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STANDARD MANUFACTURING PROCEDURE (SMP) OF *PREENANA MODAKA* AND ITS GRANULES

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Abstract

Background: *Preenana Modaka* is a classical formulation described in Ashtanga Hridaya for the management of *Karshya*. As the classical text does not describe a standard manufacturing procedure, pharmaceutical standardization and dosage form modification were undertaken for increase stability and palatability. Aim: To develop SMP of *Preenana Modaka* and *Preenana Modaka* Granules. Materials and Methods: Three pilot batches followed by three main batches were prepared using the optimized *Paka* methods. Raw materials were authenticated, powders were prepared using an 80# sieve, and both formulations were evaluated for pharmaceutical observations, yield, and reproducibility. Results: The average yield of *Preenana Modaka* was 99.08%, while *Preenana Modaka* Granules showed 96.37% yield. The standardized procedures produced uniform batches with proper *Paka Siddhi Lakshana*, acceptable pharmaceutical characteristics, and reproducible results. Conclusion: A Standard Manufacturing Procedure (SMP) is successfully established for both *Preenana Modaka* and *Preenana Modaka* Granules. The granule formulation preserved the classical ingredients while providing a stable, uniform, and child-friendly dosage form suitable for pharmaceutical production and pediatric use.

Keywords: *Preenana Modaka*, SMP, Pharmaceutical standardization, *Paka*, Granules

Introduction

Standardization of compound Ayurvedic formulations is essential to ensure their authenticity, quality, safety, and therapeutic efficacy. As many Ayurvedic practitioners prepare classical formulations independently for clinical use, it is necessary to establish scientifically validated quality control parameters. Therefore, standardization plays a vital role in maintaining the consistency, safety, and effectiveness of Ayurvedic medicines.

The therapeutic efficacy of any formulation depends not only on the selection of appropriate drugs but also on the dosage form, method of preparation, pharmaceutical processing, and storage stability. Classical dosage forms such as *Churna*, *Vati*, *Modaka*, *Avaleha*, and *Ghruta* were designed to enhance palatability, improve patient compliance, and ensure optimum therapeutic action according to the needs of the patient.

Among these dosage forms, *Modaka* is a secondary dosage form prepared from powdered drugs with sweetening agents such as *Sharkara* or *Guda*. It is considered a variety of *Vati Kalpana*. The classical formulation *Preenana Modaka*, described in Ashtanga Hridaya, is indicated for promoting nourishment (*Preenana*), improving strength (*Balya*), and supporting the growth of children suffering from *Karshya*.^[1]

However, the classical text mentions only the ingredients of *Preenana Modaka* and does not describe a detailed pharmaceutical procedure, standard manufacturing method, or quality control parameters. In addition, conventional *Modaka* has practical limitations such as comparatively higher moisture content, sticky consistency, shorter shelf life, and inconvenience in storage and transportation. These limitations may reduce its acceptability as a modern paediatric dosage form.

To overcome these pharmaceutical drawbacks, *Preenana Modaka Granules* (PMG) were developed as a modified dosage form. Granules were prepared by adopting the same ingredients with a modified *Khanda Paka* process, producing free-flowing granules without altering the classical composition. The modification was intended to reduce moisture content, improve flow property, facilitate accurate dosing, enhance palatability, minimize microbial susceptibility, and increase storage stability while preserving the therapeutic principles of the original formulation. Therefore, the present pharmaceutical study was undertaken to develop a Standard Manufacturing Procedure (SMP) for both *Preenana Modaka* and *Preenana Modaka Granules*, to standardize their preparation through reproducible batches, and to evaluate their organoleptic

and pharmaceutical parameters for establishing a stable and quality-assured Ayurvedic formulation.

Materials and Methods

The pharmaceutical study was carried out in two phases-

1. Procurement and authentication of raw materials
2. Preparation of drug

A. Procurement and Authentication of Raw Materials

Yashtimadhu (*Glycyrrhiza glabra* Linn.) and *Sharkara* were procured from the Government Ayurved Pharmacy, Rajpipala, Gujarat, India. *Priyala Beeja* (*Buchanania latifolia* Roxb), *Laja* (*Oryza sativa* Linn.) and *Madhu* (as per FSSAI standards) were procured from the local market of Vadodara, Gujarat. Identification and authentication of the collected raw materials were done by studying their organoleptic, macroscopic and microscopic characters and comparing them with the characters mentioned in various texts and published papers. The samples were identified at Pharmacognosy laboratory of the Upgraded Department of Dravyaguna, Government Ayurved College, Vadodara, Gujarat.

