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PHARAMACEUTICO - ANALYTICAL STUDY OF KAMADUGHA RASA EFFERVESCENT GRANULES: A NOVEL DOSAGE FORM

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ABSTRACT

Background: Kamadugha Rasa is a classical Ayurvedic herbo-mineral formulation widely indicated in Amlapitta (hyperacidity), Pittaja disorders, gastritis and peptic irritation. Conventionally available as tablets or powder form. Patient compliance may be reduced due to taste, swallowing difficulty, and delayed onset. Effervescent granules offer rapid dispersion, improved palatability, and faster action. **Aim:** To develop and a novel dosage form of Kamadugha Rasa Effervescent Granules and evaluate its Pharamaceutico-analytical parameters. **Methods:** Kamadugha Rasa was prepared as per classical references and blended with citric acid, tartaric acid, sodium bicarbonate, sweetener, and flavouring agents to formulate effervescent granules by dry granulation method. Analytical parameters such as organoleptic characters, angle of repose, bulk density, tapped density, Carr's index, Hausner ratio, moisture content, effervescence timeand stability were evaluated. **Results:** The prepared granules showed satisfactory flow properties, rapid effervescence, low moisture content, and good stability. The formulation was palatable and dispersed in water within 2 minutes. **Conclusion:** Kamadugha Rasa Effervescent Granules may be considered a patient-friendly innovative dosage form with potential rapid therapeutic action in acid-peptic disorders.

KEYWORDS: Kamadugha Rasa, Effervescent Granules, Novel Dosage Form, Hyperacidity.

INTRODUCTION

Drug delivery through oral route is the most common and preferred route of drug administration both for solid and liquid dosage forms. Solid dosage forms like tablets, capsules are most widely manufactured and prescribed because of the ease of administration, accurate dosage and pain avoidance. But because of unpalatable taste of drugs and difficulty for administration in case of Pediatric, Geriatric, Bed ridden patients and mentally retarded patients, the drug cannot be given as such through oral conventional method. To overcome this, a new approach i.e. development of mouth dissolving tablets and effervescent granules have been evolved.[1]

Kamadugha Rasa is a classical Ayurvedic formulation indicated mainly in Pittaja disorders and gastrointestinal complaints such as Amlapitta, Urodaha, Parinama Shoola, gastritis, and hyperacidity. Ingredients commonly include Pravala Bhasma, Mukta Bhasma, Kaparda Bhasma, Mukta Shukti Bhasma, Shankha Bhasma, Guduchi Satva, SwarnaGairika etc, possessing cooling and antacid properties.[2]

Effervescent granules are popular delivery systems for many pharmaceutical products such as antacids, laxatives, pre probiotics, cough sachets etc. They are fast dissolving, highly soluble, stable and convenient dosage forms. These are quickly dispersed by internal liberation of carbon dioxide in water due to interaction between acid with alkali, metal carbonates or bicarbonates in the presence of water. The advantages of effervescent granules compared with other oral dosage forms is, due to its faster action and easy to administer.[3]

The present aim of the study is to develop Kamadugha Rasa Effervescent Granules and evaluate its Pharamaceutico-analytical parameters.

MATERIALS AND METHODS

- Kamadugha Rasa which contains Pravala Bhasma, Mukta Bhasma, Kaparda Bhasma, Mukta Shukti Bhasma, Shankha Bhasma, Guduchi Satva, Swarna Gairika was prepared as per classical reference.
- Excipients required to prepare effervescent granules are purchased from local market of food grade.

Table no. 1: showing the Apparatus, Exicipients and quantity used in preparation of effervescent granules.

Apparatus	Exicipients	Quantity
Gas stove	Citric acid	0.64 gm
Porcelain dish	Tartaric acid	0.97 gm
Spatula	Sodium Bicarbonate	1.83gm
Sieve	SodiumSaccharide	0.54 gm
Water bath	Kamadugha Rasa	250 mg
Pair of tongs		

Method of Preparation: (Dry/Fusion method)

- Mix the powders and transfer them to a hot porcelain dish.
- Heat the powder mixture using water bath, pressing the powder with spatula to form a damp coherent mass.
- Sieve the resultant mass using sieve no.12#
- And weigh and pack 2 gm each sachet in air tight

Fig.no 1 mixing of citric acid tartaric acid along with sodium bicarbonate

Fig.no 2 adding Kamadugha rasa

Fig.no 3 formation coherent mass

Fig.no 4: sieve of mass.

Fig.no. 5: packing of granule sachets.

Table no. 2: showing the organoleptic charactertics of Kamadugha Rasa effervescent granules.

Colour	Pale pinkish white
Odor	Pleasant citrus
Taste	Sweet-sour
Particle size	Uniform granules

Angle of repose

Angle of repose is determined by using funnel method. The accurately weighed blend is taken in a funnel. The height of the funnel is adjusted in such a way that the tip of the funnel just touches the apex of the heap of blend. The drug is allowed to flow through the funnel freely on to the surface. The diameter of the powder cone is measured and angle of repose is calculated using the following equation.

