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A Physico-chemical assay of a herbal formulation - Smrutisudha granules

Research Article

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Abstract

Ayurveda is an ancient medical practise that focuses on the prevention of illness and the treatment of conditions that are related to the human body. Ayurveda provides information on a wide variety of herbal remedies that can be used to cure a variety of disorders. In such a scenario, standardisation is necessary for ensuring uniformity from one batch of drug production to the next and for carrying out routine drug manufacturing on a large scale. In this age of shifting lifestyles and increased public interest, the process of modifying older dosage forms and the development of new dosage forms is an ever-evolving process that makes a significant contribution to the expansion and development of scientific knowledge. Granules are produced from a refined form of *Ghana*, which is a solid preparation of herbal extract, and *Khanda Kalpana*, which are solid preparations that are comparable to granules. Because it contains medications that are *medhya*, *Smrutisudha* granules are developed for their beneficial benefits, such as boosting children's memories. In the current work, standardisation, physio-chemical properties, qualitative analysis, and chromatography (HPTLC) of *Smrutisudha* granules have been produced. Prior to its application in therapeutic settings, the standardisation of *Smrutisudha* granules will be aided by this research.

Key Words: *Smrutisudha granules,* Medhya drugs, Phytochemical Analysis, Chromatography, Ayurveda.

Introduction

Ayurveda is one among the Indian systems of medicine that contain a large number of medications that contain herbs for the prevention and treatment of a variety of diseases.

Ayurvedic drug discovery employs 'reverse pharmacology,' in which drug candidates are identified based on large-scale population use and then validated in clinical trials. According to experts, this approach can reduce drug discovery time from 12 years to 5 years or less, at a fraction of the usual cost.

Ayurvedic formulations contain a large number of bioactive principles contributed by the ingredient herbs allowing the formulation to act on a disorder through multiple mechanisms of action while being low in toxicity and side effects.

Physiochemical, Phytochemical and HPTLC analysis are the backbones of herbal drug research. These analytical methods assist in the reliable detection of phytoconstituents contained in herbal medicines even in trace amounts.

The majority of herbal pharmacopoeias now include these analytical techniques for the proper identification and standardization of herbal medications as their application in herbal drug analysis has grown in popularity. These methods provide an accurate picture of the type and concentration of phytoconstituents found in herbal medicines. A formulation must be standardized to get widespread acceptability in the modern global marketplace in order to remain relevant.

Smrutisudha granules is a medication which can be used to enhance memory in children. *Smrutisudha* granules were manufactured in a GMP certified pharmacy using standard operating procedures. As the formulation is not mentioned in ayurvedic classics, as a result a quality evaluation of the formulation is essential because the therapeutic values and efficacy of the formulation are dependent on a variety of factors. The current study has focused on pharmaceutical analysis and standardization of the *Smrutisudha* granules and quality assurance standards have been studied.

Aims & objectives

1. Identification and authentication of raw drugs used for the preparation of *Smrutisudha* granules.
2. Preparation of *Smrutisudha* granules at GMP certified pharmacy.
3. Physicochemical, phytochemical and HPTLC analysis of *Smrutisudha* granules.

Materials & methods

Collection of plant material

All raw materials for this study were purchased from the local market of Vadodara, Gujarat.

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Identification and Authentication of plant material

The identification and authentication of the raw drugs were carried out by the Raw drug authentication committee of Parul Institute of Ayurved, Vadodara, Gujarat. All the details of raw drugs have been given in table 1.

Method of preparation of the *Smrutisudha* granules

Smrutisudha granules was prepared at the Pharmacy of Parul Institute of Ayurved, Vadodara, Gujarat.

Preparation of *Kashaya*

Required quantity of all drugs were taken and soaked overnight in water (16 folds). Next day these soaked drugs were processed to heat and reduced to 1/8th as per the standard *Kashaya* Preparation. *Kashaya* was filtered through a cotton cloth and required quantity of sugar candy powder was added to it. After which it was kept on low flame (900C - 1000C) for boiling until it attained two thread consistency of sugar syrup.

Preparation of *Smrutisudha* Granules

As the mixture attained sugar syrup consistency vessel was taken off from the heat source, to this fine powder of the drugs and honey were slowly added with continuous stirring to attain homogenous mixture and uniform mass. This mass was passed through a sieve (# 20) and converted into granules form. Granules was dried at room temperature and later it was oven dried at 60^{0}C.

