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Standardization of *Rajapravartini Vati* Tablets

Research Article

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Abstract

"Standardization" expression is used to describe all measures, which are taken during the manufacturing process and quality control leading to a reproducible quality. Standardization of *Ayurvedic* drugs is a need of the hour in the field of Pharmacy. In Classical *Ayurvedic* texts the parameters given are mostly subjective. Hence there is a need to set some objective parameters through pharmaceutical and Analytical study. *Rajapravartini Vati* (Tablets) is prescribed for the treatment of scanty bleeding and amenorrhea. Dosage form plays a important role in delivery and proper action of particular drug. In this research paper, an attempt has been made to develop pharmaceutical and analytical standards for *Rajapravartini Vati* and transform it into Tablet form. In-house preparation and which was standardized on the basis of macroscopic, microscopic, physic-chemical parameters and Fingerprinting. Three samples were prepared and evaluated on the basis of ayurvedic as well as modern parameters. All three samples shows identical parameters and shows no significant difference. The set parameters were found to be sufficient to evaluate the *Rajapravartini Vati* Tablet and can be used as reference standards for the quality control/quality assurance in future

Keywords: *Rajapravartini Vati,* Standardization, Polyherbal formulation, Ayurveda, Rasashastra, Quality control.

Introduction

Nowadays there is increase in trend towards use of herbal medicine. Because various side effects and adverse effects of modern medicine which are becoming known each day. Hence, it is the responsibility of the regulatory authorities to guarantee availability of pure, safe, potent and effective herbal medicines to the consumer. There are lots of challenges in the standardization of a polyherbal formulation since the raw material collection has a batch to batch variations in their standards in terms of identification, storage, processing, lack of reference standards. which leads to the variations in the final products standards. To overcome these shortcomings of herbal medicines, various quality standards as laid down in formularies, pharmacopeia's or manufacturing operation are followed through statutory imposed good manufacturing practices by regulatory authorities. Since there is a major portion of herbal drugs in the global market it is important to adopt quality control guidelines in the manufacturing of herbal drugs which are acceptable internationally (1).

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In Modern era, women's are suffering from various menstrual disorders. Also modern medicines are not much effective and have their side effects on health. Hence there is increase in demand for Ayurvedic medicine for Gynaecological disorders. So the appropriate parameters for standardization of a classical formulations used in Gynaecological disorders like *Rajapravartini Vati* (2) is attempted through this study. Which have its classical reference in *Bhaishajya Ratnavali Stri Rogadhikara*.

The major problems in using Ayurvedic medicine is the unavailability of herbal medicine prepared with unique pharmaceutical and analytical validation. On this contrary to avoid batch to batch variations, the department of AYUSH, is working on the development of standard operating procedures for *Ayurvedic* preparation. This can be achieved if the herbal products are evaluated and analyzed using both *Ayurvedic* as well as modern techniques of standardization during and after preparation of finished product. Standardisation of *Rajahpravartani vati* (Tablet) form is an important step for establishment of biological activity, constituent physico-chemical profile, and pharmaceutical and analytical validation of herbal drugs. Hence standardisation tests helps in authenticating the polyherbal preparation and also in ensuring the quality of the same. Due to increased demands of herbal remedies worldwide, it is responsibility to provide the quality of the product in standard dosage form is bestowed upon *Ayurvedic* industry. Dosage form plays an important role for

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specific action and their efficacy on the human body. Amongst all the dosage forms tablet is widely accepted like syrup, powder, injectable etc. tablets are easy to administer, delivers exact dose, more palatable, easy to transport, packaging etc.

Aim

To standardize an ayurvedic polyherbal formulation- Rajpravartini vati.

Objective

- To prepare three batches of Rajpravartini vati.
- To perform pharmaceutical and analytical on Rajpravartini vati.
- To standardise the formulation of Rajpravartini vati.

Materials and methods

Table No. 1. Procedure of *Rajpravartini Vati* preparation.

Raw Materials	*Shuddha Kasisa* (Purified Green Vitriol) 250 gm; *Shuddha Hing* (Purified *Ferula assafoetida*)250 gm; *Shuddha Tankana* (Purified Borax) 250 gm; *Kumari swarasa* (Liquid extract of Aloe vera) 250 gm.
Method Used	*Shodhana* (Purification), *Churna nirmana* (Preparation of powder form), *Bhavana* (Liquid extract in which material is processed), *Mardana* (Trituration)
Apparatus	Pulveriser, Mass Mixer, Mass miller, Dryer, Edge runner, Tabulating machine.

Procedure

Stage I: Checking weight dispensed of Raw material.

