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Review Article

A Review on Effervescent Granules

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ABSTRACT

Effervescent granules are a type of medication that comes in the form of dry powder particles, containing one or more active ingredients, and sometimes additional substances. Effervescent granules are commonly used due to their low toxicity and quick action. These granules are coated and usually contain a medication, acid compounds, and carbonates or bicarbonates, which react with water to release carbon dioxide. This review offers a comprehensive understanding of the fundamental mechanisms of effervescent granules, along with their essential properties and excipients employed. It explores different approaches for formulating and assessing the product. Various methods can be employed to prepare effervescent granules, including the wet method, dry method, hot-melt extrusion, and non-aqueous methods.

INTRODUCTION

Effervescent granules are among the most commonly used granular dosage forms for oral administration. These formulations typically consist of an effervescent base, comprising sodium bicarbonates, citric acid, and tartaric acid.(1) Effervescent granules are extensively employed in pharmaceutical products, including analgesics, antacids, and cough formulations.(2) These granules are highly soluble, stable, and exhibit rapid disintegration upon contact with water, making them a convenient and patient-friendly dosage form.(3) upon addition to water, the granules rapidly dissolve, releasing carbon dioxide as a result of the acid-base reaction between the acidic components (citric acid) and the basic component (sodium bicarbonate). The effervescence not only enhances the dispersion of granules but also improves the dissolution rate of the active pharmaceutical ingredient (api). Additionally, the release of co_2 contributes to improved taste masking, which in turn enhances patient compliance. The basic reaction in effervescent systems can be depicted as follows: 3NaHCO3 (aq) + H3C6H5O7 (aq) → 3H2O (aq) + 3CO2 + Na3CH5O7 (aq) (sodium bicarbonate +

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citric acid → water + carbon dioxide + sodium citrate) Mechanism of effervescent granules.

The process of effervescent granules involves a chemical reaction between acid and base components, facilitated by the presence of water. This reaction results in the release of carbon dioxide, which promotes the rapid breakdown of granules and the dispersion of the drug.

1. Wetting and starting: When the granules come into contact with water, the surface becomes wet, resulting in the dissolution of. The acidic component, such as citric acid, and the basic component, like sodium bicarbonate, are present in the mixture.
2. Acid-base reaction: When an acid and a base react, they form a salt, water, and carbon dioxide gas. 3NaHCO3 + H3C6H5O7 → Na3CH5O7 + 3H2O + 3CO2. (sodium bicarbonate + citric acid → sodium citrate + water + carbon dioxide)
3. CO2 evolution and disintegration: The generation of co2 produces a bubbly effect, causing the granules to break down into tiny particles. This helps ensure that the active pharmaceutical ingredient (API) is evenly distributed in the solution.
4. Improved solubility and absorption. The presence of effervescence improves the solubility and dissolution rate of apis, especially those with low water solubility. Furthermore, the bubbly action conceals unpleasant tastes, thereby enhancing patient compliance.
5. Outcome: The process leads to a uniform and enjoyable drink, with enhanced accessibility and convenience compared to traditional solid forms of medication.(4,5)

