



PHARMACEUTICAL MODIFICATION OF SAMASHARKARA CHURNA INTO GRANULES FORM AND ITS ANALYTICAL STUDY

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Abstract:

Introduction: Samasharkara churna is a classical Ayurvedic compound formulation, administered to treat various ailments. Despite of therapeutic utility, the churna form have certain limitation like poor palatability, variability in dose administration, reduced patient compliance etc. Pharmaceutical modification of traditional dosage form into new dosage form is therefore relevant to overcome such limitations. The granules are solid dosage forms in which drugs are mixed with sweetening and flavoring agents. The granule form helps in improving physical characteristic, easy dose administration, flowability etc. Hence the present study aimed to develop granule form of Samasharkara churna and evaluate it through different analytical parameters.

Aim and Objective: To modify Samasharkara churna into Granules form and carry out its analytical study.

Method: All the ingredients were collected and authenticated. The content of Samasharkara churna were divided into two categories containing aqueous soluble extractive value to prepare kwatha and containing volatile content to prepare Arka. Using these liquid medias the granules were prepared. The developed granules were subjected to systemic evaluation of organoleptic characters, physicochemical and phytochemical parameters, microbial contamination, HPTLC and shelf-life study.

Result: The prepared Samasharkara granules demonstrated acceptable organoleptic characteristic and physicochemical parameters. The microbial count remained within the normal limit. The phytochemical screening and HPTLC confirmed the presence of phytoconstituents and the raw material in the granule form. The shelf- life study ensured the quality and stability of the Samasharkara granules throughout the study period.

Conclusion: The study of modifying Samasharkara churna into Granule form demonstrated that the granules maintain acceptable quality characteristic and improve the palatability, dose accuracy and patient compliance.

Key words: Samasharkara granules, physicochemical parameter, HPTLC, Shelf-life study.

INTRODUCTION

Ayurvedic formulations are traditionally prepared in various dosage form based on the requirements and the properties of the drug. Samasharkara churna is a classical formulation mentioned in Bhaishajya Ratnavali and Yogaratnakara in treating different diseases. ^{1,2} The churna Kalpana represents one of the most widely used dosage form of fine powdered medical substances prepared according to the pharmaceutical procedure.

Although the churna Kalpana has advantages, it is also associated with certain limitations related to palatability, handling, dose administration and acceptability. In the present era, modification of traditional dosage form into more acceptable and convenient forms has gained importance to overcome these limitations. Granules are solid dosage forms of medicaments in which the powdered drugs are mixed with sweetening and flavouring agents.³ In the Ayurveda Pharmaceutics, the root meaning of the term khand is a fragment or a small piece or part or a granule. Khanda Kalpana is said to be similar to Avaleha Kalpana. However, in khanda preparation, the drava dravya and madhura dravya is boiled one step further until a granular is formed.

Khanda Kalpana is considered to have good palatability, appearance and accepted for all age groups. Screening the Ayurvedic Literature, the word khand is used for various formulations like Haridra khand etc.

Advantages of Khanda Kalpana:

- The water-soluble extractives can be effectively solidified in the khanda form.
- It is more convenient to pack, preserve and dispense.
- It helps in masking the bitter taste due to the presence of a sweetening agent

➤ Ideal characteristics of granules:⁴

1. Shape: Granules should have spherical shape.
2. Granule should have good flowability.
3. Particle size and distribution: Granules should have small particle size for uniformity, volumetric dispensing and to fill the void spaces between larger granules which aids in compaction.
4. Adequate moisture content mostly between 1-2% is required for the granules to be sufficiently dense and to prevent cracking and dusting.
5. Granules should have proper hardness and density to withstand breaking.
6. Granules should have good compressibility

In the present era of pharmaceutical research, analytical evaluation has become the essential tool for establishing the quality, safety, efficacy and stability of the formulation. The increasing demand for scientific validation of the formulation, the systemic analytical approach is very crucial. It involves evaluation of organoleptic characteristics and physicochemical analysis essential for acceptability and quality of the formulation. The phytochemical study identifies the presence of bioactive compound important for therapeutic action while the microbial contamination evaluation is crucial for the stability and safety of the formulation. HPTLC provides a characteristic phytochemical fingerprinting of the drug in the formulation. Therefore, the present study was undertaken to modify the Samasharkara churna into granule form and evaluate it through different analytical parameters and shelf-life study at 0,6 and 12months.