Stage II:

- **Shodhan of *Kasisa*:** The raw *Kasisa* of quantity 500 gm was taken for *Shodhana*. *Shodhana process* was carried out; by 3 hours sudation with *Bhringaraja Swarasa* (extract of *Elipta alba Niss*.) (3).
- **Shodhan of Tankan:** *Shodhan* process of *Tankan* was carried out by heating it on mild gas flame till its water content gets evaporated and it swells like a flower (4).

Stage III: Pulverization of Raw Material: All the raw materials mentioned in table no. 1 were taken in prescribed quantity and mixed together. These raw materials were pulverized in mass pulveriser to obtain its powder.

Stage IV: Mixing of Powder in Mass Mixer: Pulverized powder was weighed again to check processing loss and uniformly mixed in mass mixer.

Stage V: Sifting of Powder: The obtained material was then sifted in mass sifter using mesh No. 80 to obtain its fine powder.

Stage VI: Preparation of Liquid Extract: *Ghritkumari* 250 gm was taken in Stainless steel vessel, 4 times (of *Ghritkumari*) water was added and boiled, till it was reduced to 50%. Filtered and used for *Bhavan* process.

Stage VII: *Bhavana:* Mixed the shifted powder (Stage V) with liquid extract of *Ghritkumari* for in Edge runner machine for about 3 hours.

Stage VIII: Drying: Dried the bulk in the tray dryer for 3 hours at 60-80^{0}C

Stage IX: Addition of Excipients: Starch and Microcrystalline cellulose were added as an excipient in above mixture for proper binding of tablets. In batch of 1 kg starch 120gm and Microcrystalline cellulose 80gm was added. The mixture was uniformly mixed in suitable Stainless steel vessel. It was then subjected to drying in electric air dryer at 60^{0}C.

Stage X: Granulation in Multi Miller: Above material was passed through Multi miller through sieve no. 2 for granulation of material.

Stage XI: Compression: Uniform tablets each of 280-300 mg were prepared using automated tablet pressing machine, in which the active ingredient was 250mg. About total 4000 to 4500 tablets were obtained of each sample batch A, B and C. Tablets were packed in air tight bottle and stored in cool dry place. All the hygienic conditions were maintained during preparation.

Stage XII: Sampling & Analysis: Samples were tested on various analytical parameters.

Table.2: Showing the result of preparation of *Rajpravartini Vati*

Weight of total contents taken	Quantity of drug obtained
1000 gm	4000- 4500 tablets of 280 to 300 mg each

Observations and Results

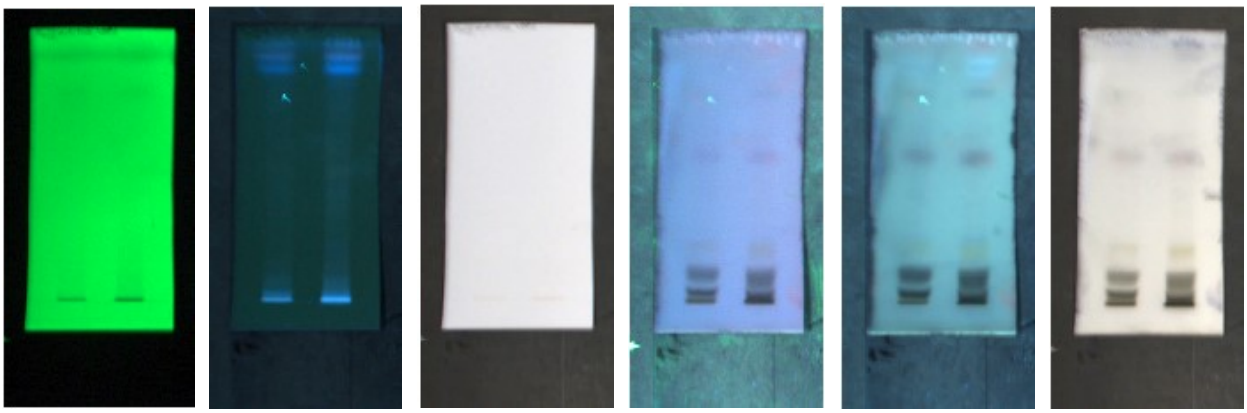
Physico-chemical analysis: (5) To check quality of the formulation all three samples of finished products were checked using relevant modern parameters viz color, Uniformity in weight, Diameter, Thickness, Hardness, Friability, Disintegration time and Fingerprinting. The Results are tabulated below in table no.3

Table No.3: Comparative physico-chemical values of three batches of *Rajapravartini Vati*.

