ORIGINAL ARTICLE

Pharmaceutical Standardization of a Herbomineral Formulation (*Jeeva Rasa Churna*) for *Vajeekarana*

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Abstract

Background: *Vajeekarana* deals with fertility, potency, and healthy offspring along with diseases like erectile dysfunction (ED). This is a widespread disease among men having negative impact on the quality of life of the patients and their partners. **Aim:** This study aims to prepare and characterize the formulation (*Jeeva Rasa Churna* [JRC]) used in ED. **Materials and Methods:** JRC has been prepared by homogeneous mixing of two mineral drugs, namely *Shuddha Hingula* and *Shuddha Shilajatu* and fine powder of five herbal ingredients, namely *Akarakarabha, Ashwagandha, Shweta Mushali, Shatavari,* and *Vidarikanda.* JRC was subjected to various physiochemical parameters such as moisture content, water-soluble extractive, thin-layer chromatography, and energy-dispersive X-ray spectroscopy (EDX) for its standardization. **Results:** The total of 3.750 kg of JRC was prepared using 150 g, *Hingula* and 3.600 kg of homogeneous mixture of *Shuddha Shilajatu, Akarakarabha, Ashwagandha, Shweta Mushali, Shatavari,* and *Vidarikanda.* It was observed that 5.6% moisture content and 1.80% water-soluble extractive were in JRC, respectively, and EDX study showed that formulation was free from heavy metals except mercury which is an ingredient of JRC. **Conclusion:** The physiochemical parameters of formulation JRC fall within the range of Ayurvedic pharmacopeia for *Churna* so it may be a safe and effective medicine for ED.

Key words: Erectile dysfunction, *Jeeva Rasa Churna*, Standardization

INTRODUCTION

The need for sex education, enhancement of performance, and desire was executed since ancient time that is why specialized branch for this subject called *Vajeekarana* exists as a separate branch in *Ashtanga* Ayurveda. It deals fertility, potency, and birth of healthy offspring. Here, the male sexual dysfunction has been elaborately described as *Klaibya* in other words impotence or erectile dysfunction (ED). The worldwide prevalence of ED was probably 152 million men in 1995 and will be 322 million men in 2025.[1] Much of this increase will occur in the developing world. A study, involving more than 27,000 men from eight countries, showed an ED prevalence of 8% among men in 20–29 years age group and 11% among 30–39 years age group.[2]

The key intention of pharmaceutical research is to produce a safe, effective, and quality drug for the treatment of ED. Efficacy and safety depend solely on the quality of the drug. The quality of the pharmaceutical product depends not only on the care taken in its preparation but also in confirming that the authentic raw materials have been used with standard manufacturing process. In this study by considering all these aspects, we had tried to design new formulation with the help of Ayurvedic literature. The pharmacological properties of ingredients such as *Shilajatu*, *Ashwagandha*, and *Shatavari* may cover major aspect of pathophysiology of ED. Hence, it may be used in *Jeeva Rasa Churna* (JRC).

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MATERIALS AND METHODS

JRC has been prepared by homogeneous mixing of two mineral drugs, namely *Shuddha Hingula* and *Shuddha Shilajatu* and powder of five herbal ingredients, namely *Akarakarabha*, *Ashwagandha*, *Shweta Mushali*, *Shatavari,* and *Vidarikanda*.

Procurement and authentication of the raw materials

Hingula, Shilajatu, Akarakarabha, *Ashwagandha*, *Mushali*, *Shatavari,* and *Vidarikanda* were procured from Gola Dinanath market, Varanasi. The mineral drugs were authenticated by Prof. A. K. Chaudhary, Department of Rasa Shastra and Bhaishajya Kalpana (by voucher no. Hingula/RS/2017/01 and Shila/RS/2017/02) kept in museum of department and plant drugs by Dr. J. M. Singh, from the Department of Dravyaguna, by voucher specimen no. Anacyclus/DG/2017/01, Withania/DG/2017/02, Mushali/DG/2017/03, Asparagus/DG/2017/04, and Pureria/DG/2017/05, Faculty of Ayurveda, Institute of Medical Sciences, Banaras Hindu University.

