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Standardization of Jeera Vati: An ayurvedic Polyherbal formulation

[1] Drashti Desai and [2] Rupa Sen Gupta

1. Shri G.M. Bilakhia College of Pharmacy, Gujarat. Vapi, Gujarat, India
2. Assistant Professor. Rofel, Shri G.M. Bilakhia College of Pharmacy, Gujarat. Vapi, Gujarat, India.

Abstract
As per the T-GMP guidelines, for standardization, manufacturing, quality control and scientifically rigorous research is necessary for traditional system. *Jeera vati* is an ayurvedic formulation prepared for the digestive disorders. Information on the qualitative and quantitative parameters of *Jeera vati* to guarantee the quality and the safety of the product to the consumer. With this aim in the recent study an attempt has been made to develop standardization methods of *Jeera vati*. A comparative study has been made between in-house preparation and one marketed formulation. This formulation was 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.

Keywords: Ayurvedic formulations, Jeera vati, Quality, Standardization, pre-formulation, post-formulation etc.

1. Introduction
India has a rich heritage of traditional medicines constituting with its different components like Ayurveda, Siddha and Unani [1]. 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 [2]. Ayurveda is now being imparted through institutions, colleges, hospitals and through ancient treatises. This has necessitated the establishment of standards for ayurvedic drugs and formulations so as to ensure proper use of the medicines so prepared for the benefit of the end user without any unwanted complications.
Standardization of drug means confirmation of its identity and determination of its quality and purity. The quality assessment of herbal formulations is of paramount importance in order to justify their acceptability in modern system of medicines. Also one of the major problem faced by herbal drug industry is unavailability of rigid quality control profile for herbal materials and their formulations [3]. The subject of herbal drug standardization is production of standardized, therapeutically effective Ayurvedic formulations [4].
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 massively wide and deep. India can emerge as the major country and play the lead role in 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 [5].

2. Materials and Methods
2.1Procurements of Plant material
The crude drugs used in preparation were purchased from the local Market, Vapi and were identified and Authenticated by Department of Pharmacognosy, Rofel Shri G.M.B College of Pharmacy; vapi,by correlating their morphological and microscopical characters with those given in literatures**.**

2.2 Method of preparation of Jeera vati
Standard laboratory reference sample of jera 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

2.3 Marketed samples
The marketed sample of vati was procured from Vishal pharmaceuticals,Vapi and jeera vati was obtained from Vishal Ayurvedic Pharmacy,Vapi was standardized based on their morphological description and physic-chemical parameters.

2.3 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 [6, 7].

2.4 Pharmacognostic Standardization Organoleptic Descriptions
Organoleptic evaluation was carried out to assess the color, odor and taste of In-house and marketed formulations [8].

2.5 Physicochemical Evaluation
Analysis of Physicochemical Constants Inhouse 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, 9]. 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, 10].

2.6 Phytochemical Evaluation

The qualitative chemical tests were carried out for the identification of nature of phytoconstituents present in the formulations.

2.7Quantitative Parameters

2.7.1 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 [6, 7].

2.7.2 Hardness test

Pfizer hardness tester was used for the determination of the hardness [11].

2.7.3 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 [12].

3. Result and Discussion

Preformulation studies of the intermediate granules produce during the preparation of formulation by using the ingredients mentioned in Table 1 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 Vati

S. No.	Plant Name	Quantity
1	Amchur powder	100gm
2	Cumin powder	60gm
3	Black salt	45gm
4	Sea salt	15gm
5	Sugar	400gm
6	Fennel powder	15gm
7	Ginger powder	15gm
8	Black pepper powder	15gm
9	Red chilli powder	15gm
10	Citric acid	q.s
11	Honey	q.s

Table 2: pre-formulation study of in house Jeera Vati granules

S. No.	Parameters	In House
1	Appearance	Dusky-bright
2	Taste and odour	Sweet and salty,Characteristic.
3	Colour	Light brown
4	Bulk density	0.625 ± 0.03
5	Tapped density	0.952 ± 0.03
6	Hausner's ratio	1.523± 0.02
7	Carrs Index	34.34%± 0.12
8	Angle of repose	$\tan^{-1}2/1.93$= 45.84°