The granules were packed in air tight containers and labelled as *Smrutisudha* granules.

Table 1: Ingredients of *Smrutisudha* granules

Sl no.	Drug	Scientific Name	Family	Parts Used
1	*Brahmi*	*Bacopa monnieri* (L.) Pennel	Scrophulariaceae	Whole Plant
2	*Shankhapushpi*	*Convolvulus pluricaulis* Choisy.	Convolvulaceae	Whole plant
3	*Jatamansi*	*Nardostachys jatamansi* (Jones) DC.	Valerianaceae	Root
4	*Vacha*	*Acorus calamus* L.	Acoraceae	Root and bark
5	*Gorakhmundi*	*Sphaeranthus indicus* L.	Asteraceae	Whole plant
6	*Yashtimadhu*	*Glycyrrhiza glabra* L.	Fabaceae	Rhizome
7	*Ela*	*Elettaria cardamomum* (L.) Maton	Zingiberaceae	Seeds
8	*Twaka*	*Cinnamomum verum* J.Presl	Lauraceae	Bark

Methods of evaluation of Smrutisudha granules

Smrutisudha granules was analyzed by using standard qualitative and quantitative parameters. Organoleptic characters, physicochemical parameters etc. were analyzed at Central Research Laboratory, Parul Institute of Ayurveda, Vadodara, Gujarat and HPTLC study done Central Research for Development Laboratory, Parul University, Vadodara, Gujarat. (Sample ID-02 Dated: 04/10/2022).

Organoleptic characters

It includes parameters like color, odor, taste, consistency (1).

Physio-Chemical Analysis

It includes parameters like Loss on Drying, Total Ash Value, Acid Insoluble Ash, Water Soluble Extractive, Alcohol Soluble Extractive, pH Value, Bulk density, Tap density, Angle of repose, Mesh analysis and total sugar. (2)

Qualitative analysis

The qualitative analysis of *Smrutisudha* granules was done for alkaloids, tannins, starch, flavonoids, glycoside, triterpenoids and essential oil (3).

Chromatography

Smrutisudha granules were examined using high performance thin layer chromatography (HPTLC). HPTLC is an advanced instrumental technique based on the whole capabilities of thin-layer chromatography. It is an effective analytical tool for obtaining chromatographic information on complex mixtures of inorganic, organic, and biomolecular substances because of its automation, scanning, comprehensive optimization, selective detection principle, minimum sample preparation, hyphenation, etc. (4)

Results and Discussion

Smrutisudha granules were prepared in a GMP certified pharmacy of Parul Institute of Ayurved, Vadodara by using standard operating procedures and subjected to qualitative and quantitative analysis. The pharmaceutical analysis findings are discussed further below.

Organoleptic Characteristics

The organoleptic parameters are the fundamental criteria for verifying the finished formulation's quality. The finished formulation's had granular texture. Because of the unique properties of the ingredients used, the color was sage green, the taste was sweet, and the smell was aromatic. All the details of organoleptic parameters have been given in table 2.

Table 2: Organoleptic Characteristics of *Smrutisudha* granules

Sl.No	Sample	Smrutisudha Granules
1	Color	Sage green
2	Odor	Aromatic
3	Taste	Sweet
4	Consistency	Granules

Physio-Chemical Analysis of *Smrutisudha* granules

Loss on drying

Loss on drying of samples shows that there is no microbial growth or insect infestation, as the samples are free of excess water content. The loss of drying in the sample of *Smrutisudha* granules was observed to be 2.50%, indicating that the samples have a long shelf life and won't degrade when stored.

Total Ash and Acid Insoluble Ash

It gives more knowledge on adulteration, substitution, and contamination. Low amounts of inorganic matter and silica content are indicated by low total ash and acid insoluble ash. In this sample, the value of *Smrutisudha* granules Total Ash was 9.95%, & Acid insoluble Ash 2.45%.

