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Physicochemical and heavy metal analysis of Yavani-Sadav Churan – An ayurvedic formulation

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Abstract

Ayurveda, the most ancient documented healing heritage of the world, describes health management through natural products. Bhaishjya kalpana, a branch of Ayurveda, details pharmaceutical preparations of different dosage forms. Chooran kalpana is one such solid dosage form considered as the secondary kalpana of kalka kalpana. In common language, it is known as powder medicine and is extensively used in Ayurvedic treatment. To promote Ayurveda, traditional health management introduces the term "drug standardization" in the manufacturing of Ayurvedic medicine to ensure the production of good quality medicines for customer satisfaction in the international market. Drug standardization is not only a core issue for Bhaishjya kalpana but also for the entire Ayurvedic healthcare system. In the present study, Yavani-Sadav Churan was prepared, and the main aim is to conduct physico-chemical and heavy metal analyses of the churan. Various parameters for assessing the purity, quality, and safety of Yavanisadava chooran will be carried out, including organoleptic characters, loss on drying, total ash, acid insoluble ash, water-soluble extractives, alcohol-soluble extractives, pH, bulk density, tap density, particle size, TLC, and heavy metal analysis by ICPMS and AAS methods, which contribute significantly to standardization.

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INTRODUCTION

Ayurveda stands as the most ancient documented healing heritage globally, elucidating health management through natural products. A branch of Ayurveda, Bhaishjya kalpana, delves into pharmaceutical preparations of varied dosage forms. Chooran kalpana, recognized as a secondary form of kalka kalpana, manifests as a solid dosage form commonly known as powder medicine, extensively employed in Ayurvedic treatment.

To advance Ayurveda, traditional health management introduces the term "drug

standardization" in the manufacturing of Ayurvedic medicine, ensuring the production of high-quality medicines for customer satisfaction in the international market. Drug standardization emerges as a core issue not only for Bhaishjya kalpana but also for the entire Ayurvedic healthcare system, representing a fundamental requirement for industries and organizations dealing with Ayurvedic and herbal products.

Yavani-Sadav Churan has been selected for study due to its widespread usage in managing various diseases. Described in Ayurvedic classical texts such as Charak Samhita, Bhaishjya Ratnawali, and Astanga Hridaya, Yavani-Sadav Churan finds application in the treatment of different ailments, particularly highlighted in the Rajyakshma Chikitsa of Charak Samhita. Its usage extends to conditions such as loss of appetite, constipation, abdominal gas, various types of pain, cough, and respiratory disorders.

The formulation of Yavani-Sadav Churan typically consists of common ingredients possessing Vata-pacifying properties, beneficial for digestion improvement, alleviating constipation, and other digestive issues. Additionally, sugar present in the formulation also pacifies Pitta dosha. The recommended dosage for adults is 1-3 grams twice daily with warm water, and it is advisable to take the churan with an appropriate Anupana to prevent potential respiratory issues.

The present study aims to prepare Yavani-Sadav Churan and conduct physico-chemical and heavy metal analyses. Various parameters will be assessed, including organoleptic characters, loss on drying, total ash, acid insoluble ash, water-soluble extractives, alcohol-soluble extractives, pH, bulk density, tap density, particle size, TLC, and heavy metal analysis by ICPMS and AAS methods, all contributing significantly to standardization.

MATERIAL AND METHODS

Material: Authentic raw materials procured from the local market of Kurukshetra, Haryana, India were utilized in the present study. The formulation was prepared according to the Ayurvedic

Figure 1 Images of Different ingredients of Yavanisadav Churan

Formulary of India, with ingredients as shown in Table 1. Sample physico-chemical and heavy metal analyses were conducted at the ITC PVT. LTD Lab, Panchkula, Haryana, India.

Method of Preparation: Yavani-Sadav Churan was prepared according to churan kalpana, where all ingredients were taken in specified quantities, dried thoroughly, finely powdered, filtered through 100-number meshes, and mixed thoroughly. The prepared churan was packed in plastic containers for subsequent analysis.

Dose: The recommended dosage for adults is 1-3 grams twice daily with warm water, as stated by the Ayurvedic Formulary of India.

