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STANDARDIZATION AND QUALITY CONTROL PARAMETERS OF *SHILADHATRI* TABLET: AN *AYURVEDIC* PROPRIETARY HERBOMINERAL PREPARATION

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ABSTRACT

Herbo-mineral preparations have a comprehensive therapeutic value since decade and are still serving many of the health needs of a great population of India & worldwide. However, the quality control and quality assurance still remains a challenge because of the high variability of chemical components involved. These preparations contain numerous compounds in complex matrices in which no single active constituent is responsible for the overall efficacy. This creates a challenge in establishing quality control standards and standardization of finished products. Many preparations have been mentioned in classical books of *Ayurveda* for the treatment of Diabetes mellitus. *Shiladhatri* Tablet is one such known proprietary formulation. In this study, *Shiladhatri* Tablet was prepared & subjected to organoleptic analysis, physico-chemical analysis, and qualitative analysis to detect the presence of benzoic acid. Elemental analysis reveals that Potassium & Calcium are present in major quantity and percentage of Phosphorus & Iron is less in the formulation.

KEY-WORDS- *Shilajeet*, XRF, quality control, standardization, *Shiladhatri* Tablet

INTRODUCTION

Shilajeet [Black Bitumen] is an important herbo-mineral drug among the *Maharasa* (a classified group in *Ayurveda* containing 8 major minerals).[1] Describing its importance *Charaka* mentioned that there is hardly any curable disease which cannot be alleviated or cured with the aid of Shilajeet. [2] *Shilajeet* has been referred to as "Panacea", which means, 'a cure for all diseases'. *Shilajeet* is a herbo-mineral drug which oozes out from special types of mountains rocks in the peak summer months. [3] Pharmacological proportions of *Shilajeet* have been elaborately explained by *Acharya Charaka* in *Chikitsasthana*. [4] Further references of *Shilajeet* can be traced in *Sushruta Chikitsasthana*, [5] in *Astanga Sangraha sutra sthana* [6] and in *Sharangadhara Madhyamakhanda*. [7] It is a potent tonic and unconventionally useful in a variety of diseases. In sexual weakness it is generally administered with *Ashvagandha*. Dr. H. C. Sen concludes that Shilajeet should be tried extensively in Obesity, Diabetes, Dyspepsia, Anasarca, Enlargements of liver and spleen, Bleeding Piles, Asthma etc. Shilajeet has been reported to increase free radicals scavenging enzymes like superoxide dismutase, catalase and glutathion peroxide activities in rat brain striatum and frontal cortex. [8]

Many *Ayurvedic* and modern literatures are available regarding Shilajeet. "*Shiladhatri* Tablet" is an effective proprietary formulation used in the treatment of Diabetes which contains *Shilajeet* as major ingredient. All the contents of *Shiladhatri* Tablet have proved anti-diabetic property. Although *Shiladhatri* Tablet can be a drug of choice to control diabetes mellitus, the pharmaceutical standardization aspects are still untouched. Now a day to prove *Ayurveda* in India as well as internationally, there is very much needs to maintain standard quality of medicines. Being proprietary medicine the standards parameters are not mentioned in *Ayurvedic* pharmacopeia of India & *Ayurvedic* Formulary of India. So an attempt was made to standardize this novel preparation on basis of textual as well as pharmacopeial standards for Tablet formulation.

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AIM

To carry out standardization of *Shiladhatri* Tablet applying pharmaceutical tests and to develop Quality control parameters

MATERIALS

Procurement of Raw Materials

Raw *Shilajeet* (*Asphaltum* or *Black bitumen*), *Haritaki* (*T. chebula*), *Haridra* (*C. Longa*), *Amalaki* (*E. officinalis*), *Guduchi* (*T. cordifolia*), *Shatavari* (*A. recemosa*) & *Chitaka* (*P. zelynica*) were used as raw materials. **[Table 1]**

Accessory Drugs

For purification of *Shilajeet* – *Godugdha* (Cow's milk), *Triphala kwatha* (aqueous extract of *T. chebula, T. bellerica & E. officinalis* as decoction) *Bhringaraja Swarasa* (Juice of *E. Alba*)

For *Bhavana* (Levigation process) –Decoction of *Musta* (Aqueous extract of *S. rotendus* as decoction)

