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Research Article

PHARMACEUTICAL PROCESSING AND STANDARDIZATION OF MODIFIED DOSAGE FORM OF *JEEVANEEYAGANA KASHAYA* AS SPRAY DRIED POWDER CAPSULES

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ABSTRACT

Jeevaneeyagana Kashaya is an Ayurvedic formulation that can be used for its preventive and therapeutic properties. However, its liquid dosage form has a limited shelf life and is difficult to administer. The present study works on standardizing and evaluating the *Jeevaneeyagana Kashaya* (JGK) extract capsules prepared using spray dryer technology, which consist of *Withania somnifera*, *Asparagus racemosus, Pueraria tuberosa, Vigna trilobata, Teramnus labialis, Leptadaenia reticulata,* and *Glycyrrhiza glabra.* The spray-dried extract was evaluated for phytochemical characters. Moreover, physical property analysis, such as bulk density, tapped density, compressibility index, and angle of repose for the formulated JGK extract capsules, was done. The capsules were evaluated for their organoleptic characters. Microbial load, heavy metal analysis, and disintegration time were also determined. The JGK extract capsule formulation complied with the assessed qualities. JGK extract capsule formulation complied with the assessed qualities. The JGK extract capsules can be used as a modified dosage form with increased shelf life and easy administration. The results of this study can be utilized as a reference standard for quality assurance of JGK capsules.

INTRODUCTION

The Ayush systems of India, especially Ayurveda, have a large infrastructure and unique approaches to addressing illnesses, preventing disease, and fostering well-being. Ayurveda provides a distinctive method of fostering health and wellbeing because of its focus on preventive measures like daily and seasonal routines, restorative herbs, and therapeutic therapies. The first set of the 50 *Mahakashayas* listed in the *Charaka Samhita* is called *Jeevaneeyagana*, which refers to "beneficial for life" and comprises ten herbal medicines[1] Among the ten herbs Acharya Bhavaprakasa mentioned *Prathinidhi dravyas* for some of the endangered herbs.[2]. Therefore, the *Pratinidhi dravyas* were used in the current *Jeevaneeya Gana Kashaya* extract capsule composition. *Ashwagandha, Vidarikanda, Shatavari, Mudgaparni, Mashaparni, Jeevanti*, and *Madhuka* are therefore included in the JGK extract capsule. Numerous pharmacological properties, including antiviral, antibacterial, antioxidant, antitussive, neuroprotective, hepatoprotective, cardioprotective, and nephro-protective properties, are assessed for these particular drugs[3]. This *Kashaya*'s suggested drugs are readily available and reasonably priced. As a *Naimithikarasayana*, *Kashaya* can be used to avoid treating specific ailments. Since the traditional dosage form demands *Kashaya*, it is quite challenging to prepare fresh *Kashaya* for each administration in the hectic world of today. Therefore, a strategy was developed for the current investigation to manufacture the *Kashaya* extract using spray-dried technology and then further encapsulate it. The standardization of JGK extract capsules and raw ingredients was another goal of the study.

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MATERIALS AND METHODS

Procurement of drugs

Crude herbal materials were purchased from an authentic herbal dealer. The authenticity of the crude drug had been identified by botanists by various pharmacognostic tests. Authentic plant specimens were collected, and the plant material was identified

by taxonomist Jawaharlal Nehru, the Tropical Botanic Garden and Research Institute. The herbarium voucher specimen was deposited at the herbarium. Further, the bulk drug was sent to Haridev formulations, Nellad, Muvattupuzha, Kerala; an ISO GMP-certified company for *Kashaya* extract preparation and capsule production.

