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Ranjeet Bargode, Alok Sharma, S C Mahajan

Mahakal Institute of Pharmaceutical Studies, Ujjain, (M.P.) India

Rakesh Kashyap

Ex-Assistant Professor (Guest) DOPS, Dr. Hari Singh Gour University (A Central University), Sagar M.P.

Karunakar Shukla

Royal Institute of Management and Advanced Studies, Ratlam (M.P.) India

Correspondence

Ranjeet Bargode

Mahakal Institute of Pharmaceutical Studies, Ujjain, (M.P.) India

E mail: rocky24kashyap@gmail.com

Standardization of *Rajahpravartini vati*: A Poly-herbal Formulation

Ranjeet Bargode, Rakesh Kashyap, Alok Sharma, Karunakar Shukla, S C Mahajan

ABSTRACT

Ayurveda is an ancient science of life, based on its unique principles of health and diseases. Ayurvedic formulations are safe but adulteration and substitution reduce the quality so the therapeutic efficacy of the formulation also decreases, hence standardization is essential. Standardization is a process through which the quality, safety and efficacy of the formulation is recognized. *Rajahpravartini vati* is an official ayurvedic formulation for dysmenorrhoea. Standardization of *Rajahpravartini vati* was performed to develop the standard set of parameters to maintain the uniformity and quality production of formulation.

Keywords – Ayurveda, ayurvedic formulation, standardization, *Rajahpravartini vati*

1. INTRODUCTION

Ayurveda is an ancient science of life based on its unique principles of health and diseases. Ayurveda the word made up of two words, first one is 'Ayu' which means 'life' while the other one is 'veda' which means 'knowledge', hence the basic meaning of ayurveda is the 'knowledge of life'.¹ Ayurveda has variety of dosage forms, depending on physical properties they can be classified in to solid (churna, vati, bhasma), liquid (swarasa, arka, sneha) and semisolids (kalka, avaleha, lepa).²

The vati or gutica is the forms of tablet or pills which are made up of one or more drugs obtained from plant, animal or mineral origin. *Rajahpravartini vati* is an ayurvedic formulation used in treatment of primary and secondary amenorrhoea, scanty bleeding and dysmenorrhoea.³⁻⁴

The formulation was standardized to prepare a set of parameters for uniform and quality production of formulation. According to WHO, standardization is the quality control of herbal drugs. Standardization includes set of parameters like characteristics, constant parameters, quantitative and qualitative values. It is needed to check the quality, purity, efficacy and safety of drug(s).⁵

Rajahpravartini vati is composed of *Aloe vera* (musabbar), *Ferula foetida* (hing), Kasisa (ferrous sulphate) and tankana (borax powder).³ Musabbar is the traditional medicinal plant obtained from *Aloe vera* Linn. (Liliaceae). *Aloe vera* is used for its medicinal and nutraceutical value. It is good source of vitamins. It has detoxifier, antiseptic, immune-boosting and anti-viral properties. It is used as health tonic.⁶⁻⁷ The hing (oleo gumresin) is obtained after deep incision made in the roots and rhizomes of the *Ferula foetida* Regel (Umbelliferae). *Ferula foetida* has anticoagulant, antifertility, antifungal, antihepatotoxic, anti-inflammatory, antioxidant, antiparasitic, smooth muscle relaxant properties.^{6,8}

Ferrous sulphate is source of iron supplement, contains 20% elemental iron commonly used for tablet preparation.⁹ Borax is a source of boron and chemically it is salt of weak boric acid. It has antifungal, antiviral and antiseptic properties. Boron is essential for regulation of absorption, metabolism of calcium, magnesium and phosphorus, and for proper functioning of joints.¹⁰

Dysmenorrhoea word is composed of Greek words 'Dys' (painful, difficult or abnormal), 'mens' (month) and rrhoea (flow). Dysmanorrhoea is defined as painful menstruation in women. It is not a serious problem, it is gynaecological condition of adolescence coupled with abdominal cramps, backache, nausea and vomiting etc. Pathophysiology of dysmenorrhoea elucidated that primary dymenorrhoea is related to abnormal ratio of PGF₂ alpha:PGE₂. PGF₂ alpha causes myometrial hypertonus and vasoconstriction, which in turn produces ischemia and pain¹¹⁻¹².

2. MATERIALS AND METHODS

2.1 Collection, identification and authentication of raw materials

The aloe (voucher no - MIPS/A/28/2013) and hing (voucher no - MIPS/H/29/2013) were purchased from the local market of Ujjain and they were identified and authenticated from the botany department of Vikram University, Ujjain (M.P.).

Marketed formulation of the Rajahpravartini vati was purchased from Mahakal Ayurveda Sansthan, Ujjain.

2.2 Purification of Tankana (Borax)

Fine powder of tankana was prepared in khalwa and transferred to earthen pot (sharava) then heated first on mandagni followed by tivragni till white puffy light tankana obtained. The purification of tankana was performed for three times¹³.

2.3 Method of preparation of vati

The Rajahpravartini vati was prepared according to Ayurvedic Formulary of India (Table 1).³

2.4 Evaluation of vati

2.4.1 Organolaptic evaluation

The organoleptic evaluation of both vati was performed for the colour, odour, taste, and texture¹⁴⁻¹⁶ (Table 2).

2.4.2 Physicochemical evaluation

Physicochemical evaluation of laboratory prepared and marketed formulation of Rajahpravartini vati was performed according to the World Health Organization (WHO) for the ash

values, extractive values, foaming index, swelling index and loss on drying contents and according to Pharmacopoeia of India for weight variation, hardness, friability and disintegration^{14-15, 17} (Table 3).