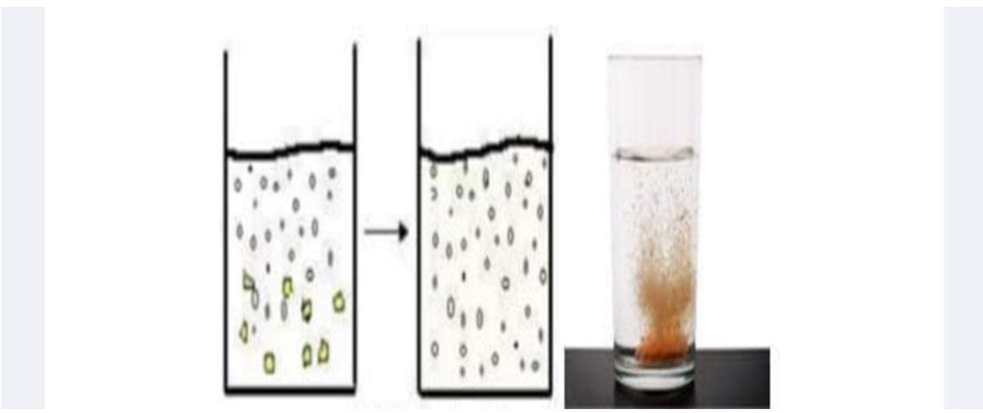

Fig No.1 Mechanism of Effervescent Granules

Fundamentals of Effervescent:

Effervescence is a result of a soluble organic acid and an alkali metal carbonate salt, with the latter often being the api. When CO2 comes into contact with water, it is released. The necessary components for effervescent granules are acid and base, along with a sweetener and a binding agent.

- Acids: Samples of such acids include Citric acid, Tartaric acid, Malic acid, Adipic acid and Fumaric acid.
- Bases: Samples of bases include Sodium carbonate, Sodium hydrogen carbonate, Potassium bicarbonate, Sodium sesquicarbonate.
- Sweetener: Mannitol, Sucrose.
- Binding Agent: Starch paste
- Vehicle: Ethanol (non aqueous method).(6)

Table No 1 : Excipient used in Effervescent Granules

Sr. No.	Excipient	Category
1	Citric acid	Acidifying agent
2	Tartaric acid	Acidifying agent
3	Fumaric acid	Acidifying agent
4	Ascorbic acid	Antioxidant
5	Sodium bicarbonate	Alkalizing agent
6	Sodium carbonate	Alkalizing agent
7	Polyvinyl pyrrolidone-30	Binding agent
8	Polyethylene glycol-6000	Binding agent
9	Mannitol	Binding agent
10	Sodium citrate	Buffering agent
11	Sodium lauryl sulphate	Lubricant
12	Sodium benzoate	Lubricant

ADVANTAGES :

1. Easy to administer for patients
2. Quick Onset of action.
3. It also mask unpleasant taste.
4. More stable than liquid dosage form. (7)

DISADVANTAGES :

1. It is not recommended for children to consume this product due to the potential toxicity of carbon dioxide gas.
2. If the packaging is not done correctly, there is a possibility of physical deterioration.
3. It has shorter shelf life compared to the other dosage form.(8)

PACKAGING OF EFFERVESCENT GRANULES

1. Effervescent packaging on market,
2. Primary packaging: blisters, bottles, tubes, sachets, and stick packs;
3. Secondary packaging: paperboard cartons, side sealed bags, and wallet packs;
4. Product type: tablets, powders, granules;
5. Material type: plastic [PE, PP, PVC], aluminium, metal . (9)

FORMULATION METHODS:

There are different ways to prepare effervescent granules, such as mixing them with water or adding them to a liquid. The wet method, hot melt extrusion technique, dry method, and non-aqueous method are the different techniques used in the production of plastic film.

1. Wet method : It is the most ancient technique of grain refinement. Initially, all the ingredients are ground into a fine powder and then passed through a sieve to ensure consistent particle size. Wet massing is the most crucial step in the wet granulation process. During this stage of the process, a granulating agent is incorporated into the powdered mixture. Once the powdered mixture is adequately dampened, it is then passed through a fine mesh screen to achieve the desired particle size. After the granules are formed, they are dried using a hot air oven. (10)

2. Hot melt extrusion technique : Firstly weigh the required quantity of ingredients and pass them through sieve no 18.Heat it a temperature of about 50o c to 80o c until a molten mass is obtained. Allow the mass to cool down to room temperature and then pass it through either sieve no8 or sieve

no10 to obtain granules. Finally, dry the granules at a temperature not exceeding 60°C. (11)