Aim and Objective:

To modify Samasharkara churna into Granule form and carry out its analytical study.

MATERIALS AND METHODOLOGY

1. Authentication of Drugs:

- All the raw materials are procured from authentic sources.
- All the raw drugs were identified and authenticated by the Department of Dravyaguna Vigyan, Gomantak Ayurveda Mahavidyalaya and Research Centre, Shiroda, Goa.
- Pharmaceutical preparation was carried out in the PG Department of Rasashastra and Bhaishajya Kalpana, Gomantak Ayurveda Mahavidyalaya and Research Centre, Shiroda, Goa.

2. Materials Used:

- Vessel and spoon
- An electrical weighing machine
- The Pulveriser for churna preparation
- Cloth for filtering.
- Heating equipment.
- Measuring cylinder
- Wide-mouth airtight container

Pharmaceutical Study:**Ingredients:****Table no. 1: ingredients of samasharkara churna**

Ingredients	Botanical names	Part used	Ratio
Ela	<i>Elettaria cardamomum</i> Maton	Seed	1 Part
Twak	<i>Cinnamomum zeylanicum</i> Blume	Bark	2 Parts
Tejapatra	<i>Cinnamomum tamala</i> Nees & Eberm	Leaf	3 Parts
Nagakeshara	<i>Mesua ferrea</i> Linn	Flower stamen	4 Parts
Maricha	<i>Piper nigrum</i> Linn	Fruit	5 Parts
Pippali	<i>Piper longum</i> Linn	Fruit	6 Parts
Shunthi	<i>Zingiber officinale</i> Roxb.	Rhizome	7 Parts
Sita	-	-	28parts

The ingredients of Samasharkara churna were classified into 2 categories:

1. Arka preparation:**Table no. 2: Ingredients Used for Arka Preparation**

Ingredient	Botanical name	Part used	Part	Quantity
Ela	<i>Elettaria cardamomum</i> Maton	Seed	1 Part	10 gms
Twak	<i>Cinnamomum zeylanicum</i> Blume	Bark	2 Parts	20 gms
Tejapatra	<i>Cinnamomum tamala</i> Nees & Eberm	Leaf	3 Parts	30 gms
Nagakeshara	<i>Mesua ferrea</i> Linn	Flower stamen	4 Parts	40 gms
Water	-	-	10 times	1000ml

2. Kwatha preparation:**Table no. 3: Ingredients of Kwatha preparation**

Ingredients	Botanical names	Part used	Ratio	Quantity
Maricha	<i>Piper nigrum</i> Linn	Fruit	5 Parts	50 gms
Pippali	<i>Piper longum</i> Linn	Fruit	6 Parts	60 gms
Shunthi	<i>Zingiber officinale</i> Roxb.	Rhizome	7 Parts	70 gms
Water	-	-	8 times	1440 ml



Arka and kwatha were prepared as per the method mentioned in the classics

3. Granule Preparation:

Ingredients:

Table no. 4: Ingredients used for Granules preparation

Sr. no.	Ingredients	Quantity
1.	Arka	600 ml
2.	Kwatha	360 ml
3.	Sita	960 gms

Method of preparation:⁵

- The prepared Arka and Kwatha were taken in the quantity mentioned in Table No. 4 and to that equal quantity of Sita was added and subjected to mild heat.
- Continuous stirring was done throughout the procedure; heating process was continued till the granular form was achieved.
- The formed granules were allowed to cool and then sieved to get uniform size.
- The granules were stored in the clean, wide-mouth, air-tight container.

Total quantity obtained: - 880gms

Total duration taken for preparation: -

Arka preparation: 2 hours

Kwatha preparation: 1hour 10 mins

Granule preapartion: 50 mins

Observations:

- During thickening of the mixture frothing was noticed.
- Cream colour granules with specific taste of ingredients was noted.
- Paka lakshanas were noticed.