B. Preparation of Drug

All the batches of *Preenana Modaka* and *Preenana Granules* were prepared in pharmaceutical laboratory of Upgraded Department of Rasashastra and Bhaishajya Kalpana, Government Ayurved College, Vadodara, Gujarat. To develop SMP, three batches of *Preenana Modaka* and *Preenana Granules* were carried out in the following steps entitled with headings:

1. Preparation of *Churna* of *Yashtimadhu*, *Priyala Beeja*, *Laja*, *Sharkara*
2. Preparation of *Preenana Modaka*
3. Preparation of *Preenana Modaka Granules*

A total of five pilot batches of *Preenana Modaka* were prepared using the *Mardana* and *Paka* methods with different proportions of *Sharkara* to optimise the manufacturing process and obtain a properly formed *Modaka*. The pilot study was conducted to standardize the preparation method and identify the optimum sugar ratio required for desirable consistency, shape, and pharmaceutical characteristics.

Similarly, three pilot batches of *Preenana Granules* were prepared employing the *Kwatha* and *Paka* methods with varying ratios of *Sharkara*. The batches were evaluated for granule

formation, texture, flow properties, and overall process feasibility to select the most suitable manufacturing method.

Based on the optimised conditions obtained from the pilot studies, the main batches of both formulations were prepared by adopting the finalised method and sugar ratio. The same standardized procedure was reproduced in all main batches to ensure the reproducibility, uniformity, and reliability of the pharmaceutical manufacturing process.

1. Preparation of Churna of Yashtimadhu, Priyala Beeja, Laja, Sharkara

Yashtimadhu, Priyala Beeja, Laja, Sharkara were pounded in mortar and pestle individually for made small pieces and ground in the mixer grinder. *Yashtimadhu, Laja, Sharkara Churna* were sieved through 80#. Sieved fine powders were collected and packed in air tight container.

2. Preparation of Preenana Modaka

Sharkara and water were taken in a stainless-steel vessel and heated over *Mandagni*. After complete dissolution of *Sharkara*, the syrup was filtered through a cotton cloth to remove impurities. The filtrate was again heated on *Mandagni* until the *Paka Siddhi Lakshana* were attained. Thereafter, all powdered ingredients were added and mixed thoroughly to obtain a homogeneous mass. After the mixture cooled, *Madhu* was incorporated uniformly. *Modaka* of 3 g each were prepared, dried, weighed, labelled, and stored in an airtight container. Figure 1 shows the preparation of *Preenana Modaka*.