Black bitumen was considered as *Shilajeet* for their similar characteristics and was collected from local market of Nanded, Maharashtra and authenticated as per classical texts mentioned. [9] Samples of Herbal ingredients were procured from local market. Authenticity of materials was confirmed by experts of respective fields. Their originality, purity was identified and selected as per standard mentioned in Ayurvedic pharmacopoeia of India (A.P.I.). [10]

Table 1 Ingredients of Shiladhatri Tablet

Ingredient	Latin Name	Part used	Proportion	Quantity used
Shilajeet	*Black Bitumen*	-	2 parts	50g
Haritaki	*Terminalia chebula* Retz.	Fruit	4 parts	100g
Haridra	*Curcuma longa* Linn.	Rhizome	4 parts	100g
Amalaki	*Phyllanthus emblica* Gaerth.	Fruit	4 parts	100g
Guduchi	*Tinospora cordifolia* Wild.	Stem	4 parts	100g
Shatavari	*Asparagus racemosus* wild.	Root	4 parts	100g
Chitraka	*Plumbago zeylanica* Linn.	Root	1 part	12.5g
Musta	*Cyperus rotundus* Linn.	Rhizome	Q.S.	1.3L

Purification of *Shilajeet*

Shilajeet purification was carried out in 3 steps-

Step 1-250 gm of raw *Shilajeet* was powdered and mixed with 500 ml of water and 500 ml of milk in an iron pan & then heated on medium heat& stirred continuously. Then, this mixture was kept undisturbed for 24 hours. Next day supernatant liquid was decanted and filtered by a clean cotton cloth. This mixture was again heated on mild flame and was continuously stirred. This mixture became thick paste (thick layers) as watery portion was evaporated. Finally semisolid form of Shilajeet was collected and dried. [11]

Step 2- *Shilajeet* processed with cow milk was powdered& kept in iron pan. Decoction of *Triphala* added to it. It was stirred for 30 minute continuously. This mixture was kept for three hours and supernatant liquid was decanted and filtered. Then it was heated on mild fire in iron pan and stirred continuously. After that it became thick paste (semisolid). Watery portion was evaporated; finally semisolid form of Shilajeet was collected and dried**.** [11]

Step 3–Freshly extracted juice of whole *Bhringaraja* plant was added to previously obtained *Shilajeet* in iron pan. It was stirred for 30 minutes. Then it was filtered by a clean muslin cloth. This mixture was heated till it became thick paste. Finally semisolid form of purified Shilajeet was collected and dried. [11]

Method of preparation of *Shiladhatri* Tablet

Authenticated herbal crude drugs were powdered and sieved through mesh no. 120 each ingredient separately. These ingredients were weighed and taken in quantity as per formulation decided by *Vridhha vaidyas* for preparation. Then these are mixed properly in mortar & pestle. Purified *Shilajeet* powder was dissolved in decoction of *Musta*. It was then added to this mixture in end runner. This mixture was triturated (*Bhavana*) for eight hours to get semisolid mass. The product obtained was dried at 50^{o}C in hot air oven for 12 hours. The dried granules were passed again through a no. 20 sieve. The formulation was then compressed in a single-punch press with a target weight of 250 mg.

Shiladhatri tablets were subjected to various analytical parameters as follows:

- **Organoleptic parameters:** *Rupa* (color), *Rasa* (taste), *Gandha* (odor) & *Sparsha* (touch)
- **Physico-chemical parameters:** Specific gravity test, p^{H} of 5% aqueous soln., loss on drying at 110°C, ash value, acid insoluble ash, extractive values
- **Quantitative tests for:** Weight variation test, hardness test, disintegration time, friability
- **Qualitative tests for functional group:** Benzoic acid identification test

METHODS OF PHYSICO-CHEMICAL ANALYSIS

Specific gravity:
For finding out the specific gravity of the sample the above operation is repeated using the sample instead of water at the same temperature and from the weights of water and sample obtained the specific gravity of the sample was calculated. The medium used for extraction is water with Specific gravity equal to one. Since the extract contains active constituents that are not highly water soluble. Specific gravity of extract is expected to be slightly more than one.

Benzoic acid identification test:
Warm a gently 0.2 gram with 20 ml of water and add 1 ml of N sodium hydroxide and filter. To filtrate add ferric chloride, test – solution; a buff colored precipitate is produced. A solution is acid to methyl red solution. This experiment was determined by the method described in text-Indian Pharmacopoeia (I.P.) and B.P.

