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# PHARMACEUTICAL AND ANALYTICAL STANDARDIZATION OF RASAPACHAK VATI (TABLET)

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**ABSTRACT :**

In Ancient *Ayurvedic* texts, many formulations are mentioned that are effective differently on different diseases depending upon the properties and qualities of the constituents may be of plant, mineral or herbal origin. Medicines prepared using traditional method may not have the desired quality, batch to batch consistency. Hence, there is a need of standardization of these raw materials used and its standard operating procedures as per scientific parameters in today's era to prevent use of spurious drugs and increase the standard of the final product. *Charakacharya* have mentioned Rasa*pachak Yoga* in *Jwarachikitsa adhayay* of *Charak Samhita* for all the *dhatugat jwar*, wherein *Rasapachak yoga* for the *treatment* of *Rasagat Jwar* i.e. *Santat jwar(~* continuous fever). Ayurveda physicians prescribe this Yoga in kwatha, churna, etc. forms as per the convenience which results in dose variation and affect the efficacy of the medicine. Hereby, to avoid batch to batch variation, changes in its friability, disintegration time, etc. and to increase the dose accuracy and palatability, an effort has been made to standardize the raw materials and the dosage form of the final product has been changed to tablet form. As no significant information regarding standardization of this yoga is available, this study can be referred for further pharmaceutical processes.

**Keywords:** *Jwarchikitsa*, Charak samhita, *Dhatugatjwara*, *Rasapachak vati*, HPTLC.

**INTRODUCTION:** According to an estimate of the World Health Organization (WHO), about 80% of the world population still uses herbs and other traditional medicines for their primary health care needs. Herbal formulations have reached widespread acceptability as therapeutic agents for arthritis, diabetes, liver diseases, cough remedies, memory enhancers and adaptogens.[2] As per WHO's definition, there are three kinds of herbal medicines: raw plant material, processed plant material and medicinal herbal products. Herbal drugs are the finished labeled products that contain active ingredients such as aerial or underground plants or other plant material or combination thereof, whether in the crude state or as plant preparations. Herbals are traditionally considered harmless and increasingly being consumed by people without prescription. However, some can cause health problems, some are not effective and some may interact with other drugs. Standardization of herbal formulations and *Rasaushadhis* is essential in order to assess the quality of drugs, based on the concentration of their active principles.[3]

In day to day practice includes Junk fried fast food; too salty or added with tastemaker like ready food or Chinese food, excess use of Vinegar like preservatives, Tin packed/ salted food in which already many preservatives of *amla*

*lavana prayoga rasa* are present. It does *rasa raktadushti*. On the other hand too sweet, excessive or over eating, over starvation, fashion covering fasting or dieting, weight gain drugs, does *rasa dushti* through *kledabhuyishta*. Also uncounted stress of work responsibility, carrier expectations, competitions, unsatisfactory evaluation of life, marital disharmony, monetary over expectations are hidden/uncalculative factors also works for *rasa dushti*. It does *prana* and *vyanadushti*, disturbs higher centre and disturbs *dhatuvyuhana*. In other words, it destroys normalcy of rasa through *rasagnimandya*.

**Standardization:** Standardization of *Ayurvedic* formulations is an important step for establishment of biological activity, consistent chemical profile, or quality assurance for production and manufacturing of herbal drugs. Most of the industries are using substitute drugs instead of authentic drugs. Hence, standardization tests help in authenticating the polyherbal preparations and also in ensuring the quality of the same.

*Ayurveda* physicians use *pachak yoga* in *churna*, *kwath* or some other form for prescription. In such cases there may be a variation in the dose taken affecting the efficacy of the medicine. Hence, to standardize the dose the dosage form of this *vati* is changed to tablets that keeps the dose constant, makes the medicine convenient for manufacture and transport and also increases its shelf life.

## PROPERTIES OF INGREDIENTS:

**TABLE 1: Contents of the drug are**

| **Characteristics** | *Patol* | *Indrajav*[5] | *Kutki*[6] |
|---|---|---|---|
| **Latin Name** | *Trichosanthes Dioca or Pointed Gourd* | *Holarrhena Antidysentrica/ Wrightia Tintoria R. Br.* | *Picrorhiza kurroa* |
| **Chemical Composition** | Vitamin A, Vitamin C, Tannins and Saponin. | Seeds yield 30.5% fixed oil, Indicant is found in barks and seeds. | D-Mannitol, Kutkiol, Kutkisterol, Apocyanin: phenol glucosides; androsim & picein iridoid glycosides; kutkin, Picriside I, II, III; Kutkoside, Minecoside, Picrorhizin, Arvenin III, etc. |
| **Effects on *Doshas*** | Pacifies all three *doshas* | Balances *kapha* and *pitta* | Balances *kapha* and *pitta* |
| **Properties** | *Rasa- Tikta* (Bitter) *Guna-Laghu, Ruksha* (Light, Dry) *Veerya- Ushna* (Hot) *Vipaka- Katu* (Pungent) | *Rasa – tikta* (bitter), *kashaya* (Astringent) *Guna – laghu* (lightness), *rooksha* (dryness) *Veerya- sheeta* –cold potency Vipaka – Katu | *Rasa- Tikta* (Bitter) *Vipaka – Katu* (pungent) *Guna-Ruksa, Laghu* (Light to digest) *Veerya-Sheeta* (Cold potency) |
| **Medicinal Uses** | Soft laxative, detoxifies body, cleanses the blood, | Bark valued as tonic and seeds are considered | Useful in bleeding disorders viz. menorrhagia, nasal |