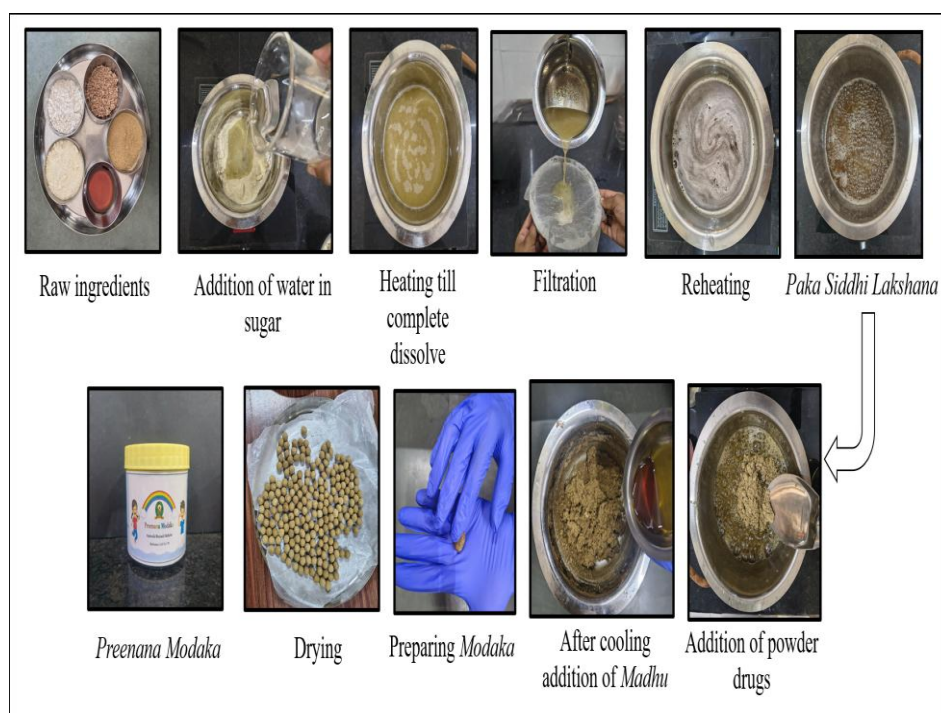


Fig. no. 1: Preparation of Preenana Modaka

3. Preparation of *Preenana Modaka Granules*

Sharkara and water were taken in a stainless-steel vessel and heated over *Mandagni*. After complete dissolution of *Sharkara*, the syrup was filtered through a cotton cloth to remove impurities. The filtrate was further heated on *Mandagni* until the *Khanda Paka Siddhi Lakshana* were attained. Thereafter, all powdered ingredients were added and mixed thoroughly to obtain a homogeneous mass. After cooling, *Madhu* was incorporated uniformly into the mixture. The mass was then passed through a 10# sieve to obtain uniform granules. The granules were dried, weighed, labelled, and stored in an airtight container. Figure 2 shows the preparation of *Preenana Modaka Granules*.

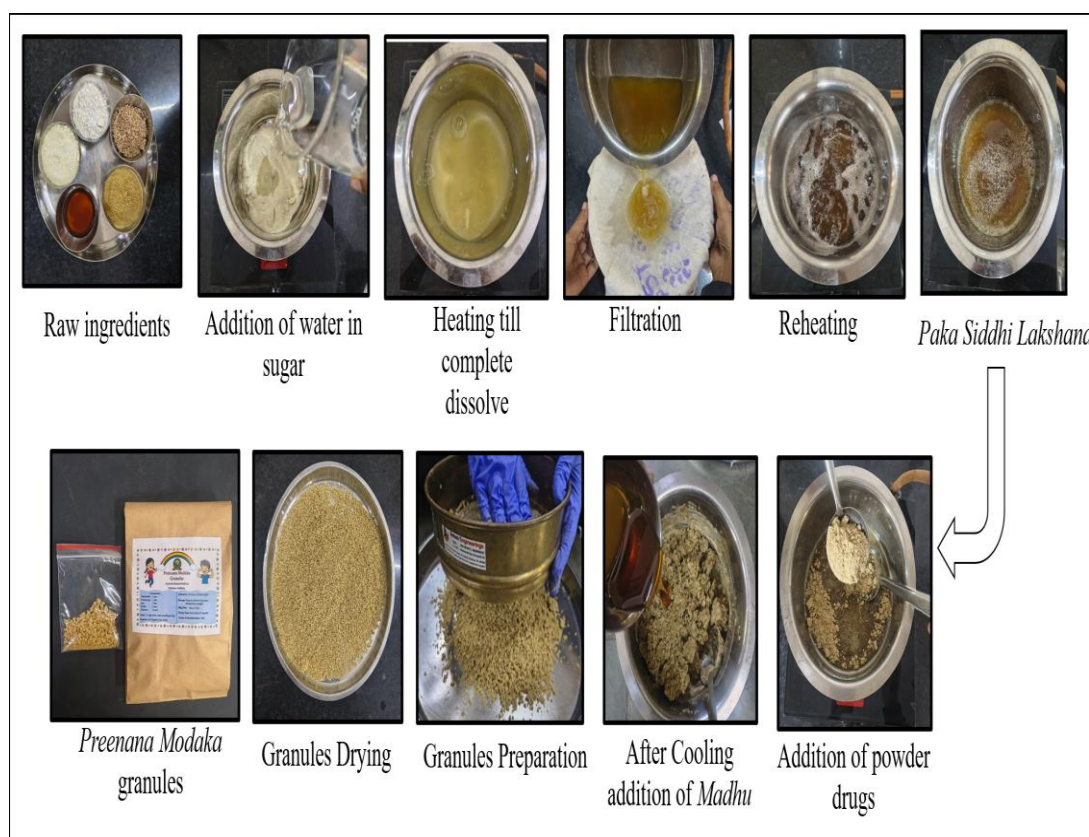


Fig. no. 2: Preparation of *Preenana Modaka Granules*

Observation and Results

1. During Churna Preparation

During pharmaceutical processing, *Yashtimadhu* exhibited a fibrous nature, causing the powder to adhere to the mixer jar and producing a characteristic sweet odour. *Priyala Beeja* showed an oily consistency, resulting in a paste-like mass that hindered the formation of fine powder and its passage through the sieve. *Laja* absorbed atmospheric moisture and became soft; therefore, mild roasting was performed to restore its puffiness and facilitate powdering. *Sharkara* produced fine airborne particles during grinding because of its dry crystalline nature.

