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Research Article

PHARMACEUTICAL STANDARDIZATION OF *RAKTAPACHAK VATI* (TABLET) – A POLYHERBAL FORMULATION

Vijay G. Pawar[1]*, Vinod M. Ramteke[2], Sarang Deshpande[3], Kishor Gadkari[4], Tarun Pable[4]

*[1]M.D.(Ayu) Scholar, [2]Associate Professor, Shri Ayurved Mahavidyalaya, Nagpur, Maharashtra, India.

[3]Production Manager, Unijules Life Sciences Limited, Kalmeshwar, Nagpur, Maharashtra, India.

[4]Unijules Life Sciences Limited, Kalmeshwar, Nagpur, Maharashtra, India.

ABSTRACT

In Ancient Ayurvedic texts, there are many formulation, some of them are herbal, mineral and herbo-mineral in origin. These formulations are effective in many diseases depending upon their qualities and properties. In *Charak Samhita*, *Uttarsthana*, *Acharya Charak* mentioned *Pachak Yoga* in the Treatment of *Vishamjwara*. *Raktapachak yoga* which is useful in the treatment of *Raktagat jwar* (*Satat jwar*). Many of the Ayurvedic practitioners prescribe *Raktapachak Yoga* in various dosage forms like *Kashaya* (Decoction), *Churna* (Powder) etc as per their convenience. Dosage form for administration plays an important role in the packaging, action and delivery of the particular drug on a specific system. Tablets are easy to prepare, packaging, transportation and administration to the patients Hence tablet form is the most accepted dosage form amongst all. This formulation is transformed to the tablet form by using modern equipments and analytical techniques. An effort is made to validate the pharmaceutical and analytical procedures to maintain the quality of product and to avoid batch to batch variation. Pharmacopoeial standards are set for this Ayurvedic formulation in tablet form. All the three samples were prepared by this method shows identical characteristics and analytical parameters do not show much significant difference. The set parameters may be used for the further pharmaceutical preparations.

KEYWORDS: *Charak Samhita, Pachak Yoga, Raktpachak vati* (Tablet), Pharmaceutical standardization, Dosage form.

INTRODUCTION

Five *Pachak Yoga* mentioned in treatment of '*Vishamjwara*' in *Jwara Chikitsa Adhyaya*, they are *Rasapachak*, *Raktpachak*[(1)], *Manspachak*, *Medopachak* and *Astimajjapachak*. Excessive consumption of *Amla* and *Lavan ras* (like Junk food, fast food, vinegar containing substances etc.), also excessive oily, spicy, more liquid diet and working in hot area or near furnace causes *Raktavah Strotas Dusti*.

WHO have stated that 80% of total population are using herbs and other traditional medicines as their primary health care needs. 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 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. So efforts are made to transformed the *Raktapachack yoga* into tablet form.

In original reference *Raktapachak kalp* is nowhere mentioned as in *Vati* (Tablet) form. Here for proper administration of dosage and to avoid its bitter taste the *kalpa* modulated in *Vati*[(2, 3)] (Tablet) form. One of the major problems faced by the *Ayurveda* physicians is the unavailability of unique pharmaceutical and analytical validation for herbal medicines and their formulations. Also department of AYUSH, Government of India is now working on development of standard operating procedures for the manufacturing process of *Ayurvedic* preparation to avoid batch to batch variations. 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. The ingredients and *Bhavana Dravya* used were same as described in original reference. Standardisation of *Raktapachak* in its *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.

MATERIALS AND METHODS

Raktpachak yoga contains total 5 ingredients viz *Patol*, *Sariva*, *Musta*, *Patha*, *Kutki*. The details of parts and quantity used are given below in table no.1.

All the ingredients for this *Kalpa* were collected from local authentic market and identified and authenticated at the Quality control laboratory of Unijules life Sciences Ltd., Kalmeshwar, Nagpur , Maharashtra. All these herbal ingredients passed quality parameters described in API.