Sr	Test Name	Sample A	Sample B	Sample C	Mean SD ±
1	Description	Blackish grey, circular, Flat, uncoated tablet compressed flat, uncoated tablet	Blackish grey, circular, Flat, uncoated tablet	Blackish grey, circular, Flat, uncoated tablet	-
2	Average Weight	0.2518gm	0.2528gm	0.2546gm	0.2531
3	Uniformity in weight	0.2459-0.2522g	0.2408-0.265g	0.2441-0.2667g	Complies 0.246-0.2613g
4	Diameter	8.25mm	8.11mm	8.09mm	8.15mm
5	Thickness	3.65mm	3.10mm	3.09mm	3.28mm
6	Hardness	2.00 Kg/Sq.cm	3.50 Kg/Sq.cm	3.50 Kg/Sq.cm	3 Kg/Sq.cm
7	Friability	0.17 %w/w	0.04 %w/w	0.15 %w/w	0.12 %w/w
8	Disintegration time	23 to 24 min	20 to 22 min	16 to 18 min	Passes 19 to 21 min
9	TLC	Complies	Complies	Complies	
	TLC Spots observed	0.00, 0.08, 0.16, 0.44, 0.54, 0.60	0.01, 0.16, 0.26, 0.30, 0.35, 0.37, 0.42, 0.54, 0.71, 0.80	0.00, 0.08, 0.16, 0.42, 0.44, 0.54, 0.71, 0.80	vide range of spots observed as it contains more than one herbs and minerals

Fingerprinting (6) study of *Rajapavartini Vati* was performed using Ethyl acetate : Methanol : Water 6 ; 1.4 : 1 ratio as mobile phase as Methanol as a solvent. TLC plate (5.0 x 10 cms, 0.2 mm thickness), HPTLC plates silica gel 60 F 254. The bands were observed in wavelength from 254 and 366nm.

HPTLC PLATES UNDER DIFFERENT WAVELENGHTS



Wavelengths under 254 nm, 366nm, white R of sample A, B and C respectively.

Discussion

In traditional system of medicine, the quality control aspect has been covered by careful observation of physical parameters during and after preparation of medicine (7).According to modern pharmaceutics concept; quality control of medicine are developed in terms of modern methodologies. Thus, today quality assurance is a trusted area for the evaluation of traditionally used medicinal plants and herbal formulations. But in today's Ayurvedic Pharmaceutical Manufacturers set their own standards parameter for quality assurance by testing their own formulation; out of which most of them are only preliminary in nature. Combined and well-coordinated efforts from scientific workers of different disciplines are required to set universal parameters for quality assurance in Ayurvedic Pharmaceutical field.

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Rajpravartini Vati was found to have (mean ± SD) 0.2531g average weight. 90% tablets were within acceptable range of weight variation; According to Ayurvedic pharmacopeia of India (API) ±10% range of weight variation is acceptable. *Rajpravartini Vatti* was found to have 3.00 kg/cm^2 hardness and 20 min disintegration time which was noticed with in accepted limits (8). There should not be large variation in between batches for various parameters like Disintegration time, Friability, Hardness, Thickness & Uniformity in weight. Variation in weight of tablet causes improper doses of active medicament which changes the bioavailability of medicine. This may be due to causes such as variation in granule size, poor flow, bridging, rat holing, punch variation and poor mixing. Both hardness and disintegration time interfere with the bioavailability of drug. Hence there should be universal parameters for quality assurance of Ayurvedic formulations. By evaluating all above parameter results are tabulated in table No.4 below.

Table No.4. Showing Set of parameters for Rajahpravartani Vati Tablet

Sr	Test Name	Set Parameters
1	Description	Blackish grey, to Brownish gray, circular, Flat, uncoated tablet
2	Average Weight	0.2500 to 0.2700 gm
3	Uniformity in weight	Varaiation not More than 5%
4	Diameter	8 to 9 mm
5	Thickness	3 to 3.5mm
6	Hardness	2 to 3.50 Kg/cm^2
7	Friability	Not more than 1%
8	Disintegration time	16 to 18 min
9	TLC	Complies the observed spots

Conclusion

Through this present work effort were taken to develop analytical profile of *Rajpravartini Vati;* which deals with weight variation, hardness, Disintegration time, In fingerprinting, 6 spots at 350 nm were observed. This piece of work is just a pilot study which can serve as a preliminary step towards standardization of a herbo-mineral drug *Rajpravartini Vati*. Hence these can used as reference parameters for further pharmaceutical processes. Further study is necessary to explore other parameters related to standardization and quality control.

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