Table no: 1 Organoleptic Parameters of Raw Materials

Sr. No.	Parameters	<i>Yashtimadhu Churna</i>	<i>Priyala Beeja Churna</i>	<i>Laja Churna</i>	<i>Sharkara Churna</i>
1	Colour	Yellowish brown	Light brown	White	Light yellowish white
2	Odour	Characteristic	Characteristic	Odourless	Odourless
3	Touch	Smooth	Smooth	Smooth, soft	Smooth
4	Taste	Sweet	Sweet	Pungent	Sweet
5	Appearance	Fine powder	Paste like	Fine powder	Fine powder

Table no. 2: Results of Churna Preparation

Sr. No.	Parameters	Unit	<i>Yashtimadhu Churna</i>	<i>Priyala Beeja Churna</i>	<i>Laja Churna</i>	<i>Sharkara Churna</i>
1	Initial quantity of drug	g	500	100	500	2000
2	Final yield of Churna	g	380.6	98	434.6	1974.66
		%	76.13	98	86.93	98.73
3	Total gain/loss	g	119.3	02	65.3	25.33
		%	23.86	02	13.06	1.26
4	Reason of loss		Due to powdering, sieving	Due to powdering	Due to powdering, sieving	Due to powdering, sieving
5	Total time taken for Churna preparation	hrs/min	7 hrs	10 min	7 hrs	2 hrs

2. Preenana Modaka

Sharkara was completely dissolved in water within 10 minutes under *Mandagni*. Progressive heating resulted in a gradual colour change of the sugar syrup from yellow to brownish yellow, indicating the development of the *Paka* stage. The characteristic *Paka Siddhi Lakshana-Tantumtva*, *Sthiratva*, and *Apsumajjanam* were observed and are presented in Table 3. Subsequently, the addition of *Priyala*, *Yashtimadhu*, and *Laja Churna* produced a homogeneous mass, with the colour changing to brown. After cooling, *Madhu* was incorporated uniformly

without altering the consistency of the formulation. 3 g *Modaka* were prepared from the mixture, which required 48 hours (2 days) of drying to achieve a stable dosage form suitable for storage.

Table no: 3 Paka Siddhi Lakshana of PM

<i>Siddhi Lakshana</i>	Time of appearance (min)			Temperature (°C)		
	B-1	B-2	B-3	1	2	3
<i>Darvipralepatva</i>	After 33 min	35	30	95.1	94.5	95.6
<i>Tantummatvam</i> – 1 thread, 2 threads	37	42	38	95.8	95.3	95.8
<i>Tantummatvam</i> – 1 thread, 2 threads	41	47	40	96.1	95.1	96.8
<i>Apsumajjanama</i>	45	49	46	96.3	95.5	97.1
<i>Sthiratva</i>	47	50	48	97.1	96	97.6
<i>Patitastu na shiryate</i>	49	53	49	97.5	97.8	97.8
<i>Addition of other ingredients</i>						
Powder ingredients	After 50 min	54	50	98	98.4	98.5
<i>Madhu</i>	After 56 min	60	55	40	39.5	39.8

Table no: 4 Result of Preenana Modaka Preparation

No.	Parameters	Unit	B-1	B-2	B-3	Avg.
1.	Initial quantity of ingredients of <i>Preenana Modaka</i>	g	800	800	800	800
2.	Final yield of <i>Preenana Modaka</i>	g	791	792	795	792.6
		%	98.87	99	99.37	99.08

3.	Total gain/loss	g	9	8	5	7.4
		%	1.13	1	0.63	0.92
4.	Reason of gain/loss		Due to sticking to the Vessel	Due to sticking to the Vessel	Due to sticking to the Vessel	Due to sticking to the Vessel
5.	Total time taken for preparation of <i>Preenana Modaka</i> (days) (<i>Modaka</i> preparation + drying)		1+2	1+2	1+2	1+2

3. *Preenana Modaka* Granules

Sharkara completely dissolved in water within 10 minutes. During heating, the colour of the sugar syrup gradually changed from yellow to brownish yellow. The characteristic *Khanda Paka Siddhi Lakshana* (*Tantummatva*, *Sthiratva*, and *Apsumajjanam*) were observed and are presented in Table 5. After the addition of all powdered drugs, the colour of the mixture changed from brownish yellow to brown, forming a homogeneous mass. Following the incorporation of *Madhu*, the mixture attained a *Khanda*-like consistency. The mass was easily passed through a 10# sieve to obtain uniform granules. The granules required 1 day for complete drying before weighing, labelling, and storage.