Hingula Shodhana

Shodhana (purification) of *Hingula* was done with 7 times *Bhawana* (impregnation) of juice of ginger (*Zingiber officinalis*).[3] The summary of *Hingula Shodhana* has been given in Table 1 [Appendix Figure 3].

Shilajatu Shodhana

Shilajatu was purified by dissolution in half quantity of the *Triphala Kwatha* (w/v) and double quantity of hot water to that of *Shilajatu* (v/w), then filtration of solution and evaporation of watery content [Table 2 and Appendix Figure 4].[4]

Preparation of powders

Akarakarabha, *Ashwagandha, Shweta Mushali, Shatavari,* and *Vidarikanda Churna* (powder) were prepared as per standard protocol for powder preparation and strained through 80 mesh of sieve [Appendix Figure 1].[5,6]

Preparation of JRC

JRC was prepared in the departmental laboratory of Rasa Shastra and Bhaishajya Kalpana as per standard protocol. All the ingredients were taken in prescribed ratio and mixed homogeneously, then filtered through a sieve of mess no. 80. The medicine was prepared in three batches. The ingredients and ratio of per batch have been presented in Table 3. Packaging and labeling of containers were done as per the rule 161 of Drug and Cosmetic Rule 1945 [Appendix Figures 1 and 2].[7]

Analytical study

The analytical tests of JRC were done as possible as per guidelines of Pharmacopeial Laboratory of Indian Medicine.[8]

Determination of loss on drying

About 2 g powder of sample was taken in a clean, dried, and tarred silica crucible. The sample was kept in an oven at 105°C for 5 h. After 5 h, crucible was picked out from oven and weighed it and calculated.

Determination of total ash value

About 2 g accurately weighed sample was taken in tarred silica crucible and incinerated at temperature not exceeding 450°C, until free from carbon. The sample was cooled and weighed. Then, the percentage of ash with respect to air-dried sample was calculated.

Determination of acid-insoluble ash

The obtained ash was transferred to flask and added 25 ml of 6 N HCl and boiled for 5 min, then filtered by ashless filter paper, washed with hot water, and dried. Then, it was taken in Gooch crucible and ignited to constant weight, then weighed it and calculated the percentage of insoluble ash with respect to the air-dried drug.

Determination of water-soluble ash

Boiled the ash for 5 min with 25 ml of water, insoluble matter was collected in a Gooch crucible, or on an ashless filter paper, washed with hot water, and ignited to constant weight at a low temperature.

Determination of alcohol-soluble extractive value

About 2 g of powdered drug was taken in conical flask and added 50 ml of ethanol and shacked for 6 h, continuously then

Table 1: Summary of *Hingula Shodhana*

Weight before *Bhawana* (kg)	Quantity of *Bhawana Dravya* (ml)	Weight after *Bhawana* (kg)	Color
250.0	180	251.5	Red

Table 2: Summary of *Shilajatu Shodhana*

Weight of impure *Shilajatu*	Weight of purified *Shilajatu*	% yield
5 kg	1.4 kg	28%

Table 3: Ratio of ingredients in JRC per batch

Ingredients	Ratio	Weight as per batch (g)
Shuddha Hingula	0.25	50
Shuddha Shilajatu	01	200
Akarakarabha	01	200
Ashwagandha	01	200
Shweta Mushali	01	200
Shatavari	01	200
Vidarikanda	01	200

JRC: *Jeeva Rasa Churna*

allowed to stand for 18 h. Next day, the extract was filtered. The filtrate was evaporated to dryness in tarred evaporating dish on water bath and dried at 105°C to a constant weight.

Determination of water-soluble extractive

About 2 g of powdered drug was taken in conical flask and added 50 ml of distilled water and shacked continuously for 6 h then allowed to stands for 18 h then filtered. The filtrate was evaporated to dryness in tarred evaporating dish on water bath and dried at 105°C to a constant weight.

