



**Research Article**

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## Analytical Study of *Prajasthapana mahakashya* Granules: Quality Assessment and Safety Validation

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### ABSTRACT

Background: Pregnancy loss is a common concern affecting many women, and the fear of miscarriage or abortion emotionally impacts expectant mothers. In Ayurveda, *Prajasthapana mahakashya* granules, a combination of 10 medicinal plants, are believed to play a crucial role in maintaining a healthy pregnancy. Methodology: *Prajasthapana mahakashya* was modified into granules for easy administration during pregnancy. This article presents an analytical study of *Prajasthapana mahakashya* granules, focusing on quality assessment and safety validation. The study involved pharmacognostical, physicochemical, and microbial analyses to ensure the efficacy, safety, and quality of the granules. Result: The results indicate that the granules meet the necessary quality requirements, making them suitable for use during pregnancy. Conclusion: Based on the observations, the findings of this study could serve as the reference for future work projects.

**Keywords:** *Prajasthapana mahakashya*, Granules, Analytical study, Pregnancy, Abortion.

### INTRODUCTION

It is very pleasurable experience for a couple to have a child in their life. Even though pregnancy is a normal physiological phenomenon, there is always the chance of mishappening. Among many problems associated with pregnancy, one of the most common problems which emotionally affect the mother is fear of abortion. Pregnancy loss is one of the most common adverse pregnancy outcomes and up to 20% of pregnancies end in early pregnancy loss, which is defined as a nonviable, intrauterine pregnancy within the first 12 weeks of gestation<sup>[1]</sup>. Maternal age, abnormal parental genetic makeup, infections, hormonal imbalances, uterine dysfunctions, comorbidities, and lifestyle factors are the attributable risk for higher pregnancy loss; however, the cause of miscarriage remains unknown<sup>[2]</sup>. Patki et al. study observed reported higher prevalence (32%) of spontaneous miscarriages among Indian women<sup>[3]</sup>.

Ayurveda considers food to be the best source of nourishment as well as medication for the pregnant woman. Many medicines have been mentioned in Ayurveda which play an important role in preventing miscarriage or abortion and *Prajasthapana mahakashya* is one of them. As its name suggests, *Prajasthapana mahakashya*<sup>[4]</sup> is a group of 10 medicinal plants that are helpful in maintaining a healthy state of pregnancy. It comprises 10 herbal drugs such as *Aindri* (*Centella asiatica* (Linn.) Urban.), *Brahmi* (*Bacopa monnieri* (Linn.) Wettst.), *Shatavari* (*Asparagus racemosus* Willd.), *Durva* (*Cynodondactylon* (Linn.) Pers.), *Amalaki* (*Emblica officinalis* Gaertn.), *Guduchi* (*Tinospora cordifolia* (Willd.)), *Haritaki* (*Terminalia Chebula* Retz.), *Kutki* (*Picrorhizakurroa* Royle ex Benth.) *Atibala* (*Abutilon indicum* (Linn.)), *Priyangu* (*Callicarpa macrophylla* Yahl). According to Acharya Susruta, *Hrdya* (palatable), *Drava* (liquid) and *Snigdha* (unctuous) substances should be used in pregnant women<sup>[5]</sup>. So, keeping in mind the palatability or easy administration of *Prajasthapana mahakashya*, granules were made at National Institute of Ayurveda, Jaipur, Rajasthan, India.

*Prajasthapana mahakashya* granules is formulated combination (*Anubhoot yoga*) that has been developed with the intention of being used during pregnancy, thus it is important to thoroughly assess the product's efficacy, safety and quality. It is utmost important to regulate the quality standards of herbal medications & products, and testing is one way to make sure that these levels are met. The first step in standardization is to identify and evaluate the legitimacy of herbs. The use of modern analytical techniques for herbal drug analysis is crucial for the approval of ayurveda and traditional herbs<sup>[6]</sup>. Physicochemical and pharmacognostical studies, as well as organoleptic testing, are essential parameters

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for standardization and authentication. Studies using both microscopic and macroscopic methods can help to verify the authenticity of genuine herbs and identify adulterants. To ensure the quality standards of the individual raw drug and the final product, pharmacognostical and pharmaceutical standards of *Prajasthapana mahakashya* granules were done in present study.

## MATERIAL AND METHOD

### Collection and authentication of drugs

Individual raw drugs (Figure 1) namely Whole plant of, *Aindri* (*Centella asiatica* (Linn.) Urban.), whole plant of *Brahmi* (*Bacopa monnieri* (Linn.)