Sr. No.	Sanskrit Name	Latin Name	Parts Used	Quantity for batch size 2kg
1	*Patol*	*Trichosanthes dioica*	Leaves	400 gm
2	*Sariva*	*Hemidesmus indicus*	Roots	400 gm
3	*Musta*	*Cyprus rotendus*	Rhizomes	400 gm
4	*Patha*	*Cissampelos pareira*	Root	400 gm
5	*Kutki*	*Picrorhiza kurroa*	Stem bark	400 gm

Pharmaceutical procedure

All the ingredients mentioned in above table were mixed together in equal quantity of 400 gm each. It was then processed in mass pulveriser and sifted in mass sifter using sieve no. 80 to obtain fine power from it. The obtained mass was uniformly mixed in mass mixture and triturated in end runner for three prahar (9 hr approx) with the decoction made of the same ingredients which are mentioned above. After trituration it was dried in electric hair dryer at temperature not more than 60^0C. The excipients were added in dried mass in the quantity of MCC 160 gm, Starch 240 gm, SMHB 4gm and SPHB 0.4 gm. Than the mass was passed through multimill with sieve no. 2 and granules were prepared. After that tableting was done using tableting machine each of size 250 mg. About 7400 to 7600 tablets were obtained from each batch.

OBSERVATION AND RESULTS

Classical parameters

The tablets of three samples of *Raktpachak Vati* were examined using classical parameters like *Shabda* (Sound), *Sparsha* (Touch), *Rupa* (Appearance), *Rasa* (Taste), *Gandha* (Odour). All three samples were within compliance of classical parameters mentioned in the *Ayurvedic* texts and also in API.

Table 2: Showing Classical parameters for *Raktpachak vati* (tablet)

Sr	Test Name	Sample A	Sample B	Sample C
1	*Shabda* (Sound)	*Madhyam*	*Madhyam*	*Madhyam*
2	*Sparsh* (Touch)	Soft in touch	Soft in touch	Soft in touch
3	*Rupa* (Appearance)	Brown	Blackish brown	Brown
4	*Rasa* (Taste)	Bitter	Bitter	Bitter
5	*Gandha* (Odour)	Pleasant sweet smell	Sweet smelled smell	Pleasant sweet smell

Physico- chemical analysis

To assess the analytical profile all three samples of finished products were checked using relevant modern parameters viz., Colour, Uniformity in weight, Diameter, Hardness, Friability, Disintegration time, HPTLC chromatogram etc. Obtained results are tabulated in following table no.3.

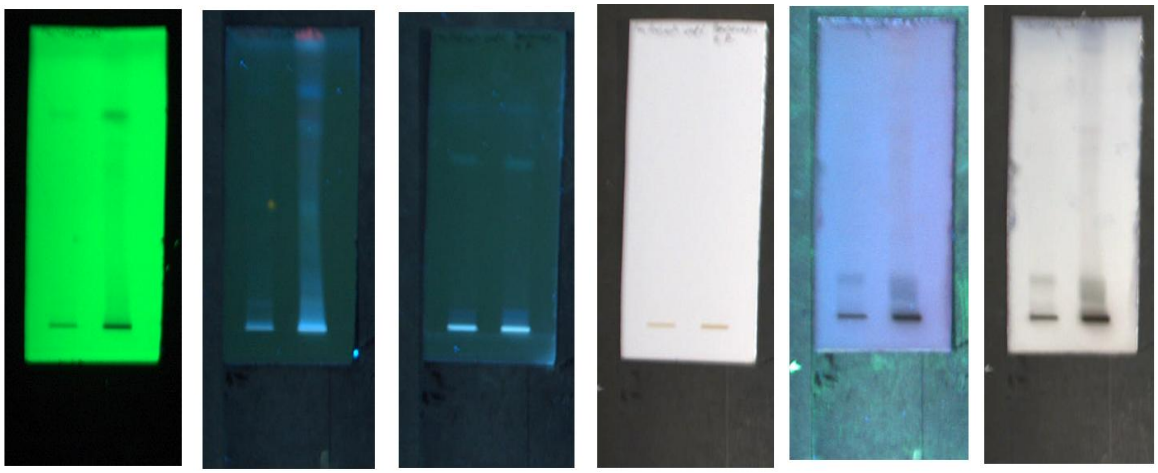
Table 3: showing comparative Physico-chemical values of all three samples