Table no: 5 Paka Siddhi Lakshana of PMG

<i>Siddhi Lakshana</i>	Time of appearance (min)			Temperature (°C)		
	B-1	B-2	B-3	1	2	3
<i>Darvipralepatva</i>	After 36 min	37	30	96.1	94.5	95.6
<i>Tantummatvam</i> – 1 thread, 2 threads, >2 threads	39	38	36	96.4	95.3	95.8
<i>Tantummatvam</i> – 1 thread, 2 threads, >2 threads	43	44	40	96.8	96.1	96.8
<i>Tantummatvam</i> – 1 thread, 2 threads, >2 threads	46	46	43	97.4	97.2	97.3

<i>Apsumajjanama</i>	47	48	46	97.6	97.5	97.1
<i>Sthiratva</i>	48	50	48	97.7	97.3	97.6
<i>Patitastu na shiryate</i>	49	53	49	98.6	97.8	97.8
<i>Addition of other ingredients</i>						
Powder ingredients	After 50 min	54	50	98.7	98.4	98.5
<i>Madhu</i>	After 55 min	60	55	40	39.5	39.8

Table no: 6 Result of *Preenana Modaka* Granules Preparation

No.	Parameters	Unit	B-1	B-2	B-3	Avg.
	Initial quantity of ingredients of <i>Preenana Modaka</i> granules	g	800	800	800	800
	Final yield of <i>Preenana Modaka</i> granules	g	765	772	776	771
		%	95.62	96.5	97	96.37
	Total gain/loss	g	35	28	24	29
		%	4.38	3.5	3	3.6
	Reason of gain/loss		Due to sticking to the Vessel	Due to sticking to the Vessel	Due to sticking to the Vessel	Due to sticking to the Vessel
	Total time taken for preparation of <i>Preenana Modaka</i> granules (days) (granules preparation + drying)		1+1	1+1	1+1	1+1

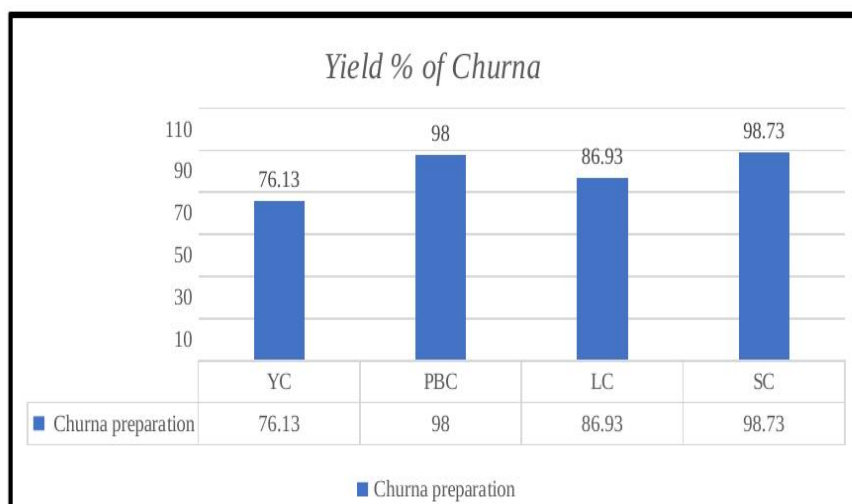
Discussion

The present study developed *Preenana Modaka* Granules (PMG) as a pharmaceutical modification without changing the classical ingredients to improve stability and patient compliance. All ingredients were authenticated by organoleptic, macroscopic and microscopic examination in the Pharmacognosy laboratory before pharmaceutical processing.

Authentication ensures the identity, purity and quality of raw drugs, which is essential for reproducible pharmaceutical preparations.

Discussion on *Churna* Preparation

The yield and processing characteristics of the four *Churna* were primarily influenced by the physicochemical nature of the raw materials. *Yashtimadhu Churna* showed the lowest yield (76.13%) due to its fibrous roots, which caused adherence to the grinder and sieve, resulting in higher processing loss. *Priyala Beeja Churna* and *Sharkara Churna* produced high yields (98.00% and 98.73%, respectively); however, the oily nature of *Priyala* reduced its free-flowing property, while the crystalline structure of *Sharkara* facilitated easy pulverisation with minimal loss. *Laja Churna* yielded 86.93%, with moderate loss attributed to dispersion of its lightweight fine particles during grinding. These findings highlight the importance of tailoring the powdering process according to the physical properties of individual ingredients to achieve uniform pharmaceutical quality.