Precautions:

- Mild heat to be maintained throughout the procedure with continuous stirring.
- Clean, dry, air-tight containers were used for storing.

Results:

a. Organoleptic characters:

Sample	Colour	Odour	Touch	Taste
Samasharkara Granules	Cream	Aromatic	Solid	Sweet and shunthi pradhana

b. Physicochemical parameters:

Analytical parameters	Samasharkara granules
Particle size	400 – 550 micrones
pH	5.6
Total ash value	6.96%
Acid- insoluble ash	1.6%v/v
Water – Soluble extractive	94.63%
Alcohol soluble extractive	7.81%
LOD at 105°C	1.45%
Reducing sugar	13.21%
Non – reducing sugar	1.35%
Specific gravity	0.581

I. Phytochemical analysis:

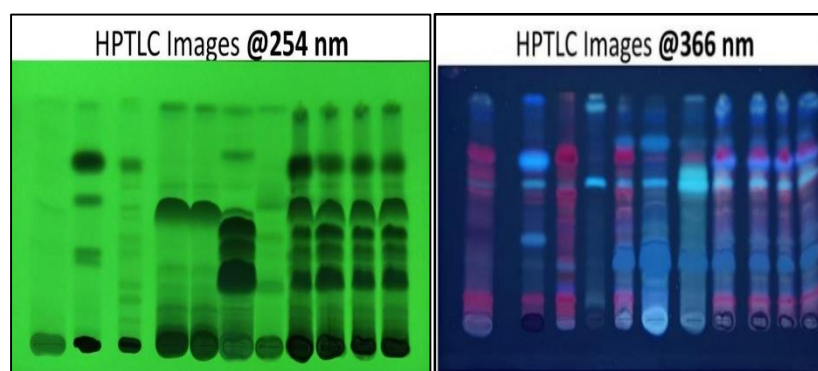
Phytochemicals	Flavones	Alkaloids	Tannins	glycosides
Samasharkara Granules	10.87%	0.04%	0.20%	33.89%

II. Microbial contamination analysis

Sample	Total microbial count CFU/gm	Pathogen E. Coli	Salmonella SP	S.Aureus	Pseudomonas Aeruginosa
Samasharkara Granules	175	Absent	Absent	Absent	Absent