Tan Θ = h/r

Where h and r are the height of cone and radius cone base respective.

Fig no. 6: Angle of repose.

Table no. 3: showing the Flow properties of angle of repose of Kamadugha Rasa effervescent granules.[4]

Angle of repose	Flow properties
<20	Excellent
20-30	Good
30-40	Slightly poor
>40	Very poor

2. Bulk density

Apparent bulk density is determined by pouring a weighed quantity of blend into graduated cylinder and measuring the volume and weight. Bulk density can be calculated by using following formula.

Bulk density = Weight of the powder / Volume of the packing.

3. Tapped density

It is determined by placing a graduated cylinder, containing a known mass of drug-excipients blend. The cylinder is allowed to fall under its own weight onto hard surface from the height of 10 cm at 2 second intervals. The tapping is continued until no further change in volume is noted.

Tapped density can be calculated by using following formula

Tapped Density = (Weight of the powder / volume of the tapped packing)

4. Hausner's ratio: Hausner's ratio can be calculated by using following formula

Hausner's ratio = (Tapped density/ (Bulk density)

Caar's Index= (Tapped density - Bulk density)

Table no. 3: showing the Compressibility indexof Kamadugha Rasa effervescent granules.[5]

Carr's index	Flow characters
1-10	Excellent
11-15	Good
16-20	Fair
21-25	Slightly poor
26-31	Poor
32-37	Very poor
>38	Extremely poor

Table no. 4: showing the Hausner's ratio of Kamadugha Rasa effervescent granules.[6]

Hausner's ratio	Flow characters
<1.25	Good
1.25-1.6	Moderate
>1.6	more cohesive powders

Fig.no.7: Buk density and tapped density.

5. Flowbility rate: to predict the flow charactertics of granules Evaluation of flowability and angle of repose aims to predict the flow characteristics of the granules. This was determined using the funnel method. The granules which weighed as much as 100 grams were put in a funnel with a closed bottom hole. At the time of measurement, the bottom hole was opened, while the time required for all the granules to flow down and form a heap was determined using a stopwatch.

Flowrate=w/t

Fig.no 8: Flowability rate.

Effervescent Cessation Time

A volume of 200 mL of distilled water was taken in a beaker, one dose of effervescent granules (3 g) was poured into the beaker, and effervescent cessation time and effervescent production were observed.

Fig no.9: Effervescent cessation time.

Physical stability

For stability study of the formulation, effervescent cessation time was carried out after the 1st month, 2nd month, and 3rd month of formulation at normal room temperature, i.e., at $27 \pm 2°$, and accelerated temperature, i.e., at $40 \pm 2°$, and also the granules were examined visually for any changes in colour, odour, and texture.

Table no. 5: Showing the analytical parameters of Kamadugha Rasa effervescent granule.

Sl. No	Test	Result
1	Angle of repose	33.7^0
2	Flowability study	1.25g/s
3	Carr‟s index	20%
4	Hausner‟s Ratio	1.25
5	Effervescent cessation time	30 sec

DISCUSSION

Kamadugha Rasa tablets may require swallowing and slower disintegration. The effervescent dosage form provides additional therapeutic advantages. When the granules are dissolved in water, citric acid and tartaric acid react with sodium bicarbonate to release carbon dioxide gas. This effervescence results in rapid dispersion and dissolution of the formulation, thereby increasing the availability of active constituents for absorption. Faster dissolution may lead to quicker onset of action and rapid symptomatic relief.

The carbon dioxide produced during effervescence improves palatability and creates a cooling sensation, which may be particularly beneficial in Pittaja disorders. The dissolved preparation also reduces direct irritation to gastric mucosa because the drug is administered in already dispersed form rather than as solid particles.

Sodium bicarbonate present in the formulation may contribute additional antacid action by neutralizing hydrochloric acid in the stomach. This may help reduce symptoms such as Amlodgara, Hritkantha Daha and Chardi. The combined effect of alkaline substances and Pittashamaka ingredients may restore normal gastric environment and reduce recurrence of symptoms.

Excellent flow property due to low Carr’s index.Rapid effervescence ensures quick dispersion and faster onset. Low moisture content prevents premature reaction. Good stability in sealed packs. The fine particle size and rapid dissolution characteristics of the effervescent granules may improve bioavailability of the drug. Immediate dispersion in water ensures uniform distribution of active ingredients, facilitating better absorption and therapeutic action.

CONCLUSION

The developed Kamadugha Rasa Effervescent Granules demonstrated satisfactory Pharamaceutico-analytical properties and can be considered a novel modern dosage form for management of Amlapitta and acid-peptic disorders. Further clinical evaluation is recommended Comparative clinical trial vs Kamadugha tablets.

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