Wettst.), Root of *Shatavari* (*Asparagus racemosus* Willd.), Whole Plant of *Durva* (*Cynodactylon* (Linn.) Pers.), fruit of *Amalaki* (*Emblica officinalis* Gaertn.), stem of *Guduchi* (*Tinospora cordifolia* (Willd.), Fruit of *Haritaki* (*Terminalia Chebula* Retz.), Rhizome of *Kutki* (*Picrorhiza kurroa* Royle ex Benth.) Root of *Atibala* (*Abutilon indicum* (Linn.), Seeds of *Priyangu* (*Callicarpa macrophylla* Yahl.) and Sita (Sugar) were procured from Pharmacy of NIA, Jaipur. The authentication and standardization of the raw drugs were done in Pharmacognosy Lab of Dravyaguna department, National Institute of Ayurveda, Jaipur. The Ayurvedic Pharmacopoeia of India (API) standards were used to authenticate the drugs based on morphological traits, organoleptic properties, and powder microscopy of each medicine.



Figure 1: Individual drugs of *Prajasthapana mahakashya* granules

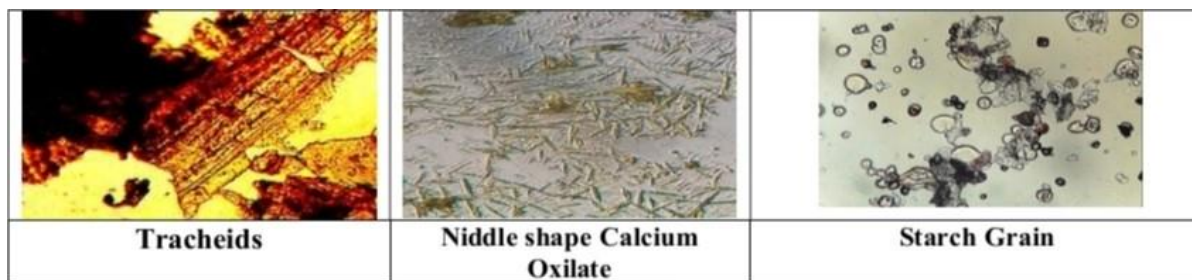


Figure 2: Microscopic study of *Prajasthapana mahakashya* granules

#### Method of preparation of *Prajasthapana Mahakashya* Granules

- 1) Preparation of *Kwath*: *Prajasthapana mahakashya* granules was prepared in National Institute of Ayurveda, pharmacy. The raw drugs [Table 1] were made into coarse powder. From this coarse powder, 1/8 part were separated and made into fine powder. The Rest of coarse powder was placed into the fire with 8 times the total quantity of drugs. The mixture was heated and stirred continuously throughout the process until ¼ quantity of water remained. It was then filtered through a cotton cloth. This prepared *kawth* (decoction) was used for further process.
- 2) Preparation of *Granules*: For preparation of granules, prepared *kwath* of *Prajasthapana mahakashya* and *Sharkara* (Sugar) were heated over mild heat till the mixture attained a thread consistency. At this stage, vessels taken out from heat source and stirred continuously. Fine powder of *Prajasthapana mahakashya* was added and mixed well to form a homogenous mixture and was allowed to cool. The mixture then passed through No. 12 sieve to get granules. These granules were dried to get rid of any moisture and stored in air tight container [Figure 2].

**Analytical Study:** To standardize and validate the safety of *Prajasthapana mahakashya* granules for the internal use, the final product was standardized and tested for organoleptic parameters, Phytochemical test, physicochemical analysis, and microbial analysis were done. All these analyses were done in GMP certified laboratory.

#### OBSERVATION & RESULT

**Pharmacognostical evaluation:** The study was carried out in two steps.

- 1) Organoleptic characteristics: organoleptic characteristics of *Prajasthapana mahakashya* granules like color, touch, odor, taste and texture were examined and recorded as shown in table 2.
- 2) Microscopic study: The observations of microscopic characters of the drugs in *Prajasthapana* granules were compared with the standards of the individual drugs mentioned in Ayurvedic pharmacopoeia of India. Under the microscope, Tracheids, Niddle shape Calcium Oxilate and Starch Grain has been seen. [Figure 2]
- 3) Bulk density: Bulk density refers to the mass of a granular material divided by its total volume, including the voids between particles. Bulk density of *Prajasthapana* granules observed 0.60249 gm/ml.

- 4) Tap density: It is the volume of powder determined by tapping a measuring cylinder containing weighed amount of powder [7]. The cylinder is tapped for about one minute (or 100 taps) to get constant volume. Tap density of *Prajasthapana* granules detected 0.651677 gm/ml.
- 5) Compress density: Compress density, also known as true density, refers to the mass of a material divided by its true volume, excluding the voids between particles and it was obtained 0.742609 gm/ml.
- 6) Flow property: Flow property refers to the ability of granules to flow freely. It is characterized by angle of repose. And its observed value was 29.566.

**Pharmaceutical analysis:** For Pharmaceutical study, Physicochemical analysis and thin layer chromatography (TLC) were carried out.