Standardization of crude drugs of *Jeevaneeyagana*

The powder's organoleptic characteristics, including colour, odor, and taste, were assessed by spreading it on a clean dry sheet and examining it through a magnifying lens via repeated observations.[4]

Other parameters of standardization of crude drugs of *Jeevaneeya gana*

The *Jeevaneeyagana* crude drugs were standardized using various parameters, including moisture content, ash values (total, water-soluble, and acid-insoluble), extractive values (water- soluble, alcohol- soluble) as per Ayurveda Pharmacopoeia of India.[5]

Preparation of *Jeevaneeya gana Kashaya* extract capsule

The crude drugs thoroughly cleaned were separately weighed and were taken in the quantity of *Withania somnifera* (12kg), *Asparagus racemosus*-fresh (24kg), *Pueraria tuberosa* (12kg), *Vigna trilobata* (6kg), *Teramnus labialis* (6kg), *Leptadaenia reticulata* (6kg), *Glycyrrhiza glabra* (6kg), (figure 1) and crush them in a disintegrator.

The same was charged to a drug boiler to make a decoction by adding water 16 times the weight of all the herbs. A crude water extract of the same was then produced in a drug boiler with a 1000L capacity, reduced to 1/8th of the original amount, and filtered. (72kg of herbal mix was combined with 1152L of water, reduced to 144L, and then filtered through muslin cloth.) After filtration, allow the same to further concentrate as 100L in a pan of 1000L/hr capacity until it reached the Brix value of 12. The extract was collected by charging the crude decoction to the 150L/hr spray dryer input (182°C intake temperature and 108°C output temperature; 50kg feed pressure). (10.8216kg total weight collected). Mix the extract with sodium benzoate (0.2% of the extract weight) in the leaf-type mass mixer for 20 minutes. 11.500kg of the extract was granulated using 4L of water. Subjected the granules to drying in a dryer at 80°C for 6-8 hours and collected 12.70kg of standardized granules. The dried granules (12.70kg) were powdered, sieved through a sieve with a mesh size of 20, and their moisture content (4.9%) was checked. Filled the herbal granules (500mg) in ′0′ sized "hard gelatin capsule shells" by manual filling machine. The filled capsules were examined for any flaws, like moisture or uneven weight. passed the tests. Polishing of capsules was done using a brush-type polishing machine. After approval, the material is placed into bottle containers, sealed, and a silica gel packet is added. Granulation produced 11.5kg of JGK extract. The organoleptic characteristics of the final goods were examined. 650mg of a capsule containing 500mg of the final product was formulated. Finished capsules were put into bottles. The containers are then packed in cartons. Control samples are drawn by quality control, and after reviewing the batch documents, the batch was released by QC. The released batch is transferred to the finished store and sent back to the study setting.

Standardization of *Jeevaneeyagana Kashaya* extract

The samples were evaluated for different organoleptic parameters as well as for the standardization parameters like determination of ash value (total ash and acid insoluble ash), determination of extractive values (in water, methanol).

Phytochemical test

The phytochemical evaluation of JGK extract was performed, for alkaloids, phenols, flavonoids, tannins, steroids, carbohydrate, glycosides

Physical property analyses of *Jeevaneeyagana* Kashaya extract granules

Bulk density, tap density and Carr's index

A 50ml measuring cylinder was filled with 15gm of precisely weighed powdered substance, and the initial volume (V0) was recorded.

After 50 taps (V50), the powdered volumes were recorded and the contents were volume validated. After completing this procedure three times, the average was calculated and noted. Bulk density is calculated by dividing the powder's weight by its volume in milliliters.

Tap density =Weight of the powder/volume occupied by the powder

Carr's index= Tapped density-Bulk density/ Tap density *100

Angle of repose

The height at which the funnel was installed was 1.5, 2.5, and 3.5 cm. A funnel was used to pour the powder, creating a pile, and measurements were made of its height and radius. Angle of repose computed using formula tan (h/r); h is pile's height and r is radius.

Hausner's ratio

Tap density/Bulk density is Hausner's ratio

Capsule evaluation

The JGK capsules were compared to Indian pharmacopeial standards for their description,

microbial load, uniformity of dosage units, weight fluctuation, disintegration time, and moisture content.

Microbial load

To ensure the safety of internal administration of JGK capsules, microbial load analyses were performed. It was checked to see if the total aerobic viable count, yeasts, and molds were within prescribed limits, and the microorganisms Escherichia coli, Salmonella, Pseudomonas, and Staphylococcus were not present in the final formulation.