Graph No. 1: Yield % of *Churna*

Discussion on Preparation of *Preenana Modaka*

Pilot batch optimization demonstrated that the *Mardana* method failed to produce adequate binding which mentioned in classics whereas the *Paka* method yielded a cohesive and stable *Modaka* mass. *Sharkara* proportion was identified as the critical factor for product consistency; 12 parts provided optimum binding, shape retention, and minimal processing loss. Classical *Paka Siddhi Lakshana* (*Darvipralepatva*, *Tantumatva*, *Apsumajjana*, *Sthiratva*, and *Patitastu Na Shiryate*) served as reliable indicators for achieving the desired syrup consistency and reproducible pharmaceutical quality. Controlled heating (94–98°C, *Mandagni*) prevented excessive caramelisation while ensuring proper sugar syrup formation and uniform incorporation of herbal powders. Drying standardization produced *Modaka* with an average

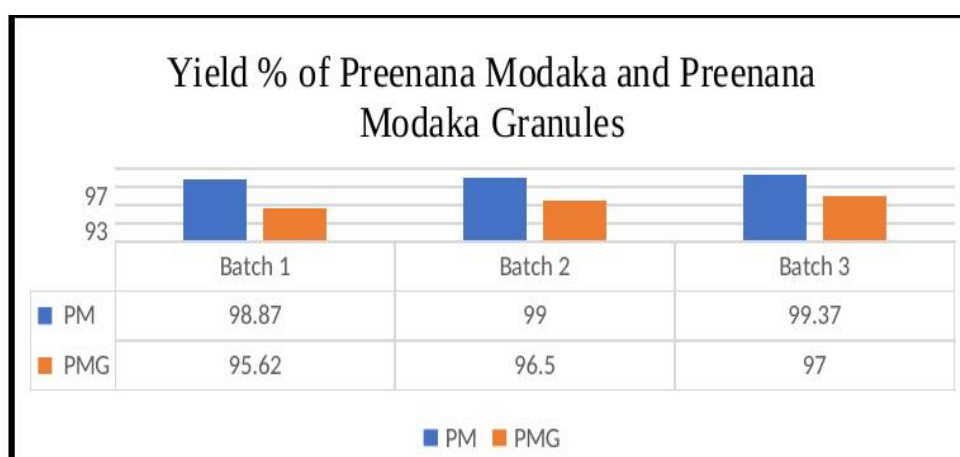
final weight of approximately 3 g, ensuring dose uniformity and better storage stability. Process reproducibility was confirmed in three main batches, with a mean yield of 99.08% and only 0.92% processing loss, indicating an efficient standardized manufacturing procedure. The optimized pharmaceutical method produced uniform, stable, and analytically suitable *Preenana Modaka*, supporting its use for subsequent quality control and clinical evaluation.

Discussion on Preparation of *Preenana Modaka* Granules

The *Khanda Paka* method produced uniform and reproducible *Preenana Modaka* Granules with optimum binding and granule formation. Achievement of classical *Khanda Paka Siddhi Lakshana* confirmed the appropriate endpoint of syrup preparation, ensuring consistency in pharmaceutical processing. The optimized formulation using 12 parts *Sharkara* facilitated cohesive granule formation and satisfactory drying characteristics.

The three main batches demonstrated excellent process reproducibility, with a mean yield of 99.08% and minimal processing loss (0.91%), mainly due to adherence of the semisolid mass to the vessel and handling during sieving. The standardised *Khanda Paka* technique therefore appears suitable for preparing stable, uniformly sized granules.

Thus, optimization through pilot batches resulted in successful preparation of *Preenana Modaka* Granules with proper binding, uniform granule formation, stable drying characteristics and consistently high yield in main batches. The *Khanda Paka* method was found suitable for large-scale preparation of granules for further analytical and clinical evaluation.



Graph No. 2: Yield % of *Preenana Modaka* and *Preenana Modaka* Granules

Conclusion

The present study successfully standardized *Preenana Modaka* and *Preenana Modaka* Granules by developing a Standard Manufacturing Procedure (SMP). The optimized *Paka* and *Khanda*

Paka methods produced formulations with uniform quality and good reproducibility. *Preenana Modaka* Granules retained the classical composition while offering improved flowability, faster drying, better storage stability, and greater suitability for paediatric administration.

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