Extractive values:
Mascriate 5 gm of air dried drug, coarsely powdered with 100 ml of appropriate solvent i.e. water or alcohol of specified strength in a closed flask for 24 hours. Shaking frequently during 6 hours and allow to stand for18 hours. At the end of 24 hours, filter rapidly, taking precaution against loss of solvent. Evaporate 25 ml of filtrate to dryness in a tardy flat bottom shallow disc and dry at 105°C to constant weight. Calculate the percentage of water or alcohol soluble extractives with reference to air dried drug.

Ash value:
Tablets of Shiladhatri tablets were crushed in mortal pestle to prepare fine powder. Accurately weighed moisture free sample were transferred in pre weighed silica crucibles. These crucibles were kept in muffle furnace at650°C for 2 - 3 hours. Then the crucibles were cooled and weighed again the amount of ash was determined.

Acid insoluble ash:
The ash obtained was boiled in 25ml of dilute Hydrochloric acid (6N) for 5 min. Insoluble matter was collected with the help of Whatman's filter paper no. 41 (Ash less filter paper). Filtrate was then transferred in silica crucible with ash less filter paper. The sample was incinerated again in muffle furnace at 650°C. Then the crucibles were cooled and weighed again for determination of percentage of acid insoluble ash.

Loss on drying:
One gram of powder of samples was taken in a glass tray and they were weighed in analytical balance. It was then kept in oven at 105°C for one hour. It was cooled and weighed again. The amount of weight loss was calculated in percentage.

Average weight of tablets:
Twenty tablets were selected from each batch and weighed on analytical balance. Mean weight was calculated. Positive and Negative Deviation from Average weight: weights of twenty randomly selected tablets were taken and reading was taken for each tablet.

pH Value:
1 gram of sample was weighed in analytical balance. It was added in 100 ml of distilled water. The mixture was stirred with the help of glass rod. Mixture was filtered with the filter paper and pH of the filtrate was calculated by Digital pH meter Instrument.

Tablet Hardness test:
Monsanto's hardness tester was used to measure hardness of the tablet. Ten tablets were selected from each batch. The surface that comes in contact with plunger was cleaned with cotton. Tablet was placed in on the lower plunger and zero reading was recorded. The upper plunger was forced against a spring by turning a threaded bolt until the tablet fractured. The force of fracture was recorded and zero force reading was deducted from it. Average hardness of tablet sample was determined.

Friability test:
Twenty tablets were selected from each batch and weighed in analytical balance. These pre weighed tablets were placed in plastic chamber of plastic friability testing apparatus. It was then switched on so that it revolves at a speed 25 per times minute. The friabilator was switched after four minutes. Tablets were taken and reweighed. The percentage difference from original weight is used to express friability. Friability test is used to determine the durability and abrasiveness of tablets.

Disintegration time:
Disintegration is defined as the state in which any residue of the tablet except fragment of insoluble portion remaining on screen of apparatus. The Disintegration time test provided to determine whether uncoated or coated tablets disintegrated within a prescribed time limit when placed in a liquid medium under prescribed experimental condition for the purpose of disintegration time.

Instrument used for tablet disintegration was standard IPS tablet Disintegration test machine 1985. Water was filled in the beaker and a temperature of 37°C was maintained. In this machine six tablets of Shiladhatri were placed. Machine was switched on and disintegration time was noted.

Disintegration time of a tablet is the time taken by it to disintegrate completely. It varies with respect to applicability of medium as well as expected action of drug of specific time or site.

XRF (X-Ray Fluorescence) Method:

X-Ray Fluorescence Analysis-one of the best Analytical techniques to perform elemental analysis in all kind of samples, no matter if liquids, solids or loose powders have to be analyzed. XRF combines highest accuracy and precision with simple and fast sample preparation for the analysis of elements from Beryllium (Be) to Uranium (U) in the concentration range from 100% down to the sub-ppm-level. The XRF spectrometer measures the individual component wavelengths of the fluorescent emission produced by a sample when irradiated with X-rays.

WDXRF spectrometer (Wavelength Dispersive XRF):

X-ray spectrometry methods to measure elements are founded on Moseley's relationship, showing that the reciprocal of Wavelength of characteristic of radiation for any given spectral line of a series (i.e. K, L, M etc.) is directly related to the square of atomic number. These Wavelengths are well documented. By measuring the wavelengths of characteristic X - radiation one can infer the atom from which it originates.

