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STANDARDIZATION OF JAMBIRA LAVANA VATI

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ABSTRACT

Introduction: Vati kalpana (tablet) is one of the most commonly used dosage form because of its easy administration, dosing, palatability and transportation. Jambira lavana vati is a preparation mentioned for the treatment of loss of appetite and indigestion. The uniqueness of this vati is that it does not follow the usual method of preparation and hence standardization becomes essential to maintain quality and efficacy. In this study an attempt has been made to prepare and analyse jambira lavana vati to set the preliminary standards for the same. **Materials and Methods:** Preparation of jambira lavana vati was done as per reference of Siddha yoga sangraha. Three batches were prepared and analysed for quality control parameters of tablet. **Results:** 171.6gm of drugs were taken for each batch and the average yield was 49.67gm. The results of organoleptic characters, physical characters and physicochemical characters were noted. **Conclusion:** The pharmaceutical and analytical results can be used as reference standard for quality assurance.

KEYWORDS: Jambira lavana vati, vati kalpana, standardization, quality control.

INTRODUCTION

Vati kalpana or tablet is one of the most commonly used dosage form because of its easy administration, dosing, palatability and transportation. It is a secondary preparation in ayurveda pharmaceutics that can also be prepared by processing of guda (Jaggery), sharkara (sugar candy), or guggulu (*Commiphora mukul*), added with fine powders of other medicinal drugs.[1]

In ancient period, the medicines were prepared by the physician himself. This practice of identifying drugs and preparing the medicine himself has been largely overtaken by pharmaceutical industries. The chronic shortage of authentic raw materials due to many reasons, tendency of patients to purchase readymade preparations have resulted in the deterioration of the quality of medicines. This makes the medicine not only ineffective but sometimes renders it harmful to health. So there is a need to standardize a formulation to ensure the quality of medicine and to give protection to manufacturers of ethical ayurvedic drugs, doctors and consumers. Standardization of ayurvedic medicines has become necessary to keep up their therapeutic efficacy.

Jambira lavana vati[2] (JL vati) does not follow the usual method of preparation. The dose of the vati is said as 3 ratti (375mg) and is indicated in loss of appetite as a chewable pill. This formulation is not commonly used in clinical practice and also there is no data available regarding process of standardization of jambira lavana vati. Hence, one of the objectives was to standardize the formulation.

OBJECTIVES

- Process standardization of Jambira lavana vati.
- Standardization of final product of Jambira lavana vati on the basis of quality control parameters.

MATERIALS AND METHODS

PHARMACEUTICAL STUDY

Table 1: Ingredients and proportion used for preparation.

Sl. no.	Ingredients	Botanical name/ English name	Parts Used	Proportion
1.	Jambira (Lemon)	Citrus limon	Fruit juice	130gm
2	Saindhava lavana	Rock salt	Whole	13gm
3	Shunti	Zingiber officinale	Rhizome	2.2gm
4	Ajamoda	Trachyspermum ammi	Fruit	2.2gm
5	Sarja kshara	Sodium bicarbonate	Whole	2.2gm
6	Pippali	Piper longum	Fruit	2.2gm
7	Hingu	Ferula asafetida	Resin	2.2gm
8	Karanja	Pongamia pinnata	Fruit	2.2gm
9	Maricha	Piper nigrum	Fruit	2.2gm
10	Lashuna	Allium sativum	Bulb	2.2gm
11	Punarnava	Boerhavia diffusa	Stem	2.2gm
12	Sarshapa	Brassica campestris	Seed	2.2gm
13	Jeeraka	Cuminum cyminum	Fruit	2.2gm
14	Atasi	Linum usitatissimum	Seed	2.2gm
15	Samudra lavana	Common salt	Whole	2.2gm

Method of preparation

Stage 1: Keeping jambira swarasa mixed with Saindhava lavana in sun light.

Matured fruits of jambira were washed properly. Juice was extracted in beaker and specified quantity of Saindhava lavana was added, and stirred well. Then white cloth was tied to the mouth of beaker kept under sunrays for four days. Rest of the ingredients were made into fine powder, weighed properly and stored. Lashuna was made into kalka and weighed.

Stage 2: Paka of jambira swarasa along with other ingredients

On fifth day, jambira swarasa along with dissolved lavana was heated on mandagni till it became slightly thick in consistency. Then, the fine powders of rest of the ingredients and lashuna kalka were added and mixed properly till it attained the consistency where it could be rolled into pills.

Temperature was recorded every two minutes.

Stage 3: Pill making process

Then pills/ vati of 3 ratti (375mg) size were prepared manually and dried in shade. After drying, tablets were stored in an air tight container. Three such batches were prepared.