Average weight of the capsule (mg/capsule)

20 randomly chosen capsules were weighed, and the average weight was determined.

Moisture level

The amount of moisture in air was measured using automatic Karl fischer titration equipment.

Uniformity in drug content

Weighed 20 randomly selected capsules and calculated the percentage variation from the average weight. The capsules comply with the test if not more than two individual weights deviate from the average weight by more than the specified percentage.

Disintegration time

Two 1000ml beakers filled with the appropriate liquid medium were placed in the designated spots on the beaker stand. Adjusted the volume of the liquid in the beaker such that the wire mesh of the basket is at its highest point, which is at least 15mm below the surface of the liquid. Set the temperature to about 37℃. Placed 6 capsules in six tubes. Recorded the time at which each capsule gets disintegrated.

Locking length (mm)

Measured using vernier calipers.

Heavy metal analysis

The analysis of heavy metals was done using at omic absorption spectroscopy.

1% HCl was used to prepare the samples for lead and c admium.

20% HCl was used in the processing of samples contai ning arsenic and mercury.

Aspirated distilled water was used to directly measure the metal concentration.

RESULTS AND DISCUSSSION

Organoleptic parameters and physicochemical parameters of JGK extract is summarized in table 1.

Table 1: Standardization of *Jeevaneeyagana Kashaya* extract

Name of test	Observations
Colour	Light brown
Taste	Sweet, astringent
Odor	Characteristic
Acid insoluble ash (%)	0.25
Alcohol soluble extractive	13.68
Water soluble extractive	12.11
Moisture	4.9
PH	4.32
Arsenic not more than 3 ppm	Nil
Lead (not more than 10 ppm)	Nil
Cadmium (not more than 0.3 ppm)	Nil
Mercury (not more than 1 ppm)	Nil
Total viable aerobic count (Not more than 10^5cfu/gm)	Absent
Total yeast and mold count (Not more than 10^3cfu/gm)	Absent
Escherichia coli (should be absent)	Absent
Staphylococcus aureus (should be absent)	Absent
Salmonella spp (should be absent)	Absent
Pseudomonus aeruginosa (should be absent)	Absent

Phytochemical investigations

JGK extract were investigated phytochemically. Alkaloids, tannins, flavonoids, steroids, carbohydrate were detected. The results of phytochemical investigations are shown in the table 2.

Table 2: Chemical composition of seven herbal plants used in the preparation of JGK extract capsule

Chemical composition	*Jeevaneeyagana* extract
Alkaloids	+
Glycosides	_
Tannin	+
Flavonoids	+
Saponins	+
Steroids	+
Phenols	+

Flow property of powdered extract

Before fill in to the capsule the flow quality of powder was verified. The flow property of JGK extract capsule found within acceptable limits of Indian pharmacopeia. The results are depicted in the table 3.

Table 3: Preformulation parameters

Parameters	Poly-herbal formulation
Bulk density	0.7 g/ml
Tapped density	0.82 g/ml
Carrs index	14.63
Hausners ratio	1.17 ± 0.01
Angle of repose	20.02°

A carr's index below 15 indicates excellent flow where as the value in between 20-30 indicate poor flow of material. Hence JGK extract granule found to be have an excellent flow property. Also angle of repose of 30° indicate the good flowing powder whereas greater than 40^0 indicate poor flowing powder. The extract found to be having good flowing property.