Analyzing crystal:

In WDXRF spectrometry, the polychromatic beam emerging from a sample surface is dispersed into its monochromatic constituents by the use of an analyzing crystal according to Bragg's Law. The wavelength for any measured line in computed from a knowledge of the crystal parameters and diffraction angle. A selection of crystals in necessary in order to cover the wavelength range of interest. The layers of a crystal act like weak reflecting mirrors for the X-rays. Only if the path difference of the reflected X-rays is a whole number of Wavelengths does constructive interference occur. This is described by Bragg's Law is,

$$n\lambda = 2d\sin\theta$$

[Where: **λ**: Wavelength of the X-rays, **d:** The spacing of the layers **θ:** The incident angle of the photons]

In wavelength dispersive XRF (WDXRF) spectroscopy, the X-ray energies are separated by means of a diffracting crystal and a detector that are placed in positions complying with Bragg's Law. The placement is either by turning of a Goniometer, measuring the energies one after the other (sequential) or in fixed positions, measuring the energies all at the same time (simultaneous). WDXRF (Wavelength – dispersive X-ray Fluorescence) separation is achieved by diffraction, using an analyzer crystal that acts as a grid. The specific lattice of the crystal selects the correct wavelengths according to Bragg's law.

EDXRF (Energy –dispersive X-ray fluorescence):

EDXRF spectrometry works without a crystal. An EDXRFSpectrometer includes special electronics and software modules to take care that all radiation is properly analyzed in the detector. It provides a lower cost alternative for applications where less precession is required. The high end Epsilon 5XRF spectrometer uses the 3D EDXRF techniques featuring a 3- dimensional, polarizing optical geometry.

Simultaneous WDXRF Spectrometer:

A simultaneous XRF spectrometer is ideal for routine analysis, where the elements of interest are known in advance. These are measured simultaneously using a number of pre-assembled fixed 'channels' placed around the sample. Each is effectively a self – contained spectrometer, with a crystal and detector turned to receive a single wavelength, based on the conditions described by Bragg's Law.

Although simultaneous measurement means that the same excitation conditions must be used for all elements, the ability to use focusing optics enables channel sensitivities to be optimized for this mode of operation. Multi– element analysis is typically completed in a few seconds. Simultaneous instruments may also be equipped with one or more goniometers, to provide added application versatility and permit the measurement of unforeseen elements. Elemental analysis of Raw, purified Shilajeet and Shiladhatri tablets were done by this Simultaneous WDXRF spectrometer method.

OBSERVATIONS & RESULTS

Comparative Organoleptic characters were the following: *Rupa* (color) was yellowish green, *Rasa* (taste) was Sour

&bitter, *Gandha* (odor) was characteristic due to the specific properties of the cow urine and *Sparsha* (consistency/texture) was smooth as given in **[Table 2]**

Table 2 Organoleptic parameters of *Shiladhatri* Tablets

Parameter	Observation
Sparsha (Texture)	Smooth
Rupa (Color)	Yellowish green
Rasa (Taste)	Sour & bitter
Gandha (Odor)	Characteristic of cow urine

pH of the was6.05 ± 0.01, loss on drying was 1.61 ± 0.03% w/w as given in **[Table 3]**.

Table 3 Physico-chemical parameters of *Shiladhatri* Tablets

Parameter	Result
Loss on drying at 105°C (% w/w)	1.613 ± 0.336 (3)
Total Ash (% w/w)	5.756 ± 0.3385 (3)
Acid insoluble ash (% w/w)	0.927 ± 0.131 (3)
Hardness	1.55 ± 0.0866 (3)
Disintegration time	1.35 ± 0.050 (3)
pH	6.047 ± 0.005 (3)

The average weight of the tablets was 254 mg, hardness of was1.54 ± 0.09 and disintegration time was 1.35 min and friability was 1.09% as given in **[Table 4].**

Table 4 Quantitative parameters of *Shiladhatri* Tablets

Parameters	Result
Weight variation test	**Average weight** –254 mg.
	Min. weight – 252 mg
	Max. weight –258 mg
Tablet Hardness test	1.54 ± 0.09
Tablet Disintegration time	1.35 min.
Friability	1.09%

Elemental analysis reveals the presence of Potassium & Calcium in major Phosphorus, & Iron in the formulation as given in **[Table 5]**.