ANALYTICAL STUDY

The prepared JL vati were tested for organoleptic characters and following analytical parameters.

- **Hardness**[3]

Material: Monsanto hardness tester, JL vati sample of all batches.

Method: The lower plunger was placed in contact with the vati. The upper plunger was then forced against a spring by turning a threaded bolt until the vati fractures. The force of fracture was recorded.

- **Friabiltiy**[4]

Material – Friability test apparatus, Digital weighing balance, JL vati sample of all batches.

Method – The vati were de-dusted and weighed carefully. The friability apparatus was set for 25 revolutions per minute. The vati were placed in the drum and rotated for 100 times (i.e., for four minutes). Later, the vati were removed, dusted to remove any loose particle from them and weighed accurately.

- **Disintegration**[5]

Material: Disintegration apparatus, Distilled water, JL vati sample of all batches.

Method: The tank of the disintegration apparatus was filled with distilled water up to the mark. 750 ml of distilled water in each of the 1000 ml beaker was taken. The timer of the instrument was set for 60 minutes. Temperature was set to 37°C. One vati was introduced into each tube and disks were put. The assembly was suspended in the beaker containing water and the apparatus was operated. The time duration at which the vati disintegrated was noted.

- **Uniformity of weight**[6]

Material: Weighing balance, JL vati sample of all batches.

Method: 10 vati were selected randomly and weighed. The average weight was calculated. The individual weight of the vati was taken. Not more than two of the individual weights deviate from the average weight by more than the percentage shown in table 2 and none deviates by more than twice that percentage.

Table 2: Uniformity of Vati/ Tablet.

Average weight of tablet	Percentage deviation
80mg or less	10
More than 80mg but less than 250mg	7.5
250mg or more	5

- **pH**[7]

Material: pH meter, Distilled water, JL vati sample of all batches.

Method: Preparation of buffer solutions: Standard buffer solution: Dissolved one tablet of pH 4, 7 and 9.2 in 100 ml of distilled water.

Determination of pH: 1g of sample was taken and made up to 10 ml with distilled water, stirred well and filtered. The filtrate was used for the experiment. Instrument was switched on. 30 minutes time was given for warming pH meter. The pH meter was calibrated with standard buffer solutions of pH 4, 7 and 9.2. The sample solution was introduced and reading was noted. The test was repeated four times and the average reading were taken as result. In each batch same method was followed.

- **Loss on drying**[8]

Materials: Crucible, Weighing balance, Hot air oven, Dessicator.

Method: 5 g of vati sample was taken in a tared crucible. Weight along with the crucible was noted. The crucible was kept in hot air oven at 101.5°C for 5 hours. The crucible was taken out, cooled in a dessicator and weighed. Then the crucible was again kept in hot air oven for one hour. Then, it was cooled in dessicator and weighed again. The process was repeated till there was no difference in the weight. Percentage loss on drying was calculated with the reference to weight of sample.

- **Total ash**[9]

Materials: Platinum/ silica dish, Crucible, Muffle furnace, Weighing balance, Ashless Filter paper, JL vati sample of all batches.

Method: 2 g of powdered vati sample was incinerated in a tared platinum crucible at temperature not exceeding 450°C until carbon free ash was obtained. Percentage of ash was calculated with reference to weight of the sample.

- **Acid insoluble ash**[9]

Materials: Beaker, Crucible, Ashless filter paper, Hot plate, Muffle furnace, Desiccators, dil.HCL, JL vati sample of all batches.

Method: To the crucible containing total ash, 25ml of dilute HCl was added. The insoluble matter was collected on ashless filter paper (Whatmann 41) and washed with hot water until the filtrate was neutral. The filter paper containing the insoluble matter was transferred to the original crucible, dried on a hot plate and ignited to constant weight. The residue was allowed to cool in suitable desiccator for 30 min and weighed without delay. The content of acid insoluble ash was calculated with reference to the air dried drug.

- **Water soluble extractive**[10]

Material: Conical flask, crucible, hot air oven, distilled water, JL vati sample of all batches

Method: 4 g of the powdered vati was weighed accurately in a glass stoppered flask. 100 ml of distilled water was added, shaken occasionally for 6 hours. It was allowed to stand for 18 hours. Later, it was filtered rapidly taking care not to lose any solvent. 25ml of the filtrate was pipetted out in a pre-weighed 100 ml beaker and evaporated to dryness on a water bath. It was kept in an air oven at 105°C for 6 hours, cooled in a desiccator and weighed. The experiment was repeated twice. The average value was taken.

- **Alcohol soluble extractive**[11]

Material: Conical flask, Crucible, Hot air oven, Distilled alcohol, JL vati sample of all batches.