Shelf Life: The shelf life of Yavani-Sadav Churan varies, with durations of 2 months according to Sharangadhara, 1 year according to the Ayurvedic Formulary of India, and 2 years according to the Official Gazette of India.

Table 1 Showing ingredients of Yavanisadav churan and their quantity

S.N.	Name of Ingredients	AFI (8)	Parts used
1.	Yavani(Ajavayan)	12 gm	Fruit
2.	Tintidaka	12 gm	Fruit
3.	Nagara	12 gm	Rhizome
4.	Amalvetasa	12 gm	Fruit
5.	Dadima	12 gm	Dry seeds
6.	Badara phala	12gm	Fruit
7.	Dhanyaka	6 gm	Fruit
8.	Sauvarchala salt	6 gm	-
9.	Jeeraka (Sweta)	6gm	Fruit
10.	Dalchini	6gm	Stem bark
11.	Pippali	48 gm	Fruit
12.	Maricha	6gm	Fruit
13.	Sugar	192gm	-

Organoleptic characters, such as color, odor, and texture, provide initial sensory information about a substance. Physico-chemical analysis, including organoleptic characters, loss on drying, total ash, acid insoluble ash, water-soluble extractives, alcohol-soluble extractives, pH, bulk density, tap density, particle size, TLC (thin-layer chromatography), and heavy metal analysis using ICPMS and AAS methods, play crucial roles in standardization processes. These analyses collectively contribute significantly to ensuring the quality, purity, and safety of the product.

Observations and Results

Table 2 Results of Organoleptic Characters

Parameters	Findings
Colour	Yellowish Brown
Odor	Characteristic
Taste	Sweet-Pungent
Touch	Fine and Soft

Table 3 Physico-chemical Analysis of Yavani-Sadav Churan

Parameters	Findings
Loss on drying at 105^0 C	2.18
Total Ash	2.60
Acid insoluble Ash	Nil
Water soluble extractive value	80.37
Alcohol soluble extractive value	17.45
pH (5% aqueous extract)	4
Particle size	3.75 % material retained on 177 micron sieve.
Bulk density and Tap density	0 .70
Foreign matter	Nil

Table 4 Microbial limit of specific pathogens in Yavani –Sadav Churan

Pathogen	Findings
E. coli	Absent
Salmonella	Absent
S.aureus	Absent
P. aeruginosa	Absent

Thin Layer Chromatographic (TLC) Study:

Sample Preparation: 1 gram of the churan sample was accurately weighed and dissolved in 20 ml of methanol. The solution was refluxed on a water bath at 90-100°C for 15 minutes. After refluxing, it was filtered, and the solvent was evaporated to approximately 5 ml in a porcelain dish, which was then used for TLC profiling.

Solvent System: The solvent system, Toluene: Ethyl Acetate: Formic Acid (5:4:1 v/v), showing the best separation, was selected through trial and error. This solvent system was utilized for developing the TLC plates.

Development: Methanolic extracts were applied onto 0.2 mm precoated Silica Gel 60 F 254 plates

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Test Report

ORIGINAL

Page 1 of 2

Issued To Suman Lata Sec - 8, H. No. 642 Kurukshetra Kurukshetra,136119 Haryana,India	**Sample Reg. No.** : A01-2311090037 **Sample Reg. Date.** : 09/11/2023 **Report Date.** : 20/11/2023 **Report No.** : ICA-2311200076 **Customer Ref. No.** : Letter **Letter Dated** : Letter

Sample Particulars

Name of Sample#	: **Yavani Sadav Churan**		
Submitted By	: Suman Lata		
Batch No.#	: NS.	**Batch Size #**	: Not Specified
Manufactured By#	: Not Specified	**Mfg. Lic. No.#**	: NA
Supplied By#	: Not Specified		
Date of Manufacture#	: Not Specified	**Date of Expiry#**	: Not Specified
Sample Qty#	: 1 Pack	**Sample Condition**	: Good
Grade#	: Not Specified	**Brand Name#**	: NA
Official Seal	: Not Applicable	**Official Signature**	: Not Applicable
Packaging Details	: Packed in poly pack	**Declared values(if any)**	: Not Specified
Any Other Information	: Not Specified		
Test Report as per	: Inhouse Method	**With Amendent No.(s)**	: Not Specified