III. Instrumental analysis: HPTLC

Track includes:
 Raw materials
 Samasharkara churna
 Samasharkara granules



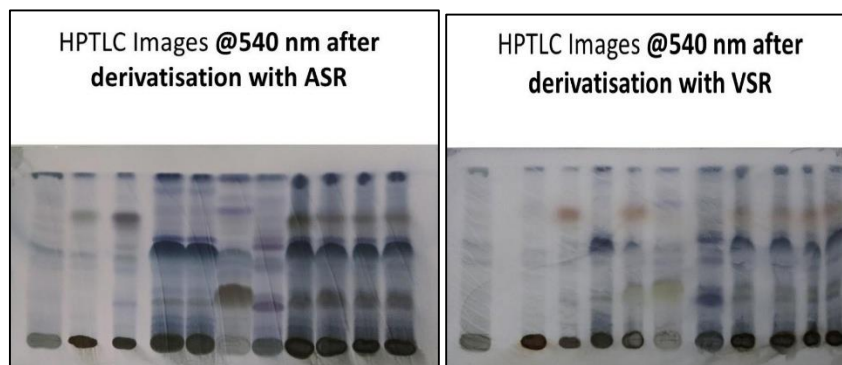
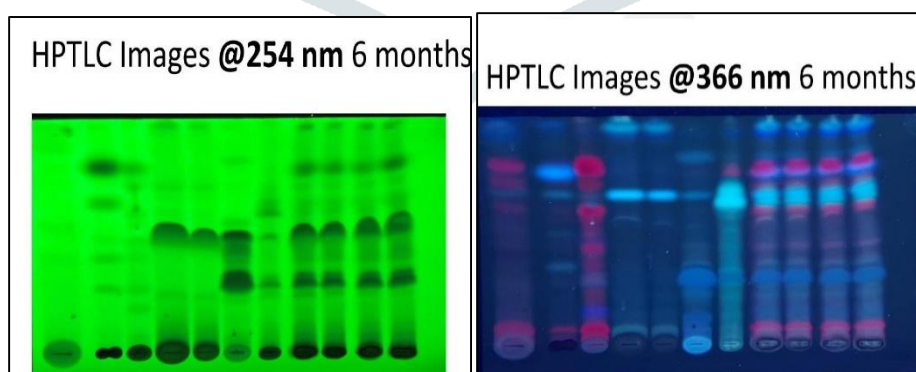
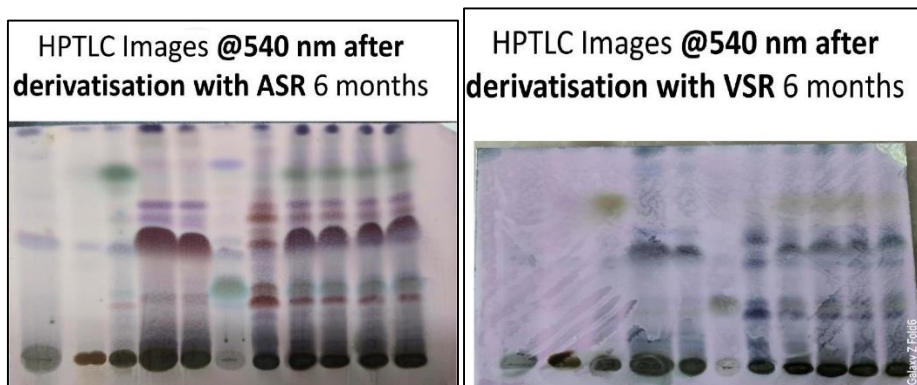


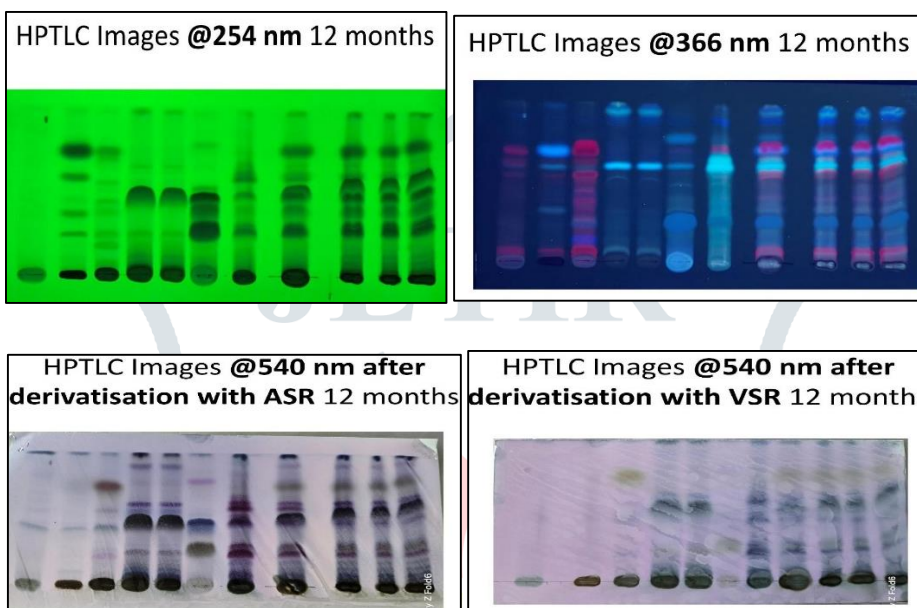
Table no. 96: Illustrating results of shelf-life study of Samasharkara Granules at 0, 6 and 12 months