Method: 4 g of the powdered vati was weighed accurately in a glass stoppered flask. 100 ml of distilled Alcohol (approximately 95%) was added and shaken occasionally for 6 hours. It was allowed to stand for 18 hours. Later, it was filtered rapidly taking care not to lose any solvent. 25ml of the filtrate was pipetted out in a pre-weighed 100 ml beaker. It was evaporated to dryness on a water bath. Later, it was kept in hot air oven at 105°C for 6 hours, cooled in desiccators for 30 minutes and weighed. The percentage of Alcohol extractable matter of the sample was calculated. The experiment was repeated twice, and the average value was taken.

OBSERVATION AND RESULT

Fig 1: Swarasa + Lavana

Fig 2: Heating on low flame

Fig 3: Adding fine powders

Fig 4: Rolled into pills

Fig 5: Dried Jambira lavana vati

Fig 1-5: Preparation of Jambira Lavana Vati.

Pharmaceutical observation

Time taken for preparation and yield were noted as given in table 3.

Table 3: Results of Pharmaceutical study.

Batch	Quantity of drugs taken	Time taken for preparation	Initial weight of jambira swarasa + saindhava lavana	Weight of jambira swarasa + saindhava lavana on 5th day	Final Yield (after drying of pills)
1	171.6g	7mins	143gm	81gm	48gm
2	171.6g	7mins	143gm	81gm	52gm
3	171.6g	8mins	143gm	80gm	49gm

Table 4: Temperature readings during preparation.

Time	Batch 1	Batch 2	Batch 3
Initial	26.3°C	22.7°C	28.7°C
After 2 mins	81.2°C	82.8°C	80.6°C
After 4 mins	95.3°C	97.5°C	92.6°C
After 6 mins	97.5°C	98.7°C	96.5°C

Table 5: Organoleptic characters.

Characters	Observation
Colour	Blackish
Odour	Characteristic
Taste	Amla, lavana
Touch	Solid, rough

The organoleptic characters were same for all the three batches.

Table 6: Results of Analytical study.

Parameter	n=3			Average
	Batch 1	Batch 2	Batch 3	
Hardness	3	3	3	3
Friability	0%	0%	0%	0%
Disintegration	35min10sec	36min09sec	40min	37min10sec
Uniformity of weight	300mg	311mg	310mg	307mg
pH	2.64	2.88	2.80	2.77
Loss on drying	13.46%	11.90%	14.22%	13.20%
Total Ash	35.50%	32.50%	32.52%	33.50%
Acid insoluble ash	1.50%	1.54%	1.94%	1.66%
Water Soluble extractive	51.85%	50.45%	48.27%	50.19%
Alcohol soluble extractive	16.42%	16.44%	16.74%	16.53%

DISCUSSION

The preparation of jambira lavana vati was done in three steps. The first step includes exposing the mixture of jambira swarasa and saindhava lavana to sun light for 4 days. This may result in certain chemical changes and evaporation of some quantity of liquid. On 5th day, weight of the mixture reduced, with the average weight being 80.67gm which may be due to evaporation of liquid.

During heating gradual rise in temperature was seen. Average time taken for the contents to become thick was seven and half minutes and average temperature being 97.57°C.

With the addition of other ingredients and homogenous mixing, the consistency obtained was suitable for making pills. Average yield obtained is 49.67gm i.e., 28.95%. The loss in weight is due to loss in moisture content in pills due to drying.

JL vati was blackish in colour, had a characteristic odour and Amla, lavana taste. Major ingredients of the vati is jambira swarasa and lavana hence dominance of amla and lavana taste is seen, indicating the predominant rasa of the ingredients employed.

The analytical parameters gives the preliminary standards for the prepared vati. The average hardness of the vati is 3 and friability is within the permissible limits. Average time taken for disintegration of vati is 37minutes 10 seconds. Though the vati has lavana as major ingredient, the heating and mixing of fine powders might have facilitated the binding nature of the vati. The uniformity of weight of vati is within permissible limit and average weight of one vati is 307mg. pH of the vati is acidic in nature. This is due to presence of jambira swarasa that has an average pH of 2.77. Average loss on drying is 13.20%. the physico chemical parameters like total ash, acid insoluble ash, water and alcohol soluble extractive values gives the primary idea about the presence of organic and inorganic matter and solubility of the vati.

CONCLUSION

Jambira lavana vati is a rare formulation which is not in clinical practice. The ingredients are easily available and also feasible. The method of preparation is also simple but slightly differs from the standard method of preparation of vati. The average yield of the pill is 28.95%. The physico chemical analysis gives the preliminary standards of the vati which can be used as further reference for standardization.

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