- 1) Physicochemical analysis: The common physicochemical parameters mentioned in API as mentioned below were analyzed for *Prajasthapana* granules and the results are depicted in table 3.
- 2) Thin layer chromatography: One technique for determining and separating the various chemical components present in a test sample is chromatography. Rf value of spots are 0.14, 0.19, 0.24, 0.29, 0.39, 0.48, 0.49, 0.58, 0.68, 0.78, 0.89, 0.95.

**Phytochemical analysis:** Phytochemical screening of *Prajasthapana mahakashya* granules revealed the presence of alkaloids, steroids, saponins, flavonoids and carbohydrates. This is represented in table 4.

#### DISCUSSION

The analytical study of granules typically involves various methods to assess their physical and chemical properties. The color of *Prajasthapana mahakashya* granule was brown and it is bitter-sweet in taste. The texture of the product was granule. The microscopic study provided insights into the structural characteristics of the individual drugs present in the granules, confirming their authenticity and quality. The bulk density, tap density, and compress density of *Prajasthapana Mahakashya* granules provide important insights into their physical properties. The bulk density of 0.602494 gm/ml and tap density of 0.651677 gm/ml indicate the degree of compaction and packing efficiency of the granules. Furthermore, the compress density reflects the ability of the granules to undergo compression, which is important for their mechanical strength and resistance to microbial ingress. Higher compress density may indicate a more compact structure, potentially reducing the likelihood of microbial contamination.

**Table 1:** Ingredients of *Prajasthapana mahakashya* granules

S. No.	Sanskrita Name	Botanical Name	Part Used	Proportion
1	<i>Aindri (Mandukparni)</i>	<i>(Centella asiatica (Linn.) Urban.)</i>	Whole Plant	1
2	<i>Brahmi (Brahmi)</i>	<i>Bacopa monnieri (Linn.) Wettst.</i>	Whole Plant	1
3	<i>Shatavirya (Satavari)</i>	<i>Asparagus racemosus Willd.</i>	Root	1
4	<i>Sahasravirya (Durva)</i>	<i>Cynodondactylon (Linn.) Pers.</i>	Whole Plant	1
5	<i>Amogha (Amalaki)</i>	<i>Embllica officinalis Gaertn.</i>	Fruit	1½
6	<i>Avyatha (Guduchi)</i>	<i>Tinospora cordifolia (Willd.)</i>	Stem	1
7	<i>Shiva (Haritaki )</i>	<i>Terminalia Chebula Retz.</i>	Fruit	½
8	<i>Arishta (Katurohini/katuka)</i>	<i>Picrorhizakurroa Royle ex Benth.</i>	Rhizome	½
9	<i>Vatypushpi (Atibala)</i>	<i>Abutilon indicum (Linn.)</i>	Root	1½
10	<i>Vishvaksenakanta (Priyangu)</i>	<i>Callicarpa macrophylla Yahl.</i>	Flower	1

**Table 2:** Organoleptic characteristics of *Prajasthapana mahakashya* granules

S. No.	Parameter	Result
1	Color	Chocolate brown
2	Touch	Smooth
3	Odor	Characteristic
4	Taste	Bitter, Sweet
5	Texture	Granule Smooth

**Table 3:** Physicochemical Analysis of *Prajasthapana mahakashya* granules

S. No.	Test	Value
1	pH	3.78
2	Loss on drying (%)	9.32
3	Aqueous Extractive Value (%)	61.85
4	Alcoholic Extractive Value (%)	45.85
5	Ether Extractive Value	9.75
6	Total Ash (%)	9.75
7	Acid Insoluble Ash (%)	3.45
8	Water Soluble Ash (%)	6.85

**Table 4:** Phytochemical analysis of *Prajasthapana mahakashya* granule

Constituents	Test	Aqueous Extract	Ethanol Extract
Carbohydrate	Molish test, Benedict test, Fehling test	+ ve + ve + ve	+ ve - ve - ve
Alkaloids	Dragendorff test Wagner's test Hager's test	+ ve - ve + ve	+ ve + ve - ve
Amino acids	Ninhydrine	+ ve	+ ve
Protein	Biuret test Xanthoprotic test Millon test	+ ve + ve - ve	+ ve + ve - ve
Saponin	Foam test	+ ve	- ve
Glycosides	Borntrager's test	+ ve	- ve
Phenolic compound	Phenolic test	+ ve	+ ve
Steroids	Salkowaski	+ ve	+ ve

Tannins	FeCl <sub>3</sub>	- ve	- ve
	Lead acetate	+ ve	+ ve
	Pot. Dichromate	- ve	- ve

