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Formulation and standardization of khadiradi vati and comparative study with marketed formulation

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Abstract
The world is witnessing a faster growth in the usage of herbal products. India is a mother hub for natural herbs based science. Herbal drug technology is used for converting botanical materials into medicines, where standardization and quality control with proper integration of modern scientific techniques and traditional knowledge is important. For global harmonization WHO specific guidelines for the assessment of the safety, efficacy and quality of herbal medicines are of utmost importance. With this aim in the recent study an attempt has been made to develop standardization methods of *Khadiradi vati*. A comparative study has been made between in-house preparation and one marketed formulations. 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, khadiradi vati, quality, standardization, pre-formulation, post-formulation etc.

Introduction
The use of traditional medicines, Complementary and alternative medicines is increased throughout the world. Already, it accounts for a major part of health care in low and middle income countries. Up to 80% world of the population use the traditional medicines for primary healthcare needs. In many developing countries complementary and alternative medicines is becoming increasingly popular [1].

Hence it is necessary to maintain reproducible efficacy and safety of herbal medicines. If herbal formulations have to regarded as rational drug they should be standardized and pharmaceutical quality must be approved. World Health Organization stresses the importance of the qualitative and quantitative methods for characterizing the samples quantification of biomarkers and fingerprint profile. Methods of standardization should take into consideration to maintain the quality of the herbal drugs, namely correct identity of the sample, organoleptic evaluation, pharmacognostic evaluation, quantitative evaluation, phytochemical evaluation, microbial load profile is of special significance since it has direct bearing on the activities of the herbal drugs. Fingerprint profiles serves as guidelines to the phytochemical profile of the drug in ensuring the quantity, while quantification of the markers compound/s would serve as an additional parameter in assessing the quality of the sample [2].

"Khadiradi vati" is a polyherbal ayurvedic medicine which consists of; Khadira (Acacia catechu/Khair), Javitri (Myristica fragrans), Kankol (Piper cubeba), Bhimseni kapoor (*Cinnamomum camphora*), Supari(Areca nut) and it is used for Mouth ulcer, Pharyngitis(Sore throat), and other diseases of teeth, gums, tongue and sore throat. It is also act as oral antiseptic, astringent, anti-inflammatory, expectorant. Therefore it is beneficial especially in sore throat and tonsillitis and pharyngitis [3]. The purpose of the present study is to prepare and standardization of in-house prepared "Khadiradi vati" and comparing it with other marketed preparations as per standard parameters.

2. Materials and Methods
2.1 Procurements of Plant material
The crude drugs used in preparation were purchased from the local Market, Bangalore

2.2 Method of preparation of Khadiradi vati
Standard laboratory reference sample of khadiradi vati was prepared as per the procedure mentioned in Ayurvedic formulary of India. All the herbal ingredients present in the formulation were mentioned in Table no.1

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, Bulk density, Tap density, Angle of repose and Carr's index indicates the flow properties as well as inter particulate resistance between the powders. The information collected from this evaluation was crucial to avoid ambiguous predictions of stability or solubility of formulation [4]. Bulk density and Tap density are used to measure a packing of particles or granules [5]. 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. Carr's index is another method for measuring the powder flow from bulk density [6].

2.4 Pharmacognostic Standardization Organoleptic Descriptions

Organoleptic evaluation was carried out to assess the color, odour and taste of In-house and marketed formulations [7].

2.5 Physico-chemical 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, 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. 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]. 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.

2.6 Phytochemical Evaluation

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

2.7 Qualitative 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 [9].

2.7.2 Hardness test

Pfizer hardness tester was used for the determination of the hardness. 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 [10].

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.

3. Result and Discussion

Table 1: Composition of Vati

S. No.	Plant Name	Quantity
1	Khadira (*Acacia catechu*)	125 mg
2	Javitri (*Myristica fragrans*)	31.5 mg
3	Kankol (*Piper cubeba*)	31.5 mg
4	Supari (*Areca catechu*)	31.5 mg
5	Karpura (*Cinnamomum camphora*)	31.5 mg

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 2: pre-formulation study of in house khadiradi vati granules

S. No.	Parameters	In House
1	Appearance	Light brown to Dark brown
2	Taste and odour	Bitter and piquant smell.
3	Colour	Light brown
4	Bulk density	0.572 ± 0.02
5	Tapped density	0.647 ± 0.04
6	Hausner's ratio	1.21± 0.03
7	Carrs Index	35.8%± 0.10
8	Angle of repose	21.94°

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 Khadiradi vati granules was smooth. Taste and odour of granules is Bitter and piquant odour respectively. The bulk density and Tap density results obtained with the In-house formulated Khadiradi vati granules was found to be0.572 ± 0.02 and 0.647 ± 0.04 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 Khadiradi vati granules was found to be 21.94°. Hausner's ratio for In-house formulated Khadiradi vati powder was found to be 1.21± 0.03 which was greater than 1.2. Hence the In-house formulated Khadiradi vati granules has high interparticle friction. Carr's index of In-house formulated Khadiradi vati granules was found to be 35.8%± 0.10.