2.5 Heavy metal analysis

Heavy metal analysis of laboratory prepared and marketed formulation of Rajahpravartini vati was carried out from M.P. Laghu Udyog Nigam Limited, Indore. Heavy metals were analysed by calibration method. The samples were prepared using wet digestion method and subjected to further analysis through atomic absorption spectroscopy. An atomic absorption spectrophotometer consists of a light source, an atomic generator, a monochromator and a detector system¹⁶ (Table 4).

3. RESULTS AND DISCUSSION

Standardization is performed to evaluate the quality, safety and efficacy of the individual drug(s), herb(s) or formulations. The ayurvedic formulation, Rajahpravartini vati was prepared in laboratory according to Ayurvedic Formulary of India and marketed formulation of Rajahpravartini vati was purchased from the market and standardized according to WHO guideline, Protocol for testing ayurvedic, siddha and unani system of medicine and Indian Pharmacopoeia.

Both the laboratory prepared Rajahpravartini vati (LPRV) and marketed formulation of Rajahpravartini vati (MFRV) were evaluated for organoleptic properties. Both formulations were brownish black in colour, have characteristic odour, rounded shape, smooth surface and bitter in taste.

The ash value gives the indication for the presence of sand or silica. The total ash was found to be 9.40±0.45 for laboratory prepared Rajahpravartini vati (LPRV) and 8.90±0.47 for marketed formulation of Rajahpravartini vati (MFRV). The acid insoluble ash and water soluble ash for laboratory prepared Rajahpravartini vati (LPRV) was found to be 2.89±0.10 and 7.90±0.56 respectively while for marketed formulation of Rajahpravartini vati (MFRV), it was found to be 2.51±0.10 and 6.20±0.37 respectively.

The extractive value gives the indication for the presence of active constituents. The water soluble and alcohol soluble extractive values were found to be 6.6±0.56 & 4.6±2.32 for laboratory prepared Rajahpravartini vati (LPRV) respectively while 5.30±0.20 & 3.50±0.30 for marketed formulation of Rajahpravartini vati (MFRV) respectively.

Table No. 1: Formulation composition of Rajahpravartini vati

S. No.	Ingredients	Local name	Part used	Quantity
1	<i>Aloe vera</i>	Musabbar	Leaf	1
2	<i>Ferula foetida</i>	Hing	Root (Exudates)	1
3	Kasisa suddha	Ferrous sulfate powder	-	1
4	Tankana- suddha	Borax powder	-	1
5	Kanya svarasa	Aloe vera juice	Leaf extract	QS for mardana

QS= Quantity sufficient

Table No. 2: Organolaptic properties of Rajahpravartini vati

S. No.	Particulars	LPRV	MFRV
1	Colour	Brownish black	Brownish black
2	Odour	Charecterstic	Charecterstic
3	Taste	Bitter	Bitter
4	Shape	Round	Round
5	Surface	Smooth	Smooth

LPRV = Laboratory Prepared Rajahpravartinin Vati

MFRV = Marketed Formulation of Rajahpravartini Vati

Table No. 3: Physicochemical properties

S. No.	Parameters	LPRV	MFRV
1	Total ash (% w/w)	9.40±0.45	8.90±0.47
2	Acid insoluble ash (% w/w)	2.89±0.10	2.51±0.10
3	Water soluble ash (% w/w)	7.90±0.56	6.20±0.37
4	Alcohol soluble extractive value (% w/w)	4.6±2.32	3.50±0.30
5	Water soluble extractive value (% w/w)	6.6±0.56	5.30±0.20
6	Loss on drying (% w/w)	9.8±0.88	8.80±0.76
7	Swelling Index	00	00
8	Foaming Index	<100	<100
9	Hardness (Kg /cm)	2.8±0.30	3.5±0.30
10	Friability (gm)	0.82±0.07	0.62±0.19
11	Disintegration (Min)	27±1.60	24.33±1.52
12	Weight variation (gm)	4.7±0.56	4.5±0.30

The values are Mean ± Standard deviation

LPRV = Laboratory Prepared Rajahpravartinin Vati

MFRV = Marketed Formulation of Rajahpravartini Vati

Table No. 4: Heavy metal analysis of formulations

S. No.	Heavy metal	Prescribed limit (ppm)	Observed limit in LPRV (ppm)	Observed limit in MFRV (ppm)
1	Arsenic	3	ND	ND
2	Cadmium	0.03	ND	ND
3	Lead	10	ND	ND
4	Mercury	1	ND	ND

ppm = Parts per million, ND = Not detected

LPRV = Laboratory Prepared Rajahpravartinin Vati

MFRV = Marketed Formulation of Rajahpravartini Vati

The loss on drying is performed to determine the moisture content. The loss on drying value was found to be 9.8 ± 0.88 for laboratory prepared Rajahpravartini vati (LPRV) and 8.80 ± 0.76 for marketed formulation of Rajahpravartini vati (MFRV). The swelling index was found nil and foaming index was found < 100 in both formulations.

The weight variation, hardness, friability and disintegration time was 4.7 ± 0.56 , $2.8 \pm 0.30 \text{ kg/cm}^2$, 0.82 ± 0.07 and 27 ± 1.60 respectively for laboratory prepared Rajahpravartini vati (LPRV) and 4.5 ± 0.30 , 3.5 ± 0.30 , 0.62 ± 0.19 and 24.33 ± 1.52 respectively for marketed formulation of Rajahpravartini vati (MFRV).

4. CONCLUSION

The Rajahpravartini vati is an ayurvedic preparation especially for dysmenorrhoea was formulated in laboratory and standardized against marketed formulation of Rajahpravartini vati. Standardization was performed for organoleptic properties, physicochemical properties as per standard books recommended by Government of India. The standard parameters were recognized and also the results showed that ingredients used for formulation was found to be of good quality.

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