#### Microbial contamination:

**Table 5:** Microbial analysis of *Prajasthapana mahakashya* granules

S. No.	Microbial contamination	Value	Reference Value	Test Method
1	Total Bacterial count	10 <sup>4</sup> /g	10 <sup>5</sup> /g	A.P.I, Part II, Vol-I, Appendices- 2.4
2	Total Fungal count	10 <sup>2</sup> /g	10 <sup>3</sup> /g	

#### Aflatoxin:

**Table 6:** Aflatoxin analysis of *Prajasthapana mahakashya* granules

S. No.	Aflatoxin	Value	Reference value	Test Method
1	Aflatoxin B1	Not Detected	0.5 PPB	A.P.I, Part II, Vol-I, Appendices- 2.7
2	Aflatoxin B2	Not Detected	0.1 PPB	
3	Aflatoxin G1	Not Detected	0.5 PPB	
4	Aflatoxin G2	Not Detected	0.1 PPB	

Flow property is a critical parameter in the pharmaceutical industry as it directly impacts the manufacturing process and the quality of the final product. Good flow ability ensures uniform distribution of the active pharmaceutical ingredients within the granules. In the analytical study of *Prajasthapana mahakashya* granules, the flow property was determined to be 29.566 by angle of repose, suggest that the granules exhibits excellent <sup>[8]</sup> flow ability.

The physicochemical analysis revealed important parameters such as pH, extractive values, and ash content, which are essential for standardization and authentication of herbal medications. In Physicochemical analysis, Low percentage of loss on drying (9.32) indicates the minimal moisture level in the finished product which reduces the chances of bacterial and fungal growth. The drug is having least hygroscopic activity with less chance of contamination of drug. Extractive value is directly relative to strength or potency of drug which estimates in different solvents. The final product contains water-soluble ingredients like sugar and carbs. This explains the formulation's high water soluble extractive value. Alcohol is a broad range aprotic solvent that is soluble in a variety of compounds, including flavonoids and molecules similar to glycosides. This is the reason for high alcohol-soluble extractive value in the formulation. Ash value is the indicator of the presence of inorganic & earthy matter in the plant. Total ash value was 9.75% that indicates less amount of inorganic material in the sample and rest was organic material that is bio human available products. Acid insoluble ash of *Prajasthapana mahakashya* granules is 3.45% that indicates the presence of siliceous matter. Water soluble ash estimate the inorganic water soluble salt in samples was found 6.85%.

Qualitative phytochemical test indicates the identification of primary metabolites (Carbohydrate, protein, fat etc) and secondary metabolites (alkaloids, glycosides tannin etc). Alkaloids were identified in aqueous and ethanol extract due to positive of Dragondroff test. Benedict test is positive in aqueous extract of sample which indicates the simple sugar

present. Fehling test was positive in aqueous extract of sample that indicates reducing sugar was present. Amino acid were present in ethanol extract due to show positive result in Ninhydrine test and protein was present in test sample due to positive in Xenthoprotic in aqueous and Ethanol extract. Foam test was positive in aqueous extract of sample that indicates saponine was present. Lead acetate test was positive in test sample that's indicating that tannin was present in sample. The presence of carbohydrate, alkaloids, Amino acids, protein, saponin, glycosides and tannins indicates the rich phytochemical composition of the granules, which may contribute to their therapeutic properties.

The microbial contamination levels in the *Prajasthapana Mahakashya* granules seem to be within acceptable limits. The total bacterial count and total fungal count are both below the reference values, indicating good microbial quality. Additionally, the presence of aflatoxins, such as Aflatoxin B1, B2, G1, and G2, is also analyzed. Aflatoxin are toxins produced by mold that can damage the liver and may lead to liver cancer and produce toxicity in vital organs of human and animals. Aflatoxin B1, B2, G1, G2 were absent in Final product of *Prajasthapana mahakashya* granules. Thin layer chromatography establish in phytochemical fingerprint profiling in drug for identity. In *Prajasthapana mahakashya* granules, TLC shows under Iodine vapors 12 spots was found. R<sub>f</sub> value of spots are 0.14, 0.19, 0.24, 0.29, 0.39, 0.48, 0.49, 0.58, 0.68, 0.78, 0.89, 0.95.

#### CONCLUSION

*Prajasthapana mahakashya* granules is intended to be given during pregnancy. Consequently, it is essential to ensure quality control that individual drugs be authenticated and the formulation be standardized. Pharmacognostical results attest to the absence of appreciable alterations in the microscopic structures throughout the *Prajasthapana mahakashya* granules preparation process, supporting the similarity between the final product and each of the component parts.

Physiochemical parameters of the granules were obtained as per standards. Based on the evidence available, it can be assumed that the formulation satisfies the necessary quality requirements. Based on the observations, the findings of this study could serve as the reference for future work projects.

#### Conflict of interest

There is no conflict of interest.

#### Funding

None declared.

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