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

S. No.	Parameters	In House	Standard Vati
1	Appearance	Smooth	Smooth
2	Colour	Light brown	Dark brown
3	Odour	Characteristic	Characteristic
4	Taste	Bitter	Bitter

Table 4: physico-chemical evaluation of samples of Khadiradi Vati.

S No.	Parameters	In House	Standard Vati
1	Total ash value (% w/w)	08.50 ±0.45	08.95± 0.50
2	Acid insoluble ash (% w/w)	01.08 ± 0.40	01.89±0.15
3	Alcohol-soluble extractive (% w/w)	17.56 ± 0.18	18.95 ± 0.52
4	Water-soluble extractive (% w/w)	20.05± 1.25	17.40±2.15
5	Loss of drying (% w/w)	5.15±0.65	4.14 ± 0.15

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 In House vati was light brown in colour and marketed formulation is Dark brown in colour, with a characteristic odour and Bitter taste. Analytical results showed total ash values for In house vati, Marketed vati were 08.50 ±0.45 and 08.95± 0.50 % respectively. The amount of acid-insoluble siliceous matter present in In-house vati and Marketed vati were 01.08 ± 0.40 and 01.89±0.15. Hence the results of ash values signify that the crude drugs used for preparation of in-house formulations were of good quality. Analytical results showed water soluble extractive values for In house vati and Marketed vati were 20.05± 1.25 and 17.40±2.15 respectively. The alcohol soluble extractive values In-house vati and Marketed vati were 17.56 ± 0.18 and 18.95 ± 0.52 respectively. 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. The loss on drying at 105°C In-house vati and Marketed vati were 5.15±0.65 and 4.14 ± 0.15 respectively.

Table 5: Phytochemical Screening of Samples of Khadiradi vati

S. No.	Parameters	In House	Standard Vati
1	Carbohydrates	+	+
2	Proteins	+	+
3	Glycosides	+	+
4	Saponins	+	+
5	flavonoids	+	+
6	Phytosterols	-	-
7	Alkoloids	+	+
8	Tannins	+	+
9	Volatile oils	+	+

+ indicates presence; - indicates absence

Chemical constituents of In House and Standard Vati were reported in the table number 6. Mainly carbohydrate, proteins, glycosides, saponins flavonoids, alkaloids, tannins, volatile oils present in both In-house and Standard vati. And phytosterols absent in both In-House and Standard vati.

Table 6: Physical evaluation of Khadiradi vati

S. No.	Parameter	In House Vati	Standard Vati
1	Weight variation	01.44 ± 0.01	01.23 ± 0.01
2	Hardness	8.9 ± 0.01	9.8 ± 0.01
3	% Friability	0.76± 0.5	0.91± 0.11
4	Disintegration	38 ± 0.02	30 ± 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 In-house vati and Marketed vati were found to be 01.44 ± 0.01 and 01.23 ± 0.01 respectively. The hardness of In-house vati and Marketed vati were8.9 ± 0.01 and 9.8 ± 0.01 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 38 ± 0.02 and 30 ± 0.02 minutes 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, Phytochemical profiles and Physical evaluation were carried out for Khadradi vati, it can be concluded that the formulation of khadiradi 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 Khadiradi vati. The result of present study will also serve as reference monograph in the preparation of drug formulation.

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6. References

1. Guidelines on developing consumer information on proper use of traditional, complementary and alternative medicines. Who-jan, 2004
2. Nikam HN, Joseph K, Aruna J, Vilasrao K. Future trends in standardization of herbal drugs. J app Pharm Sci. 2012; 02(06):38-44.
3. Singh J. Ayur times; Khadiradi vati, 2015.
4. Subrahmanayam CVS. Textbook of Physical Pharmaceutics, 2nd ed, Vallabh Prakashan, 1998, 210-226.
5. Evans WC, Trease. Evan's Pharmacognosy, 15th ed. Sounders Company Limited, 2002, 98-99.
6. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms Tablets, 2nd ed, Marcel Deckker, 1989, 1-56.
7. WHO. Quality Control Methods for Medicinal Plant Materials. AITBS Publishers, 2002, 46-51.
8. Mukherjee PK. Quality control of herbal drugs, 1st ed, Business Horizons, 2003, 97-98, 184-195, 248- 249, 529-567, 701-725,750-766.
9. Martin AJ. Physical Pharmacy, 4th ed, Lippincott Williams and Wilkin, 2001, 442- 448.
10. Aulton ME. The science of dosage forms designs, 2nd ed, New Delhi Churchill Livingstone, 2002, 205-221.