Sr. No.	Test Name	Sample A	Sample B	Sample C	Mean SD ±
1	Colour	Brown coloured	Blackish Brown	Brown	Complies
2	Average Weight	0.2540 gm	0.2495gm	0.2570gm	0.003
3	Uniformity in Weight[7]	Not >5%	Not >5%	Not >5%	Not >5%
4	Diameter	8.18 mm	8.09mm	8.17mm	0.049
5	Thickness	3.59 mm	3.55mm	3.63mm	0.05
6	Hardness[4]	1.50Kg/cm^2	1.54kg/cm^2	1.49kg/cm^2	0.026
7	Friability[5]	0.02%w/w	0.018%w/w	0.15%w/w	0.075
8	Disintegration[6]	12 min	11 min	14 min	1.527
9	HPTLC Spots Obs	9	10	8	Complies
	Spots	0.02, 0.11, 0.15, 0.20, 0.34, 0.37, 0.47, 0.59, 0.68	0.02, 0.11, 0.15, 0.20, 0.34, 0.37, 0.47, 0.59, 0.68, 0.70	0.02, 0.11, 0.15, 0.20, 0.34, 0.37, 0.47, 0.59	Complies

All three sample batches of this formulation were underwent HPTLC study for fingerprinting and Spots were observed[8].

Extract 5 gm of formulation powder was performed by using Ethyl acetate, Methanol: Water in 6:1.4:1 ratio and Petroleum benzene and ethyl acetate in 3:1 ratio as mobile phase. 10 µl layer was applied on HPTLC plate and the plate was developed to a distance of 8 cm using Ethyl acetate, Methanol: Water in 6:1.4:1 ratio and Petroleum Benzene & Ethyl acetate in 3:1 ratio as mobile phase. After development the plate was allowed to dry in air and examine under ultraviolet light (254 nm). It shows major spots as given in above table n o.3. The observed wavelengths under 280nm.

HPTLC plates under different wavelengths



Wavelengths- 254 nm, 366nm, 366 nm, white R, 254 nm, white R respectively

DISCUSSION

Dosage form is most important in any sort of formulation. Amongst all dosage form tablet is widely used dosage form. Tablets have more advantages over other dosage form as exact dose can be delivered to the patient, easy for administration, palatable, easy to transport and packaging. Pharmaceutical and Analytical validation of *Raktapachak Vati* (Tablet) become possible by strictly following every step in proper way and by modern physico-chemical analysis of finished product. It was also inferred that appropriate processing sequence was strictly followed and changes were noted after each step from pulverization of raw material to packaging of finished product. Weight was noted after each pharmaceutical process to moniter processing loss. Average 5-8% weight loss was observed in pharmaceutical process. Finished product was examined both on classical as well as Modern Physico-chemical parameters to check batch to batch variations and consistency.

In all three sample batches the quality control parameters for this drug does not show significant difference in their values. The analytical parameters for *Raktapachak Vati* (Tablet) Tablet which is prepared by the above said method may be set as per following table.

Table 4: Showing set parameters for *Raktapachak Vati*

Sr.	Test Name	Parameters
1	Colour	Brown
2	Average Weight	0.262.5 to 0.237.5 gm
3	Uniformity of weight	Complies
4	Diameter	8 mm to 8.2 mm
5	Thickness	3.5mm to 3.7mm
6	Hardness	1.5 Kg/cm^2 to 2.5 Kg/cm^2
7	Friability	NMT 1%
8	Disintegration time	NMT 30 min

As a part of standardization process and to check batch to batch consistency fingerprint of HPTLC were obtained for three consecutive batches. The occurrence of same no. of spots and fingerprinting structure on HPTLC plates confirms the consistency of finished product. Such a stipulation for obtaining HPTLC including number of spots and corresponding Rf values gives the guidelines for preparation of *Raktapachak Vati* (Tablet). Hence all the three samples of *Raktapachak Vati* does not show significant difference.

CONCLUSION

The pharmaceutical and analytical process validation of *Ayurvedic* formulation *Raktapachak Vati* (Tablet) has been validated by using modern scientific Physico-chemical parameters and *Ayurvedic* parameters. Thus the validated method can be used to lay down Pharmacopoeial standards for the preparation of *Raktapachak Vati* (Tablet) by which we get an optimal efficacy of the finished product. Hence we can say that the pharmaceutical and Analytical parameters for *Raktapachak Vati* (Tablet) are validated by above said method is standard one and will not show batch to batch variation and has optimum efficacy.

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***Address for correspondence**
Dr. Vijay G.Pawar
M.D. (Ayu) Scholar
Department of Rasashastra & Bhaishajya Kalpana, Shree Ayurved Mahavidyalaya, Nagpur.
Email: vd.vijay007@gmail.com
Mob: 09404356494