Values are expressed as mean ± SEM

The observations of the preformulation study were reported in Table 2 which shows that appearance of In-house formulated Jeera vatti 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 [9]. The bulk density and Tap density results obtained with the In-house formulated Jeera vati granules was found to be0.625 ± 0.03 and 0.952 ± 0.03 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 45.84°. Hausner's ratio isrelated 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 Jeera vati powder was found to be 1.523± 0.02 which was greater than 1.2.Hence the In-house formulated Jeera vati granules has high interparticle friction. Carr's index is another method for measuring the powder flow from bulk density [11]. Carr's index of In-house formulated Jeera vati granules was found to be 34.34%±0.12.

Table 3: Organoleptic properties of Jeera Vati and marketed formulation.

S. No.	Parameters	In House	Standered Vati
1	Appearance	Smooth	Smooth
2	Colour	Blackish brown	Blackish brown
3	Odour	Characteristic	Characteristic
4	Taste	Salty	Salty

Table 4: physical and chemical evaluation of samples of Jeera Vati.

S No.	Parameters	In House	Standered Vati
1	Total ash value(% w/w)	03.66 ±0.33	06.1 0± 0.60
2	Acid insoluble ash(% w/w)	01.50 ± 0.28	03.00±0.18
3	Alcohol-soluble extractive(% w/w)	15.30 ± 0.23	13.66 ± 0.82
4	Water-soluble extractive(% w/w)	16.52± 2.40	14.66 ± 1.85
5	Loss of drying(% w/w)	2.5±0.16	3.2 ± 0.28
6	pH of 10% solution(% w/v)	4.4	2.2

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 were 03.66 ±0.33 and 06.1 0± 0.60 %respectively. The amount of acid-insoluble siliceous matter present in In-house vati and Marketed vati were 01.50 ± 0.28 and 03.00±0.18. 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 and Marketed vati were 16.52± 2.40 and 14.66 ± 1.85 respectively. The alcohol soluble extractive values indicated the presence of polar constituents like phenols, alkaloids, steroids, glycosides, flavonoids [8]. The alcohol soluble extractive values In-house vati and Marketed vati were 15.30 ± 0.23 and 13.66 ± 0.82 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 [13]. The loss on drying at 105°C In-house vati and Marketed vati were 2.5±0.16 and 3.2 ± 0.28 respectively. The pH from 10% w/v solution revealed that pH of all the formulations were comparable and was slightly acidic for all formulations [14]. This may be because of acidic salts present in the crude drugs used for preparation of formulations.

Table 5: phytochemical screening of samples of Jeera Vati

S. No.	Parameters	In House	Standered Vati
1	Carbohydrates	+	+
2	Proteins	+	+
3	Amino acids	+	+
4	Glycosides	+	+
5	Flavanoids	-	-
6	Steroid	-	-
7	Alkaloids	+	+
8	Tannins	+	+

+ indicates presence; - indicates absence

Table 6: Evaluation of Jeera Vati

S. No.	Parameter	In House Vati	Standered Vati
1	Weight variation	00.42 ± 0.01	00.40 ± 0.01
2	Hardness	10 ± 0.02	7.8 ± 0.02
3	% Friability	0.77± 0.13	0.53± 0.23
4	Disintegration	70.05 ± 0.02	88.05 ± 0.02

The results of Quantitative Parameters used for comparative account in between the In-house vati and Marketed vati were reported in table no 6. The weight variation of a tablet/vati is used to determine the uniformity of dosage unit [11]. The weight variation of In-house vati and Marketed vati were found to be 00.42 ± 0.01 and 00.40 ± 0.01 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. **[12]** The hardness of In-house vati and Marketed vati were10 ± 0.02 and 7.8 ± 0.02 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. This was found to be 70.05 ± 0.02 and 88.05 ± 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.

4. 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 jeera 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 jeera 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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