| | | | |
|---|---|---|---|
| | help in maintaining healthy cholesterol limits and calms down the restless mind, Recommended in liver disorders. Benefits digestive system and skin. | aphrodisiac. Bark is also useful in dysentery, seeds are used in fever, dysentery, diarrhea, intestinal worms and piles. | bleeding, etc.; relieves burning sensation, useful in anorexia, in chronic recurrent fever; piercing, causes purgation, improves digestion and metabolism; good for heart; useful in *kapha pittaj jwara*, useful in weight loss treatment |

## MATERIALS AND METHODS:

### Drug preparation & Standardization:

All the ingredients of the drug were collected from genuine source, were identified and authenticated at the Quality control laboratory.

### OBJECTIVES:

- To standardize the pharmaceutical process of *Rasapachak Vati.*
- To transform this formulation into tablet form.
- To analyze the finished product on *Ayurvedic* as well as modern parameters.

### PARAMETERS USED:

- Uniformity of weight.
- Diameter of tablets
- Thickness of tablet
- Hardness
- Friability
- Disintegration time
- HPTLC

**TABLE 2: showing ingredients of Rasapachak yoga tablet**

| **Product Name** | | | Rasapachak Vati 250mg |
|---|---|---|---|
| **Reference** | | | Charak Samhita 3/200 |
| **Composition** | | | |
| **Sr.No.** | **Raw Material** | **Part Used** | **Quantity(in gms)each tab** |
| 1 | *Patol* | Leaf | 83.325 |
| 2. | *Indrajav* | Seed | 83.325 |
| 3. | *Kutki* | Rhizome | 83.325 |
| | ***Bhavana*** | | |
| | *Patol* | | 7.5 |
| | *Indrajav* | | 7.5 |
| | *Kutki* | | 7.5 |
| | **Excipients** | | |
| | Starch | | 20 |
| | M.C.C. | | 30 |
| | SMHB | | 0.5 |
| | SPHB | | 0.05 |

Standardization of all raw materials were done as per the parameters described in API were found to be within compliance. Tablets of 250mg of RPY were prepared according to reference given in *Charaka Samhita Jwaradhikar*.[1] According to GMP norms mentioned in Drugs and Cosmetics Act 1940 & Rules 1945, tablets were tested for its quality assurance for Hardness, Disintegration time, etc. done at Quality Control Laboratory, Unjiles Life Sciences Limited, Nagpur.A total 3 batches each of 2 kg were manufactured and tested for its physico-chemical parameters.

**PHARMACEUTICAL PROCEDURE:**

All the 3 ingredients were taken in equal quantity i.e. 667gms each. All raw materials were cleaned and physical impurities were removed from them. They were then mixed together and pulverized in mass pulverizer and then sifted in mass sifter using sieve no.80. Obtained powder was then mixed uniformly in mass mixer. To enhance the potency of these drugs *bhavana* of the decoction of the same ingredients were given for 3 *prahar* (9 hours). Obtained material was dried in electric air drier at temperature not more than 60$^{o}$C. Excipients were added in the mixture for proper binding of tablet in a suitable stainless steel vessel in proportion of MCC as 240gms, starch as 160gms, SMHB as 4gm and SPHB as 0.4gms and it was homogenously mixed. Granules were prepared by passing this mixture through mass miller using sieve no.2. Tablets of about 250mg each were prepared in automated tablet pressing machine. About 7,900 to 8,200 tablets were obtained from each batch A.B, and C.

Weight after each pharmaceutical step was noted to observe the processing loss.

**OBSERVATIONS AND RESULT:**

**Physico-chemical analysis:** Physico-chemical analysis was done at the quality control lab. of Unijules Life Sciences Ltd.

| TEST | SAMPLE A | SAMPLE B | SAMPLE C |
|---|---|---|---|
| Description | Brown colored circular, compressed, flat, uncoated tablets | Brown colored circular, compressed, flat, uncoated tablets | Brown colored circular, compressed, flat, uncoated tablets |
| Average Wt. | 0.254g | 0.252g | 0.254g |
| Uniformity of wt. | Not >5% | Not >5% | Not >5% |
| Diameter | 8.18mm | 8.18mm | 8.16mm |
| Thickness | 3.59mm | 3.58mm | 3.59mm |
| Hardness | 1.50Kg/sq.cm | 1.50Kg/sq.cm | 1.50Kg/sq.cm |
| Friability | 0.02%w/w | 0.02%w/w | 0.02%w/w |
| Disintegration time | 10 to 12 min. | 10 to 12 min | 10-12 min |
| H.P.T.L.C. | Complies | Complies | Complies |
| H.P.T.L.C. spots observed | 0.01,0.03,0.07,0.10,0.20, 0.26,0.48,0.62,0.68,0.77 | 0.01,0.04,0.08,0.11,0.17, 0.27,0.34,0.65,0.70 | 0.01,0.04,0.07,0.11,0.21, 0.20,0.62,0.69,0.75 |