Sr. no	Analysis	0 month	6 months	12 months
Physico-chemical Analysis				
1.	pH	5.6	5.5	5.4
2.	Total Ash	6.96%	6.44%	6.52%
3.	Acid – insoluble ash	1.6%v/v	1.45%v/v	1.35%v/v
4.	Water-soluble extractive	94.63%	96.44%	95.89%
5.	Alcohol-soluble extractive	7.81%	7.52%	7.34%
6.	LOD at 105°C	1.45%	1.58%	1.51%
7.	Reducing Sugar	13.21%	13.55%	13.64%
8.	Non-reducing sugar	1.35%	1.47%	1.42%
9.	Specific gravity	0.581	0.604	0.63
Microbial Contamination Analysis				
10.	Total microbial count	175 CFU/gm	188 CFU/gm	186 CFU/gm
11.	Pathogens: E.Coli, Salmonella, S. Aureus and Pseudomonas	Absent	Absent	Absent

HPTLC Profiling At 6 months:



HPTLC profiling at 12 months:



Discussion:

In the pharmaceutical modification of Samasharkara churna into granules form, the preparation of drava dravya is an important step required to extract the aqueous- soluble and volatile active components as well as the liquid medium facilitates proper mixing, wetting and binding to form the granules.

Granules are the solid dosage form that have several advantages like improved flow property, dose uniformity, packaging, ease of administration etc there by enhancing patient convenience and acceptability.

In the analytical study, **Samasharkara Granules** are characterised by a cream colour, an aromatic odour, a sweet and shunthi pradhana taste. Samasharkara granules have a pH of 5.6, which is mildly acidic. The total ash and Acid-insoluble ash values of the granules are 6.96% and 1.6%, respectively which remained in the acceptable range suggesting the purity of the formulation. The Samasharkara granules have a water-soluble extractive value of 94.63% and an alcohol-soluble extractive value of 7.81% this indicates that a portion of water- soluble constituent is higher than that of alcohol soluble extractives. The LOD value of Samasharkara granules is 1.45% suggesting that granules have low moisture content while the reducing and non-reducing sugar values revealed by the granules is 13.21% and 1.35 % respectively. The values provide the indication of sugar profile helping in assessing the quality and consistency of the granules. The Samasharkara granules have specific gravity value of 0.581 support improved flow and handling property. All the values are within the allowable limits.

The **Phytochemical analysis** of Samasharkara granules shows the presence assays like Flavones, Alkaloids, Tannins and Glycosides which are responsible for the therapeutic action of the formulations. Low alkaloid value in Samasharkara granules indicates reduction in s bitter taste. High glycoside value of granules suggests better solubilization and improved stability.

The **Total Microbial count** exhibited by the Samasharkara granules have the value of 175 CFU/gm which were within the limit of normal microbial count i.e. 1000 CFU/gm. The pathogens like E. Coli, Salmonella SP, S. Aureus and Pseudomonas were absent in all the samples indicating the safety and stability of the formulations.

The **Instrumental analysis, HPTLC** confirmed the identity and consistency phytochemicals in the formulations by forming different bands corresponding to the raw materials.

Shelf- life study:

The Samasharkara granules were analysed at 0, 6 and 12 months. The physico-chemical parameters along with microbial contamination and HPTLC were conducted. The result of physicochemical analysis and microbial contamination analysis were within the acceptable range. The HPTLC showed the presence of raw material in the significant quantity in the granule form.

Conclusion:

The results obtained through different analytical parameters were within the normal limits. It confirms that the Samasharkara granules has been successfully formulated with safety quality and stability. The organoleptic characters exhibit its acceptability whereas the physico-chemical metrics including pH, water-soluble extractive etc indicates stable and acceptable formulation. The phytochemical screening verifies the concentration of active components responsible for therapeutic efficacy and microbial evaluation ensures the safety of the formulation. The HPTLC screening showed the presence of raw material in the significant quantity. The shelf- life study at 0, 6 and 12 months showed no much variations in the different analytical parameters confirming its stability.

Further in vivo, in vitro studies can be conducted to evaluate effect, bioavailability, and safety profile of the modified dosage form. Well-designed clinical trials may be conducted to assess the therapeutic efficacy, patient compliance and safety of the granules. In addition, a comparative study can be undertaken to evaluate the effectiveness of the churna and granules.

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