati, Marketed vati and Marketed tablet were found to be 0.62 ± 0.01, 0.61±0.16 and 0.53±0.18 respectively. The hardness of a tablet/vati is a function of how much pressure has been exerted in making it and it varies with the composition, thickness, shape and diameter of tablets. [16] The hardness of In-house vati, Marketed vati and Marketed tablet were 10 ± 0.02 $Kg/cm^{2,}$ 17 ± 0.01Kg/cm^2 and 11 ± 0.01Kg/cm^2 respectively. The disintegration test is a measure of the time required under a given set of conditions for a group of tablets/vati to disintegrate into particles [15, 16]. This was found to be 70.30 ± 0.01 mins, 90.05 ± 0.02 mins, and 38.00 ± 0.02 mins respectively. All the results signify that In-house vati, passed all tests with the significant results with the superiority over the marketed formulations. Which also revealed that the traditional method of preparation have their own advantages over the modern techniques/method of preparation.

Table 6
Evaluation of Gomutra haritaki vati

S.N.	Parameter	In house	Standard VATI	Standard TABLET
1	Weight variation (gm)	00.62 ± 0.01	00.61± 0.16	00.53 ± 0.18
2	Hardness (Kg /cm)	10 ± 0.02	17 ± 0.01	11 ± 0.01
3	Disintegration time (Min)	70.30 ± 0.01	90.05 ± 0.02	38.00 ± 0.02

Values are expressed as mean ± SEM

CONCLUSION

From the present investigation various standardization parameters such as physicochemical standards, chemo profiles and safety evaluation were carried out, it can be concluded that the formulation of Gomutra haritaki vati contains all good characters of an ideal vati and it was found to be more effective and economic. The study shows that the

contents of formulation are of good quality and purity, all these investigations were may be helpful in authentication of Gomutra haritaki vati and its ingredients. The result of present study will also serve as reference monograph in the preparation of drug formulation.

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