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Formulation and Evaluation of Effervasant Tablet

Kawade Kartik D., Rathod Sujit S., Supekar Rohini K., Fatangde Tejas B., Bhor Vaishnavi R
Sahakar Maharshi Kisanrao Varal Patil College of Pharmacy, Nighoj
Assistant Professor, Sahakar Maharshi Kisanrao Varal Patil College of Pharmacy, Nighoj
Kawadekartik74@gmail.com

Abstract: *Oral medications are widely used despite some drawbacks, like delayed absorption. Liquid forms can help with faster absorption, but some drugs are volatile in liquid for .Effervescent formulations can help speed up drug breakdown and absorption.*

These formulations release carbon dioxide, which helps disintegrate the drug quickly . Ascorbic acid is an essential nutrient that the human body can't produce. We need to get it from external sources like food or supplements. It's an antioxidant that plays a crucial role in various bodily functions. Effervescent granules are designed to release carbon dioxide gas when they come into contact with water. This reaction helps to Break down the granule quickly, Release the active ingredient (in this case, vitamin C),Create a fizzy or bubbly effect Citric acid and tartaric acids react with sodium bicarbonate to produce carbon dioxide. Sodium bicarbonate ingredient helps to neutralize the acid and produce carbon dioxide. Calcium carbonate ingredient can help stabilize the formulation and provide additional buffering Fast dissolution The granules dissolve quickly, releasing the active ingredient. Improved bioavailability The rapid release of the active ingredient can improve its absorption in the body. Patient compliance Effervescent granules can be more pleasant to take than traditional tablets or capsules Disintegration test Measures0 how quickly the granule breaks down in water. Amount of carbon dioxide Measures the amount of gas released during the reaction.pH of formulation Measures the acidity or basicity of the final product.

Some chemicals like citric acid are stored in a form that includes water molecules bound inside their crystal structure. This is called water of crystallization. The chemical's crystal "contains" water. When you heat the material, that water "comes out" (is released).That released water, plus the small amount of water that results from the chemical reaction between acid + base, helps make the powder mixture slightly damp. This dampness binds the powder particles together, making them stick, forming a "coherent mass" (kind of like slightly wet dough).

Keywords: Vitamin c ,Release medication slowly ,Improve absorption

I. INTRODUCTION

A Oral route administration denotes the methodology of introducing pharmaceuticals or substances into the human body via ingestion, wherein the medicaments undergo dissolution and absorption within the gastrointestinal tract, facilitating systemic distribution and therapeutic efficacy. This modality of drug delivery is distinguished by its prevalence, convenience, and non-invasiveness, rendering it a preferred route for diverse therapeutic regimens.ascorbic acid, commonly known as vitamin C, is a vital water-soluble vitamin that plays an important role in maintaining good health. It is best known for its powerful antioxidant properties, which help protect the body's cells from damage caused by free radicals. This protection supports overall wellness

and helps prevent certain chronic diseases. Vitamin C is naturally found in a wide variety of fruits and vegetables. Citrus fruits such as oranges, lemons, limes, and grapefruits are particularly rich sources. Effervescence is a Latin word that means the release of gas from a liquid. Effervescent granules dissolve quickly when mixed with water or other liquids. They react fast and don't last long (they have a short half-life). When the acid and base in the granules react, they produce carbon dioxide gas, which causes bubbles and fizzing . Effervescent or carbon tablets are a specialized form of medication or supplement designed to dissolve in water, releasing carbon dioxide in the process. These tablets

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are produced by compressing powdered ingredients into a dense, compact form that facilitates rapid dissolution upon contact with water. To maintain their stability and prevent moisture-related degradation, the tablets are typically packaged in blister packs or in hermetically sealed containers. Often, the packaging includes a desiccant integrated into the cap to absorb any residual moisture and preserve the product's integrity. This unique formulation and packaging approach ensures that tablets remain effective and easy to use, offering a convenient alternative to traditional solid dosage forms. Aloe vera excels at moisturizing the skin due to its high water content (up to 99%). It provides deep hydration without leaving a greasy residue, making it suitable for both oily and dry skin types. As a natural humectant, aloe vera gel helps to lock in moisture, keeping the skin supple and reducing the appearance of dryness and flakiness.For individuals with acne-prone skin, aloe vera's composition includes salicylic acid, which helps to cleanse and purify pores, removing impurities and excess oil that contribute to breakouts. It is also known for its antibacterial and anti-inflammatory properties. These properties help in fighting acne-causing bacteria and reducing the redness and irritation associated with breakouts.In addition to hydrating and fighting acne, aloe vera can also soothe irritated skin, reduce redness, and promote faster healing of minor wounds or sunburns. Its antioxidant content, including vitamins C and E, further contributes to skin health by combating free radical damage and promoting a youthful appearance

Advantages :

- Emergency situations, such as anaphylaxis or acute asthma attacks, fast-acting medications can be lifesaving. For instance, epinephrine auto-injectors provide immediate relief during severe allergic reactions
- The development of alternative drug delivery methods has revolutionized the way medications are administered, eliminating the need to swallow tablets. These innovative approaches offer numerous benefits, particularly for patients who experience difficulty swallowing or have gastrointestinal issues
- Augmentation of Pharmacological Effectiveness
- Ensure efficacy: Precise dosing helps achieve the desired therapeutic effect.
- Minimize side effects: Accurate dosing reduces the risk of adverse reactions.