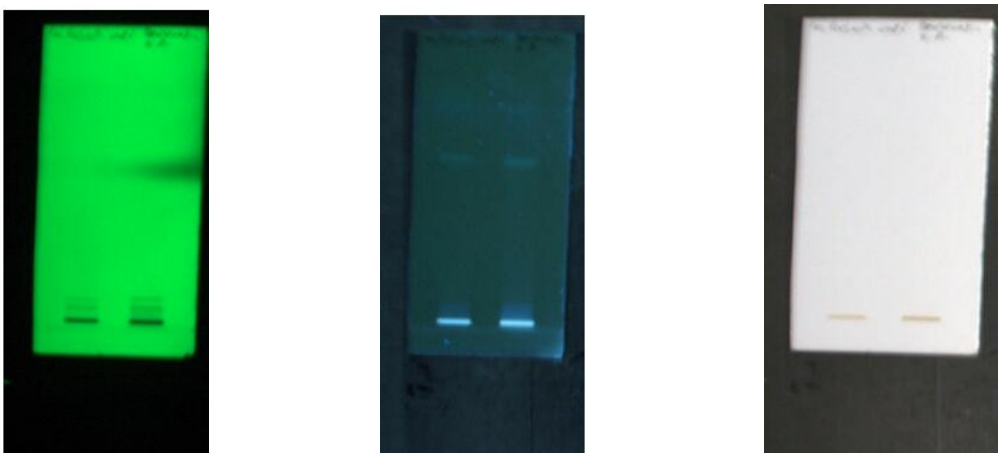
The principle spot in chromatogram obtained with test solution should correspond to that in the chromatogram obtained with reference solution.

**Remark:** The above sample complies as per reference to IHS

**Opinion:** In the opinion of the undersigned, the sample referred to above is of standard/not of standard quality as per the specification No. F0499-S

**HPTLC of Rasa Pachak Vati:**

All the three sample batches were subjected to HPTLC study. Spots were observed. Extract 5g of formulation powder by using Ethyl acetate: Methanol: Water in 6:1.4:1 proportion and Petroleum Benzene: Ethyl acetate in 3:1 proportion were used to carry out the thin-layer chromatography. 10µl layer was applied on TLC plate and the plate was developed to a distance of 8cm using Petroleum Benzene & Ethyl acetate in 3:1 proportion as mobile phase. After development the plate allowed to dry in air and examined under Ultraviolet light (254nm, 366nm).



**Images of HPTLC at different wavelength at different wavelength at 254nm, 366nm and White R respectively**

**DISCUSSION**: Standardization of a drug confirms the bioavailability and stability of the particular formulation which is achieved through different ayurvedic as well as modern formulations. Standardization of RPT is achieved through the modern techniques like Disintegration time, friability of tablets and HPTLC, etc. The ingredients used in Rasa Pachak tablets are the same which are mentioned in Charak Samhita. In order to increase the potency of these tablets bhavana with the kwath of same ingredients was given while manufacturing. The process for preparation of tablet from pulverization of raw materials to the preparation of tablets was strictly followed as per the GMP norms. The changes in each pharmaceutical step were keenly observed and noted. HPTLC spots and RF values obtained of all the three samples are nearly similar. Hence, it can be concluded that the three batches prepared are nearly similar to each other which means the operating and manufacturing process is similar and could be standardized.

RPT is found to be Blackish brown colored circular, compressed, flat, uncoated tablets, compressed, flat, uncoated tablets with hardness 1.50Kg/sq.cm, friability 0.02%w/w and HPTLC spot corresponds the chromatogram of reference solution. The D.T. observed was 10-12 minutes. Parameters can be set for the standard operating procedure of this tablet as per table below.

**TABLE 3:Showing set parameters for standardization of RPT**

| SR.NO. | TEST | SET PARAMETERS |
|---|---|---|
| 1. | Description | Blackish brown colored, compressed, circular, uncoated tablets. |
| 2 | Average Wt. | 0.23 to 0.27 g |
| 3 | Uniformity of wt. | 0.23 to 0.27 g |
| 4 | Diameter | 8 to 9 mm |
| 5. | Thickness | 3 to 5 mm |
| 6. | Hardness | 1 to 4 Kg/sq.cm |
| 7. | Friability | NMT 1%w/w |
| 8. | Disintegration time | NMT 30 minutes |

**CONCLUSION**: Standardization tests performed for Rasapachak tablet were done as per the Drugs and Cosmetics act 1940 & Rules 1945. There are no significant variations observed in all the three batches prepared. The above study reveals *Rasa Pachak* tablets prepared by the above mentioned method meets the quality parameters. As there is no standard data published anywhere for this

formulation, a comparison is not possible and the current observations in this study may be referred in for the future study.

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