Determination of pH

About 10 g of powdered drug was dissolved into 100 ml distilled water and filtrate was used for determining of pH using pH meter (Eutech Instrument Company, Model No.EU780480).

Thin-layer chromatography (TLC)

TLC plate silica gel 60 F_{254} (Merck) 10 cm × 10 cm was used as stable phase. An ultraviolet (UV) light, suitable for observation at short (254 nm) and long (365 nm) wavelength, was used for the examination of spots in the chromatogram. TLC of JRC showed eight bands in UV light at wavelength of 254 nm and three bands in UV light at wavelength of 366 nm with the mobile phase of benzene:ethyl acetate (8:2) [Figure 1].

Energy-dispersive X-ray spectroscopy (EDX)

The percentage weight of the elemental analysis of JRC revealed by energy-dispersive X-ray spectroscopy study (Instrument ZEISS EVO 18 Model).[9,10]

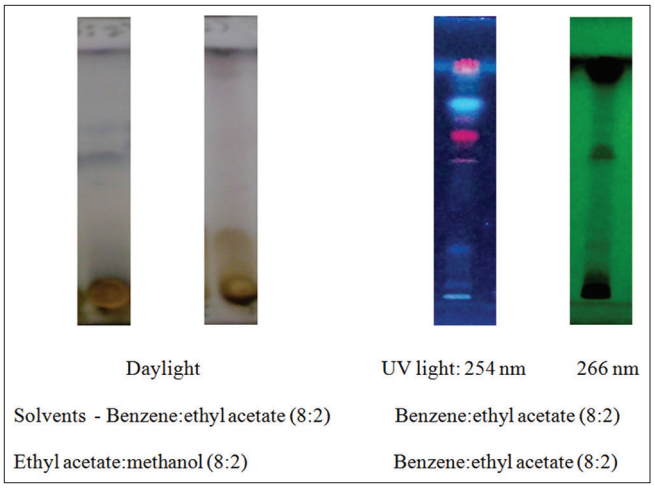

Figure 1: Thin-layer chromatography pictures of *Jeeva Rasa Churna*

RESULTS

About 250 g of *Hingula* was subjected for purification. After purification, the overall weight of *Hingula* was found increased up to 1.50 g. The total of 180 ml of ginger juice was consumed in seven *Bhawana* during purification process. About 5 kg of raw *Shilajatu* was purified in which approximately yield of *Shilajatu* was found of 28% [Tables 1 and 2].

To maintain standard operational procedures, JRC was executed to multiple analytical tests. The findings were within limits as per Pharmacopoeial Laboratory of Indian Medicine and Ayurvedic Formulary of India (AFI) norms. The values are summarized in Table 4.

TLC of JRC was done in different solvents and analyzed in sunlight UV light at wavelength of 254 nm and 366 nm. Different spots were seen at different distances.

The elemental analysis of JRC through EDX is as follows in Table 5.

DISCUSSION

The purification of *Hingula* was done with ginger juice as described methods in Rasa Shastra classics with its uniqueness. In spite of probable procedural loss, weight of *Hingula* was found gained due to adding of solid contents of ginger juice. The yield of *Shilajatu* was quite low as *Shilajatu* was mixed with impurities such as stones and mud at large. The yield of *Shilajatu* also varies as per source of collection. JRC was finally filtered through sieve of 80 mesh to get fine powder as particle size directly affects the absorption in the body. The whole method of standardization at process level is nothing, but the standardization of *Samskaras* and the mean of the alterations of qualities (of raw drugs) in a desired direction to achieve the aimed goal.[11] These physicochemical changes ultimately augment bioavailability. Reduction in particle size

Table 4: Summary of analytical tests

Analytical tests	Findings
Loss on drying at 105°C	5.60%
Total ash value	9.50%
Acid-insoluble ash	0.35%
Water-insoluble ash	0.95%
Water-soluble extract	1.80%
Alcohol-soluble extract	13.30%
pH value	5.32

Table 5: Result of EDX study

Element	Weight%
C	49.27
O	48.70
Mg	0.32
Si	0.08
Ca	0.08
Mn	0.03
Hg	1.51
Total	100.0

helps in absorption. Smoothness leads to non-irritability and all chemical changes make drug to body-friendly.[12,13]

Media in *Shodhana* process acts as solvent to dissolve insoluble impurities and eradicate toxic substance from the drug. It provides some organic and inorganic elements to the material which facilitates physical transformation of that drug to potentiate the efficacy of the material and making of compound with toxic elements to become none or less toxic for health. Ginger is a rich source of microelements, acts as chelating agent, and has good antioxidant property.