Water and Alcohol Soluble Extracts

The percentages of water-soluble extract and alcohol-soluble extract in the sample of *Smrutisudha* granules were 84% and 23.4%, respectively. The medication is best suited for extraction using water or water-based preparations due to the high solubility of the sample in water.

pH Value

Understanding the pharmacological foundation of medication absorption and metabolism requires an understanding of pH, which is used to determine the acidity or alkalinity of the drug's aqueous solution. Since the pH of the *Smrutisudha* granules in this sample was 7 percent, it is obvious that the substance being tested was neutral in nature.

Bulk density

The bulking properties of a powder are determined by how the sample was prepared, treated, and stored, i.e. how it was handled. The particles can be packed to have a variety of bulk densities, and even minor disturbances to the powder bed can result in a change in bulk density. The bulk density obtained for *Smrutisudha* granules was 0.887.

Tap density

The tapped density of a powder is the mass-to-volume ratio of that powder after a specified amount of time has been spent tapping it. A powder's tapped density represents its random dense packing. (5) At 10 and 20 taps, the tap density of *Smrutisudha* granules was 0.887% and 0.934%, respectively.

Angle of repose

Granular materials behaviour can be affected by their fabric and structural qualities, or by inter-particle properties like the angle of repose. Based on the findings of this research, it is clear that the angle of repose of granular material is a critical parameter for first understanding the micro-behavior of granular material and then relating it to the macro-behavior. (6). The obtained angle of repose was 0.239 degrees.

Mesh analysis

Mesh analysis is a particle size measurement that is frequently used to determine the particle-size distribution of a granular material. The value acquired for the mesh analysis of *Smrutisudha* granules 10-20# mesh, 20-40# mesh, 40-60# mesh, 80# mesh, 80-120# mesh was 86%,8.7%,2.6%,1.7% and 0% respectively.

Total sugar

After the analysis of total sugar in *Smrutisudha* granules the value obtained was 72.10.

All the details of Physio-Chemical Analysis have been given in table 3

Table 3: Physio-Chemical Analysis of *Smrutisudha* granules

Sl. No	Parameter	Value
1	Loss on Drying at 110 c(%w/w)	2.50%
2	Total Ash Value(%w/w)	9.95%
3	Acid Insoluble Ash(%w/w)	2.45%
4	Water Soluble Extractive(%w/w)	84%
5	Alcohol Soluble Extractive(%w/w)	23.4%
6	PH Value (10 % Aqueous)	7
7	Bulk density	0.887
8	Tap density (10)	0.887
9	Tap density (20)	0.934
10	Angle of repose	0.239
11	Mesh analysis	
12	10-20 # mesh	86%
13	20-40 # mesh	8.7%
14	40-60 # mesh	2.6%
15	80 # mesh	1.7%
16	80-120 # mesh	0%
17	Total sugar	72.10

Qualitative Analysis: Phytochemical screening

To determine the formulation's active principles, *Smrutisudha* granules were submitted to a qualitative examination, which revealed the presence of alkaloid, tannin, starch, flavonoid, glycoside, triterpenoids and essential oil as given in table 4.

Table 4: Qualitative Analysis: Phytochemical screening of *Smrutisudha* granules

Sr. No	Solvent	Result
1	Alkaloid	Present
2	Tannin	Present
3	Starch	Present
4	Flavonoid	Present
5	Glycoside	Present
6	Triterpenoids	Present
7	Essential oil	Present

High-Performance Thin Layer Chromatographic Study

Chromatography

The procedure was performed at Central Research for Development Laboratory, Parul University, Vadodara, Gujarat. The finished formulation *Smrutisudha* granules were analyzed using an HPTLC fingerprinting report.

Apparatus

HPTLC was done using a computerized densitometer scanner with multiwavelength scanning capability, CAMAG Linomat 5 (S/N: 280008), TLC Scanner 4 (S/N:271118) and the software used was Server HPTLC, version 3.0.20196.1

Preparation of Test solution

1 g *Smrutisudha* granules were extracted for 5 hours with a methanol content of 20 ml. The extract was filtered through filter paper. This solution was used as a control sample for quantification.

