

Pharmaceutical and analytical standardization of
“*Asthimajja Pachak Vati*”
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Abstract:

In ancient *Ayurvedic* classics, many formulations are there like herbal, mineral and herbomineral in origin. These formulations are effective in many diseases depending upon their qualities and properties. In this study, we are dealing with *Asthimajjapachak vati* which is herbal preparation.

In *Charak Samhita*, *Uttarsthana*, *Aacharya Charak* mentioned *Pachak Yoga* in the treatment of *Vishamjwara*. “*Asthimajjapachak yoga*” which is useful in the Treatment of *Asthimajjagatjwar*. Many of the *Ayurvedic* paractitioners prescribe *Asthimajjapachak yoga* in various dosage forms like *kashaya* (Decoction), *Churna* (Powder) as per their convenience. Dosage form for administration plays an important role in the reaction and delivery of particular drug on a specific system. Tablets are easy to prepare, packing, transportation and administration to patients. Hence

tablet form is the most accepted dosage form amongst all.

In this study, formulation of “*Asthimajjapachak Yoga*” 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.

Pharmacopeial standards are set for this *Ayurvedic* formulation in tablet form. All the 3 samples were prepared by this method show identical characteristics and analytical parameters do not show much significant difference. These set parameters may be used for the further pharmaceutical preparations.

Keywords: *Charak Samhita*, *Pachak Yoga*, *Asthimajjapachak Tablet* (AMPT), Pharmaceutical standard, Dosage form.

Introduction:

Five *Pachak Yoga* mentioned in Treatment of “*Vishamjwara*” in *Jwara Chikitsa Adhyaya*[1]. They are *RasaPachak*, *RaktaPachak*, *MansaPachak*, *MedoPachak* and *Asthimajja Pachak*.

Excessive exercise, excessive exertion, accidental injury, crushing of bones, excessive pressure on bones, *vaatvardhak* *aahar* *vihar*, *virruddhahar* in excessive quantity causes *AsthivahStrotodushti*[2].

WHO have stated that 80% of populations are using herbs and other traditional medicines as their primary healthcare needs. Due to increased demands of herbal medicines worldwide, it is responsibility to provide the quality of 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 dosage forms, tablet is widely used like syrup, powder, injectable. Tablets are easy to administer, delivers exact dose, more palatable, easy to transport, packaging. So *Asthimajjapachak Yoga* is transformed into tablet form.

AYUSH, Govt. of India, is now working on development of S.O.P. for the manufacturing of Ayurvedic preparation to avoid batch to batch variations. This can be achieved by evaluating and analyzing herbal products using both *Ayurvedic* as well as modern techniques of standardization during and after preparation of finished product.

In original reference, *Asthimajjapachak Yoga/Kalp* is nowhere mentioned as in *Vati* (Tablet) form. Here for proper

administration of dosage and to avoid its bitter taste, the *kalpa* is modulated in *Vati*[3] (Tablet) form. The ingredients and *Bhavana Dravya* used were same as described in original reference.

One of the major problems faced by the *Ayurveda* physician is the unavailability of unique pharmaceutical and analytical validation for herbal medicines and their formulations.

In this study, standardization of *Asthimajjapachak yoga* in its *vati*[4] (tablet) form is an important step.

For establishment of physiochemical profile, Pharmaceutical and Analytical validation of “given” herbal drug is done.

Materials and Methods:

Objectives of the study:

1. To standardize the pharmaceutical process of *Asthimajjapachak vati*.
2. To transform this formulation into tablet form.
3. To analyze the finished product on ayurvedic as well as modern parameters.

Asthimajjapachak Yoga contains total 3 ingredients viz. *Guduchi*, *Amalaki*, *Musta*. Decoction of all these drugs was used to give *Bhavana* in order to increase the potency of the drug.

All the ingredients for this *kalpa* were collected from local authentic market and identified and authenticated at the quality control laboratory by using facilities of Shree Bramhachaitanya Ayurved, Nagpur, Maharashtra. All these

herbal ingredients passed quality parameters described in API [5].

The details of parts and quantity used are given below in Table No. 1

Table No. 1: Contents of the drug

Sr. No.	Sanskrit Name	Latin Name	Parts Used	Quantity for batch size 1 kg
1	<i>Amalaki</i>	<i>Phyllanthus emblica</i>	Fruit	333 gm
2	<i>Guduchi</i>	<i>Tinospora cordifolia</i>	Stem, Root	333 gm
3	<i>Musta</i>	<i>Cyperus rotandus</i>	Stem, Root	333 gm

Pharmaceutical Procedure:

All the ingredients mentioned in above table were mixed together in equal quantity of 250 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 dryer at temperature not more than 60°C. The excipients were added in dried mass in the quantity of MCC 30 gm, Starch 50 gm. Then 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 3800 to 4000 tablets were obtained from each batch.

Observations and Results:

Physico- chemical analysis was done at quality control lab by using facilities of Shree Bramhachaitanya Ayurved, Nagpur, Maharashtra.

Table No. 2: Showing comparative physico- chemical study.

Sr. No.	Test Name	Sample A	Sample B	Sample C
1	Colour	Light Brown colored	Dark Brown	Brown
2	Average Weight	0.270 gm	0.248gm	0.255gm
3	Uniformity in Weight	Not >5%	Not >5%	Not >5%
4	Diameter	8.20 mm	8.18mm	7.90mm
5	Thickness	3.59 mm	3.64 mm	3.55 mm
6	Hardness[6]	2.50Kg/cm ²	2.54kg/cm ²	2.49kg/cm ²
7	Friability[7]	0.5% w/w	0.2% w/w	0.3% w/w
8	Disintegration[8]	11 min	12 min	14 min

Discussion:

Tablet is widely used dosage form. Exact dose can be delivered to the patient, easy for administration, palatable, easy to transport and packaging. This way tablets have more advantages over other dosage form.

Pharmaceutical and Analytical validation of *Asthimajjapachak* Tablet (AMPT) became possible by following every step in proper way and by modern Physico-chemical analysis of finished product.

Ingredients used in AMPT are the same as 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 appropriate processing sequence was strictly followed as per GMP norms and changes were noted after each step from pulverization of raw material to packaging of finished product. Finished product was examined by both classical as well as modern parameters to check batch to batch variations and consistency.

In all three sample batches quality control parameters for this drug doesn't show significant difference in their value which means the operating manufacturing process is similar and could be standardized. The analytical parameters for *Asthimajjapachak* (tablet) which is prepared by the above said method may be set for SOP of this tablet as per table below.

Table No. 3: Showing set parameters for *Asthimajjapachak* tablet

Sr.	Test Name	Parameters
1	Description	Light-dark Brown, circular compressed, biconvex uncoated tablet
2	Average Weight	0.240 to 0.280 gm
3	Uniformity of weight	Complies
4	Diameter	7.9 mm to 8.2 mm
5	Thickness	3.5mm to 3.7mm
6	Hardness	2.3 Kg/cm ² to 2.5 Kg/cm ²
7	Friability	NMT 1%
8	Disintegration	NMT 30min

Conclusion:

The pharmaceutical and analytical process standardization of *Ayurvedic* formulation *Asthimajjapachak vati* (tablet) has been validated by using both *Ayurvedic* as well as modern physiochemical parameters. The

validated method can be used for the preparation of *Asthimajjapachak vati* (tablet) by which we get an optimal efficacy of the finished product. There are no significant variations observed in all the three batches prepared. The above study reveals *Asthimajjapachak vati*

prepared by above method meets to the quality parameters. As there is no standard data published anywhere for this formulation, a comparison is not possible and current observations in this study may be referred for the future study.

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