Triphala has various qualities such as antioxidant property and hepatoprotective property[14] and acts as chelating agent;[15] therefore, it might reduce harmful elements of *Shilajatu* and adds beneficial elements. In AFI, the therapeutic dose of *Churna* of the single drug is mentioned as 1–6 g daily and the therapeutic dose of *Hingula* in texts of Rasa Shastra has been mentioned as 60–125 mg while the dose of *Shilajatu* has described as 250 mg–1 g in Rasa Shastra literature. Thus, considering final dose of JRC, all the ingredients were taken in the ratio of ¼:1:1:1:1:1:1 for *Shudha Hingula, Shilajatu Akarakarabha*, *Ashwagandha*, *Mushali*, *Shatavari,* and *Vidarikanda,* respectively.

The physicochemical parameters of JRC were analyzed to validate pharmaceutical processes. Reduction in moisture content reduces the chance of microbial contamination (bacterial and fungal growth) and decomposition due to unwanted chemical transformations. The assessment of moisture contents helps to determine the stability of the drug.

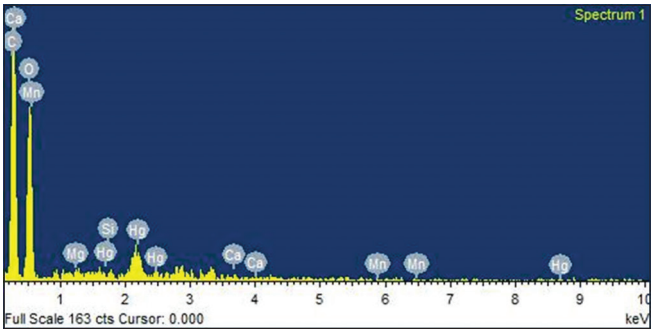

Figure 2: Elemental analysis graph of JRC

Lower moisture contents indicate more stability of the drug. The total ash value represents the inorganic salts, naturally occurring in the drug. Therefore, the determination of ash value plays an important role to justify the identity and purity of the sample. Test for acid-insoluble ash was carried out to evaluate the percentage of insoluble inorganic content (adhering dirt, silica, and sand) of JRC in dilute acid. Since a drug must go through solution before it can be absorbed, so the acid-insoluble ash test is therapeutically very important. Less the acid-insoluble ash, it should be physiologically more available in human body. The human metabolic process and pharmacokinetic depend on purity and human suitable form of drug. The water-soluble ash is the part of the total ash content, which is soluble in water. It is a good indicator of either previous extraction of water-soluble salts in the drug or incorrect separation. The alcohol-soluble extractive value indicated the presence of polar constituents such as phenols, alkaloids, steroids, glycosides, and flavonoids and secondary metabolites present in the plant sample. The water-soluble extractive value indicated the presence of sugar, acids in the compound. Less or more extractive value indicates addition of exhausted material, adulteration, or incorrect processing during drying or storage. The pH of JRC was 5.6 which are slightly acidic in nature. The acidity indicates the site of absorption and action of drug. Normally the drug to be administered should not be either too acidic or alkaline in nature. TLC is a technique to separate phytoconstituents. By matching Rf value with standard records, it can be easily identified particular phytoconstituent in the formulation.

EDX is an analytical technique used for the elemental analysis or chemical characterization of a sample. The concentration of carbon and oxygen was found more due to herbal materials. There were no heavy metals detected except mercury. Mercury was due to the presence of *Hingula* (HgS), one of the ingredients in formulation [Figure 2].