Test Results

Analysis started on : 10/11/2023 **Analysis completed on** : 20/11/2023

Description : Yellowish brown fine powder

S. No.	Parameter	Unit	Instrument	Method	Requirements	Result
	Discipline : Chemical					
	Group : Ayush Products					
1	**Chemical Parameters**					
(a)	Colour	-	Chemically	Inhouse	-	Yellowish brown
(b)	Odour	-	Chemically	Inhouse	-	Characteristic
(c)	Foreign matter	-	Chemically	Inhouse	-	Nil
(d)	Powder microscopy	-	Chemically	Inhouse	-	Sample observed under microscope
(e)	Particle size (80-100 mesh for Curna ; 40 - 60 mesh for Kvatha curna)	-	Chemically	Inhouse	-	3.75 % material retained on 177 micron sieve
(f)	Loss on drying at 105°C	-	Hot Air Oven	Inhouse	-	2.18
(g)	Total ash	-	Chemically	Inhouse	-	2.60
(h)	Acid Insoluble Ash	-	Chemically	Inhouse	-	Nil
(i)	pH (5% aqueous extract)	-	pH Meter	Inhouse	-	4.00
(j)	Water soluble extractives	-	Chemically	Inhouse	-	80.37

20/11/2023
Aditi Vyas
Reviewer

20/11/2023
Dr. Roopak Kumar
[Person In charge of Testing/Authorized Signatory]

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Figure 2 ITC Lab Report of Yavani Sadav Churan

and then developed in the above-mentioned solvent system.

Visualization: The developed TLC plates were examined under ultraviolet light at wavelengths of 254 nm and 366 nm. Subsequently, the plates were derivatized with anisaldehyde-sulfuric acid reagent and heated at 110°C until the development of colored spots. These spots were then visualized in daylight. The color and Rf values (retention factor values) of the resolved spots were noted for further analysis.

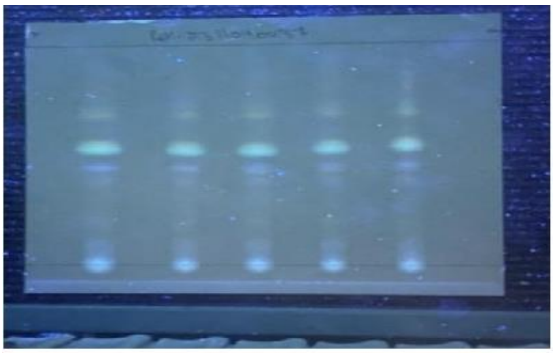

Figure 3 Photographs of TLC Screening of Yavani-Sadav Churan

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Test Report

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Page 2 of 2

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(k)	Alcohol soluble extractive	-	Chemically	Inhouse	-	17.45
(l)	Bulk density and Tap density	-	Chemically	Inhouse	-	0.70
(m)	Identification (by TLC)	-	TLC	Inhouse	-	Data submitted to customer
2	**Heavy Metals**					
(a)	Lead (as Pb)	ppm	ICPMS	Inhouse	-	0.54
(b)	Cadmium(as Cd)	ppm	ICPMS	Inhouse	-	BLQ(LOQ:0.10)
(c)	Mercury (as Hg)	ppm	ICPMS	Inhouse	-	0.22
(d)	Arsenic(as As)	ppm	ICPMS	Inhouse	-	BLQ(LOQ:0.10)

represents Customer Defined Fields
Note: BLQ- Below Limit Of Quantification, LOQ- Limit Of Quantification .
Remarks: Party asked for the above tests only.

*****End of Report*****

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Reviewer

20/11/2023
Dr. Roopak Kumar
[Person In charge of Testing/Authorized Signatory]

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Figure 4 ITC Lab Report of Yavani Sadav Churan

Table 5 Rf value of all samples of Yavani – Sadav Churan

Track	Rf Value
A	0.5
B	0.5
C	0.5
D	0.53
E	0.55

AAS Method for Heavy Metal Analysis:

For the determination of trace elements and heavy metals, an Atomic Absorption Spectrophotometer (AAS) equipped with a deuterium lamp for background correction was employed.