Table 5 Elemental Analysis of *Shiladhatri* Tablets by XRF

Elements	Mean	S.D.
Potassium (K)	28.928	0.78
Phosphorous (P)	1.155	0.0441
Calcium (Ca)	26.209	0.421
Iron (Fe)	7.202	0.778

Table 6 Qualitative Analysis of *Shiladhatri* Tablets

Benzoic acid identification test	**Positive**

DISCUSSION

Success of any standard drug depends upon its safety and efficacy. Efficacy acts like a motivating factor for the drug manufacturing sector while the safety is the quality which is very essential for any substance to be labeled as a drug.

Many Formulations are widely used for diabetes (Type II) but during course of time, it is necessary to find out a standard potent drug which is useful. Formulation containing Shilajeet may be one of those, as it not only anti diabetic but also contains many essential minerals required which may also useful in avoiding diabetes complications.

For preparation of *Shiladhatri* tablets three Samples of *Shilajeet* were collected & short listed

using criteria mentioned in *Ayurvedic* Pharmacopeia supported by modern analytical tests. *Ayurveda* text indicated that superior quality *Shilajeet* should contains iron. Determination of Iron percentage in samples was done by XRF method. Out of these 3 samples, the sample containing copper and other toxic elements were excluded & sample containing Iron (6.080%) was used in preparation of tablets. As per modern chemistry Benzoic acid present in *Shilajeet* is responsible for various actions like topical antiseptic, inhalant, decongestant, expectorant, analgesic and antiseptic.[12] Hence an identification test was carried out for Benzoic acid which revealed its presence in selected sample of Shilajeet.

Shodhana is a process by which impurities or poisonous materials of the substance are removed. The impurities of the drug cause several diseases and toxic effects. So it is advisable to administer the drug Not in pure form, only after proper purification process. The unpurified Shilajeet contains silica and hard stony particles, mud and several metallic impurities. Impure Shilajeet used internally causes diseases like *Murcha* (Giddiness), Purpura, constipation and Edema. [13] Purification of Shilajeet using Cow's milk, *Triphala* decoction, fresh juice of *Bhringraja* is the best method for *Shodhana* as these drugs are synergistic in action with Shilajeet and thus increases its efficacy.
Shilajeet has low melting point (69°C to 80°C), so the temperature was maintained during *Shodhana* process to preserve its essential contents. After purification it became brittle and very soft in nature, it passed all the tests perfectly as specified in texts.

XRF analysis helped in determining increased percentage of Iron after purification. Average specific gravity of *Musta* decoction used for levigation was 1.030 ± 0.0030 (Mean ± S.D.). Reduction in particle size i.e. fineness of medicine after proper *bhavana* (requires time up to 8 hours) helps in increasing bioavailability of drug.
Analytical study shows that *Shiladhatri* Tablet disintegration time is 1.35 ± 0.050 min. which helps to start action early and therefore fast absorption of medicine depending upon time of intake of medicine.
Final product (*Shiladhatri* Tablet) is slightly acidic in nature due to some acidic ingredients of *Shiladhatri* Tablet (e.g. *Amalaki*). As *Shiladhatri* Tablet contains Iron percentage, it also acts as a good haematinic.

FIGURES

Figure 1 Raw *Shilajeet* (Black bitumen)

Figure 2 Powder of *Shatavari* (*A. racemosus*)

Figure 3 Powder of Guduchi (*T. cordifolia*)

Figure 4 Powder of *Haridra* (*C. longa*)

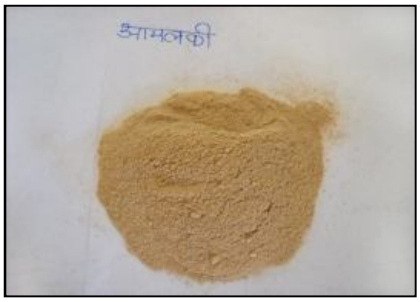

Figure 5 Powder of *Amalaki* (*E. officinalis*)

Figure 6 Powder of (*T. chebula*)

Figure 7 Powder of *Chitraka* (*P. zylenica*)

Figure 8 Powder of *Musta* (*C. rotundus*)

Figure 9 Pericarps of *Triphala*

Figure 10 Fresh herb of *Bhringaraj* (*E. alba*)

Figure 11 *Shilajeet* processed with Cow Milk

Figure 12 *Shilajeet* processed with Triphala

Figure 13 *Shilajeet* processed with *Bhringaraja*

Figure 14 *Shilajeet* processed with *Triphala*

Figure 15 *Shilajeet* (During *Bhavana*)

Figure 16 *Shilajeet* (after *Bhavana* & drying)

Figure 17 *Shilajaeet* Tablet (Final product)

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