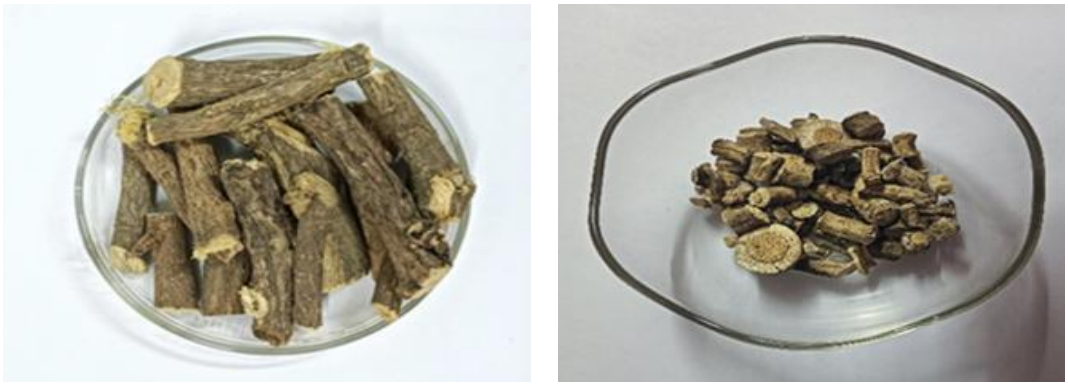
Evaluation of capsule

"0" size green coloured "hard gelatin capsule" filled with light brown coloured powder. The JGK extract capsules were compared with Indian pharmacopoeial standards for description, uniformity of weight, average weight of capsules, disintegration time, moisture, locking length. Results are shown in table 4.

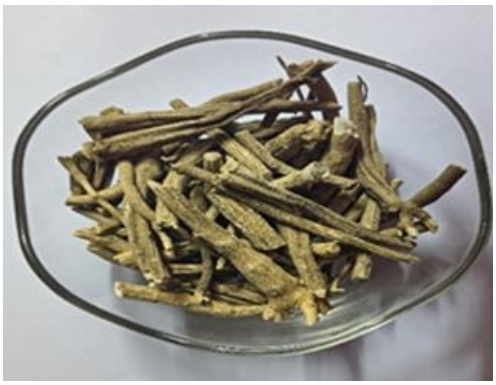
Table 4: Standardization of JGK extract capsule

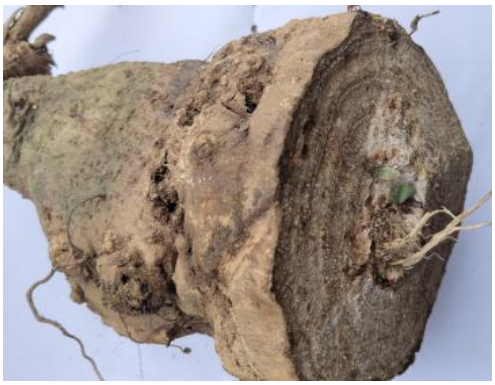
Name of test	Observation
Average weight of the capsule (mg/capsule)	595
Uniformity of weight	Complies
Disintegration time	4 minutes 14 seconds
Moisture%	4.9
Locking length	22.59

Figure 1:Raw drugs of *Jeevaneeyagana kashaya*

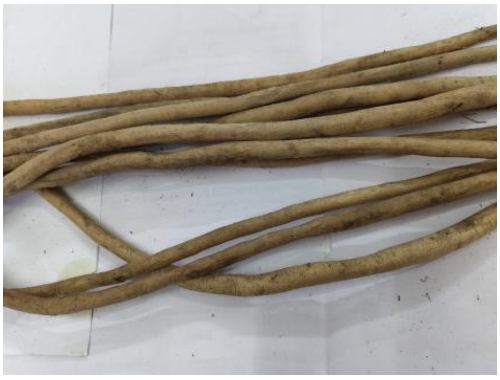


Glycyrrhiza glabra ***Leptadaenia reticulata***





Withaniasomnifera ***Pueraria tuberosa***



Teramnus labialis ***Vigna trilobata*** ***Asparagus racemosus***

Figure 2: finished *Jeevaneeyaagana Kashaya* extract

DISCUSSION

Due to the low shelf life of *Kashaya* efforts have been going on for the preservation of *Kashaya.* This dose form of dry powder guarantees repeatability and a longer shelf life than *Kashaya*. To achieve this, full aqueous extraction was carried out in order to extract every phytoconstituent and maximize yield in the *Kashaya.* To improve the extraction of phytoconstituents, this idea was implemented. A greater yield value may have an impact on the final drug's cost-effectiveness.