3. Dry method : It is the primary method for the preparation of effervescent granules. This fusion method eliminates the compression step. In this technique, the powders are heated using an oven or another heat source. The fusion technique utilizes the water of crystallization found in citric acids as a binding agent. The powdered mixture is thoroughly mixed to ensure a consistent mass and is then sieved to obtain granules. Finally, the granules are dried in an oven. (12)

4. Non aqueous method : The ingredients are measured and are placed into a porcelain dish. To the ingredients, gradually incorporate ethanol drop by drop until it solidifies into a mold. Pass the mould through the sieve no 10, granules are obtained & these granules are kept in an oven at an temperature of 55o c for 1-2 hrs, the granules are again passed through the sieve to obtain uniform sized granules.These granules are further packed in sachets and are stored for further use. (13)

EVALUATION OF EFFERVESCENT GRANULES

Angle of Repose

The angle at which effervescent granules tend to settle, known as the angle of repose, typically falls between 25° and 40°, with variations depending on factors such as the formulation, particle size, moisture content, and surface texture of the granules. If there is moisture or the granules are sticky, the angle of repose will rise, indicating a decrease in the flowability of the material.

$\tan \theta = h/r$

$\theta = \tan^{1} (h/r)$

Where:

θ = angle of repose (in degrees) h = height of the granule pile

r = radius of the base of the pile.

Table No 2 : Angle of repose with its flow nature

Angle of repose (degrees)	Type of flow
< 20	Excellent
20-30	Good
30-34	Passable
> 40	Very poor

2)Bulk density :

In a measuring cylinder, a specific amount of prepared granules was measured without compacting. The amount of space taken up by the granule is measured as v1 (bulk volume) bulk density can be determined using the following formula.

$$\text{Bulk density} = \frac{\text{Weight of granules}}{\text{Bulk volume of granules}}$$

3) Tapped density:

The amount of space taken up by the granule is measured as v2 (volume when tapped). In a measuring cylinder, a specific amount of prepared granules was taken and tapped 100 times to determine the density using the following formula.

$$\text{Tapped density} = \frac{\text{Weight of granules}}{\text{Tapped volume of granules.}}$$

4) Carr's index :

The percentage compressibility index of a granule served as a direct indicator of its potential strength and stability. The consolidation index of a car can be determined using the following formula.

$$\text{Carr's index} = \frac{(\text{Tapped density} - \text{Bulk density})}{(\text{Tapped density})} \times 100.$$

5) Hausner's ratio :

The flow property of the granule can be measured using Hausner's ratio. The flow property can be improved by lowering the hausner ratio, or vice versa. It is calculated using.

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

6) Effervescence time :

The time it took for the granules to dissolve in a beaker filled with 50 ml of water was measured in vitro. Granules were randomly chosen from the batch. The time it took for the solution to become effervescent was measured in a test tube. Repeat the procedure for all the prepared formulations and measure the effervescent time for each batch.

7) Disintegration test :

When effervescent granules are added to a beaker of water at a temperature between 15 and 25 degrees Celsius, a large number of bubbles of gas are released. When the liberation of gas around the granules ceases, the granules break down, either dissolving or dispersing in water. Repeat the procedure on 5 other doses. If each of the 6 doses disintegrate within 5 minutes, then the preparation meets the requirements of this test.

8) In vitro dissolution studies:

The effervescent granules can be tested using a dissolution apparatus (type 2 or type 1 if floating) at a speed of 75 rpm in 0.1N HCL, maintained at a temperature of 37 ± 0.5°c. Samples should be collected at regular intervals, up to 60 minutes, with each 1 ml withdrawal replaced by fresh medium to ensure a constant volume of 900 ml and maintain proper sink conditions. (14,15,16) .

CONCLUSION

Effervescent granules can be made to release carbon dioxide when they come into contact with water, leading to rapid disintegration and facilitating rapid drug release in solution. This leads to rapid medical intervention. Different techniques, such as the wet method, fusion method, dry method, and hot melt extrusion, with the fusion method being the most commonly employed for creating effervescent granules. This review acts as a helpful guide for future studies on the development of effervescent granule formulations.

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