CONCLUSION

Finally, prepared JRC was grayish white in color, astringent in taste, and smooth in tactility. The physiochemical parameters of formulation JRC were found within the range of Ayurvedic pharmacopeia of India for *Churna.* No adverse

effects were witnessed during the clinical trial of JRC in the patients of ED. Therefore, it was found safe on account of pharmaceutical procedures with reproducibility and may be prescribed for the effective management of ED as well as an aphrodisiac medicine in general.

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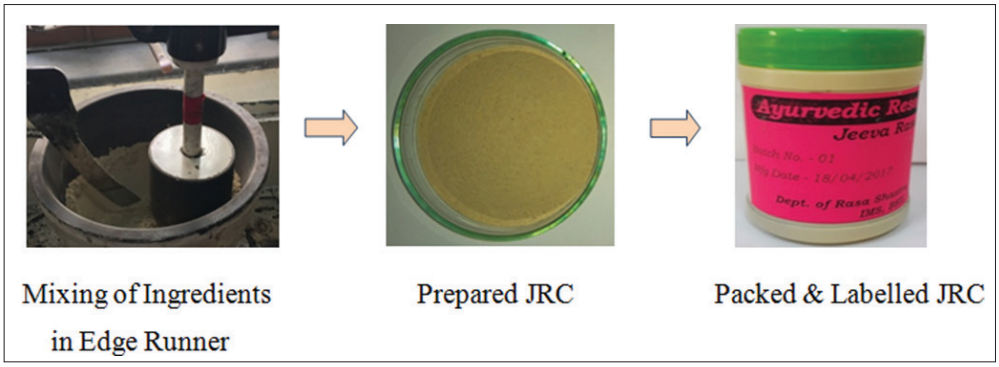
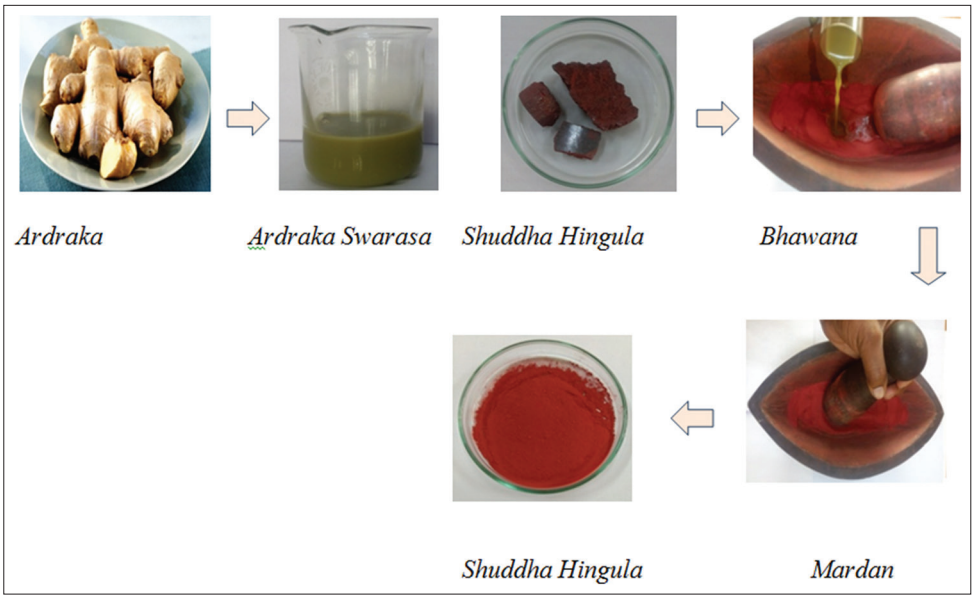
APPENDIX FIGURES

Appendix Figure 1: Ingredients of *Jeeva Rasa Churna*



Appendix Figure 2: Preparation of *Jeeva Rasa Churna*



Appendix Figure 3: *Shodhana* Process of *Hingula*

Appendix Figure 4: *Shodhana* process of *Shilajatu*