Organoleptic analysis aids in the initial assessment of a product's quality by evaluating it as it is perceived by the senses. The drug shows that the formulation was light brown (figure 2) smooth, astringent, sweet, and possessed a characteristic odour. The sweet and astringent taste is due to the *Madhura Thiktha* and *Kashaya rasa* present in the ingredients.[6]

Analytical evaluation of the *Jeevaneeyagana Kashaya* extract shows that moisture content was 4.9. Moisture content indicates the amount of water present in the sample, which contributed to the items' intactness and stability throughout time.[7] The growth of mold and bacteria is encouraged by an abundance of moisture, which leads to the drug's deterioration and spoilage.[7] Ash value is a widely used technique to

detect inorganic substance adulteration and is more significant for quality assurance and standardization. As the amount of inorganic material increases, the ash value will too. The acid insoluble ash value was 0.25%, which represents the silica content in the sample.[8] The amount of materials and phytoconstituent that dissolve in the appropriate solvent is indicated by the extractive value. It also has a relationship with the availability of drugs in a different medium in the body through different solvent carriers. It helps to standardize and reproduce the medications when there is variation in the extractive value, which reveals variation in the constituents. Methanol-soluble and water-soluble extractive values were evaluated to know the percentage of product soluble in the respective solvent and were found to be 13.68% and 12.11%, that demonstrate the higher solubility of *Jeevaneeya gana Kashaya* extract is in alcohol compared to water; however, it is somewhat comparable. It shows that its bioavailability in alcohol and water media is equivalent. The pH of the 1% solution of the *Jeevaneeyagana Kashaya* extract is found to be 4.32, which denotes that the solution of the formulation is acidic in nature. Which may be due to the addition of preservatives. All the preformulation characters indicating that the powder had good flow properties.[9]

When dosage forms such as tablets, capsules are placed in a liquid medium under specific experimental conditions, their disintegration time indicates whether they disintegrate within the prescribed period of time.

It indicates the quality of the drug and characteristics of the binding agent. If disintegration time is not uniform to all samples of a formulation, it indicates the improper standard operating procedures.

The disintegration time of JGK extract was 4 minutes, 14 seconds. It is reported that the fastest drug dissolution could be achieved for tablets/capsules prepared by the wet granulation method than other methods of tablet preparation, especially for poor wettable drugs used in high concentrations.[10]

The common person's concern about the safety and quality of Ayurvedic formulations arises from a great fear of the presence of harmful substances, especially heavy metals. Therefore, in order to increase the acceptance of formulations, it is essential to rule out the occurrence of undesirable aspects. According to reports, cadmium and lead are very concerning because they adversely affect human health.[11] Elemental analysis of three batches of *Jeevaneeyagana Kashaya* extract revealed that toxic heavy metals like lead, cadmium, mercury and arsenic were absent in JGK extract capsules.

So it was found that capsule wear safe to consume as the concentration of heavy metals was either absent or complied within the limit and which indicates the proper quality control methods adopted throughout the preparation process.

Herbal medications could contain germs from the water, air, or soil. Some of these may put their users' health at risk. The presence of microbial contamination in herbal remedies may cause adverse effects in individuals consuming them, thereby negating their medicinal effectiveness.[12] Therefore, it is essential to ensure that there is no microbial contamination in the final product. Consumption safety is ensured by the lack of microbial development or compliance within acceptable limits and it shows that appropriate hygienic practices were followed when formulating and packing. Physico chemical data support the product's stability and safety.

CONCLUSION

The oral dosage form of JGK as spray dried capsule was evaluated using organoleptic characters, physical property analysis and other capsule quality control parameters. All the findings was within the limits. Results of current study can be utilized as setting reference standards of quality assurance of JGK capsule. Every time preparation of *Kashaya* is a difficult thing in this current fast living lifestyle. Also *Kashaya Kalpana* itself is a preparation with less shelf life which is advised to be for its immediate use after preparation. The modified dosage form is more advantageous considering the increased shelf life and easy administration.

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