The analysis utilized hollow-cathode lamps for Zinc (Zn), Cadmium (Cd), and Lead (Pb) as radiation sources. These lamps emitted photons necessary for the analysis.

Two types of flames were used in the analysis: air/acetylene and nitrous oxide (N2O)/acetylene. These flames provide the necessary conditions for atomization and excitation of the metal ions in the sample.

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Additionally, nitrogen was utilized as a carrier gas to transport the sample through the spectrophotometer for analysis. This method allows for accurate determination of heavy metal concentrations in the sample.

Table 6 Heavy metals analysis by ICPMS and AAS method in Yavani –Sadav Churan Sample

Heavy Metal	Observed Value	Standard limit (ppm)[13]
Lead (as Pb)	0.54 ppm	10 ppm
Cadmium (as Cd)	BLQ (LOQ: 0.10)	0.3ppm
Mercury (as Hg)	0.22 ppm	1ppm
Arsenic (as As)	BLQ (LOQ :0.10)	3ppm

BLQ - Below Limit Of Quantification , LOQ – Limit of Quantification.

In the present evaluation, the presence of heavy metals, namely Lead, Cadmium, Mercury, and Arsenic, in Yavani-Sadav Churan was detected within the limits specified (Table no. 6).

DISCUSSION

Organoleptic features such as color, odor, taste, and touch are crucial indicators of a drug's quality. In this study, the color of Yavani-Sadav Churan is yellowish-brown, with a characteristic odor, sweet and pungent taste, and a fine and soft touch. These parameters provide primary information about the quality of the drug. Organoleptic and physico-chemical parameters play a significant role in standardization.

Determination of loss on drying at 105°C (moisture content): The moisture content in Yavani-Sadav Churan is found to be 2.18% w/w at 105°C. This parameter is essential for assessing the moisture content present in the sample, serving as a quality control parameter.

Determination of Total Ash: The total ash content is 2.60% w/w. This determination helps assess the quality and purity of drugs by removing organic matter from the sample and determining the amount of inorganic matter present.

Determination of Acid Insoluble Ash: The acid-insoluble ash is found to be nil, indicating the absence of inorganic matter. This parameter measures the amount of silica present in the sample.

Determination of Alcohol Soluble Extractives: The alcohol-soluble extractives are found to be 17.45% w/w. This determination helps assess the amount of active constituents extracted with solvents from the drug, serving as a quality control parameter.

Determination of Water Soluble Extractives: The water-soluble extractives are found to be 80.37% w/w. This determination impacts the potency of the drug with respect to water-soluble active principles, aiding in deciding the dose schedule.

Determination of Particle Size: Yavani-Sadav Churan is found to have a very fine particle size. Fineness significantly affects the absorption and binding of the medicine, with smaller particle sizes leading to increased absorption.

Determination of pH: The pH of Yavani-Sadav Churan is 4, indicating acidity. pH measurement is crucial for determining the acidity or alkalinity of a solution, with acidic solutions having pH values less than 7.

Determination of Bulk Density and Tapped Density: Yavani-Sadav Churan shows low values of bulk/tapped density, indicating poor flowability. Powder flow is crucial for pharmaceutical manufacturing processes, packaging, storing, and transportation.

Determination of Foreign Matter and Microbial Limit of Specific Pathogens: The absence of foreign matter and microbial pathogens such as Escherichia coli and Salmonella indicates the safety and good quality of the product.

Thin Layer Chromatography (TLC): TLC profiles obtained are essential parameters for standardization, aiding in the identification of phytochemical active constituents in the sample.

Heavy Metal Analysis by ICPMS and AAS Method: The heavy metal analysis detected the presence of lead, cadmium, mercury, and arsenic within specified limits, indicating the safety of use and absence of heavy metal toxicity in Yavani-Sadav Churan.

CONCLUSION

The analytical findings confirm that the prepared Yavani-Sadav Churan meets required quality and purity standards. Additionally, it contains essential elements beneficial for various diseases. The in-

house prepared Yavani-Sadav Churan demonstrates high quality and is free from heavy metal toxicity, making it suitable for therapeutic use.

Conflict of Interest

The authors declare no conflict of interest, financial or otherwise.

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