Methodology

5.0 microlitres of the extract were spotted as bands of length 8 mm at a distance of 13.4 mm on an HPTLC silica gel 60F 254 (Merck) plate using CAMAG Linomat 5 – applicator. Toluene: Ethyl acetate: Acetic acid (7: 2: 1 v/v/v) was used to develop the plates in the CAMAG twin-trough glass chamber, which had previously been saturated with the solvent for 30 minutes. The mobile phase was chosen after experimenting with various solvent systems of varying polarity. After development, the plates were dried at room temperature and scanned in absorbance mode with a CAMAG TLC Scanner. The plate was scanned at 254 nm, 292 nm, 366 nm and Rf, color spots and densitometric scan were recorded. The data was processed using the software Server HPTLC, version 3.0.20196.1

Results

Following derivatization, the plate was examined for the appearance of different bands at different Rf, and the following results were obtained:

Details of HPTLC profile of all tracks @ 254 nm: Under the 254 nm wavelength-Track -T1 of Smrutisudha granules, 4 spots were detected and starts with respect to retardation factor 0.03, 0.106, 0.352, 0.644.

Details of HPTLC profile of all tracks @ 292 nm: Under the 292 nm wavelength-Track -T1 of Smrutisudha granules, 5 spots were detected and starts with respect to retardation factor 0.031, 0.355, 0.485, 0.639, 0.784.

Details of HPTLC profile of all tracks @ 366 nm: Under the 366 nm wavelength-Track -T1 of Smrutisudha granules, 5 spots were detected and starts with respect to retardation factor 0.010, 0.082, 0.156, 0.847. As a result, the formulation is high in phytoconstituents.

Figure 1: HPTLC Chromatograph @254 nm

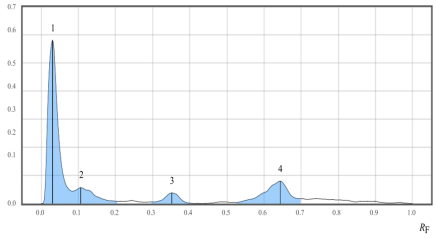


Figure 2: HPTLC Chromatograph @292 nm

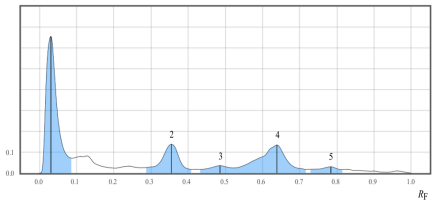
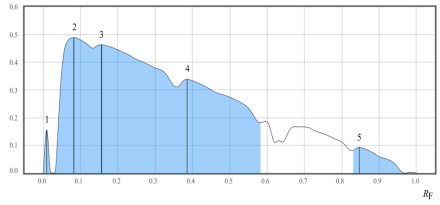


Figure 3: HPTLC Chromatograph @366 nm



Discussion

Prior therapeutic usage, every plant or medication must undergo a comprehensive analysis because the therapeutic efficacy of a medication depends upon the ingredients used in its production. Physicochemical analysis, qualitative analysis, and HPTLC were performed on the prepared formulation *Smrutisudha* granules.

Increasingly, the Ayurvedic health care system is employed to address a variety of health conditions, notably lifestyle disorders. Before being utilized in the formulation, the compounds were identified and validated pharmacognostically. The therapeutic efficacy of any plant or formulation used for medicinal purposes is based on the consistency of the ingredients employed in the manufacturing of the medicinal product. The produced medication *Smrutisudha* granules were subjected to physicochemical examination, qualitative analysis, and HPTLC. Methanolic sample of the granules were subjected to HPTLC examination, which yielded a fingerprint consisting of similarities in number, RF, intensity, and color of bands, indicating that the active ingredients present were comparable and assisting in establishing its identity. For granule consistency evaluation, HPTLC analysis utilizing toluene: ethyl acetate: acetic acid (7:2:1 v/v/v) mobile phase was determined to be suitable. All of these metrics may be used as quality control analytical standards for the formulation.

Conclusion

The investigation found that adequate quality control parameters were maintained throughout the *Smrutisudha* granules production process. Organoleptic characteristics, physicochemical parameters, phytochemical analysis, and chromatographic analysis

were utilized to compare the generated samples. Each parameter in the sample yielded extremely comparable results. The chromatogram produced from methanol extract revealed values that are comparable.

In this study, the preliminary prerequisites for the standardization of *Smrutisudha* granules have been attempted. This work will help to standardize *Smrutisudha* granules before its clinical application.

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