Disadvantages :

- The principal disadvantages of effervescent tablets comprise the necessity for larger tablets, specialized packaging materials, an intricate production process, and expensive excipients.
- Effervescent tablets exhibit a more palatable taste profile in comparison to conventional tablets.
- Formulation optimization
- Delivery system design

Experimental design and protocol: ingredents use from as ascorbic acid, citric acid, sodium bicarbonate, Malic acid, potassium carbonate.

Method:

Dry granulation process and tablet punching process:

The preparation of effervescent tablets involved the dry granulation process to produce dry effervescent granules. Initially, the active pharmaceutical ingredient (API) and excipients were accurately weighed and thoroughly mixed using a mortar and pestle. Subsequently, sweetening agents such as sodium saccharin were incorporated into the mixture, ensuring uniform distribution. The resulting blend was then passed through a sieve number 80 toachieve a consistent particle size, thereby guaranteeing the quality and efficacy of the final Product. The tablet punching process involves weighing approximately 400 mg of powder, which is then placed into a punching mold. Using a manually operated tablet punching machine, the powder is compressed into tablets of the desired shape and size.

This process requires careful control to ensure uniformity in tablet weight and content, ultimately producing tablets that meet the required specifications

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Sr no	ingredient s	Mg/tablet			role
		f1	f2	f3	
1	Ascorbic acid	150.5	150.5	150.5	Antioxidan t
2	Citric acid	130.5	130.5	130.5	Exfoliating agent
3	Malic acid	100	100	100	disintegrat ion
4	Sodium bicarbonat e	9.5	9.5	9.5	diluent
5	Potassium carbonate	11	11	11	dissolutio n

. ***Table no:-1*** **Formulation Table**

Pre-compression evaluation of effervasant tablet:

1. Untapped bulk density:

The untapped bulk density of the powder was determined using a volumeter, employing a standardized method. This involved pouring the powder into a graduated cylinder, allowing it to settle without external influence, and subsequently measuring the volume occupied by the powder. The untapped bulk density was then calculated based on the weight and volume measurements, providing valuable insights into the powder's physical properties and behavior

2. Tapped bulk density:

The tapped bulk density was determined by placing a graduated cylinder containing the powder on a tap density tester, which mechanically tapped the cylinder a specified number of times. This process allowed the powder particles to settle and pack more closely, reducing the volume occupied. The tapped bulk density was then calculated based on the weight and final tapped volume, providing insight into the powder's packing properties and potential flow characteristics**.**

3. Angle of repose:-

The frictional forces in a loose powder can be measured by the angle of repose, which is defined as "the maximum angle possible between the surface of a pile of the powder and the horizontal plane." The flow of powder and the angle of repose is given

tan¢=h\r

where,

h - Height of pile in cm

r - Radius of the base of the pile in cm

¢ - Angle of repose

Sr no	Angle of repose	Flow property
1	<25	Excellnt
2	25-30	Good
3	30-40	Passable
4	>40	Very poor

. *Table no:-2*

Angle of repose helps in predicting flow properties during compression. Compressibility helps in predicting the conditions to be adopted in the compression of dosage forms. To improve the flow properties of the material, glidants are added into the granules, such as magnesium stearate, starch, and talc. Generally, an optimum concentration of 1% or less is desirable to improve the flow properties of granules. Above this concentration, a decrease in flow rate was observed.

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4. Carr's Consolidation Index:-

CCI = Tapped density \Fluff density × 100\Tapped density

This property is known as compressibility. It is somewhat related to the flow rate. cohesiveness, shape and size of the particles, and moisture content.

5. Fluff Density

"the ratio of mass of powder to the fluff volume." Fluff volume is "the volume occupied by a certain mass when poured into a measuring cylinder.

Sr no	cci	Flow property
1	5-12	Excellent
2	12-16	Good
3	18-21	Fair
4	>23	Poor

. *Table no:-3*

6. Hausner Ratio:-

It may be defined as "the ratio of volume (V.) of powder bed at initial stage (ml) to the volume (Vi) of powder bed after tapping (ml)." The Hausner ratio is related to the morphology of the powder.

Hausner ratio=V0\Vf Hausner ratio:

If*

Hausner ratio value is equal to or less than 1.2—good flow property is observed because of less interparticle friction.

If Hausner's ratio value is more than 1.6, poor flow property is observed.

7. Disintegration Test:

For a drug to be absorbed from a solid dosage form after oral administration, it must first be in solution, and the first important step towards this condition is usually the breakup of the tablet, a process known as disintegration. The disintegration test is a measure of the time required under a given set of conditions for a group of tablets to disintegrate into particles that will pass through a 10-mesh screen. Generally, the test is useful as a quality assurance tool for conventional dosage forms. The disintegration test is carried out using the disintegration tester, which consists of a basket rack holding six plastic tubes open at the top and bottom; the bottom of the tube is covered by a 10-mesh screen. The basket is immersed in a bath of suitable liquid held at 37°C, preferably in a 1 L beaker. For compressed uncoated tablets, the testing fluid is usually water at 37°C, but some monographs direct that a simulated gastric fluid be used. If one or two tablets fail to disintegrate, the test is repeated using 12 tablets. For most uncoated tablets, the BP requires that the tablets disintegrate in 15 minutes (although it varies for some uncoated tablets), while for coated tablets, to2 hours may be required. The individual drug monographs specify the time disintegration must occur to meet the Pharmacopoeia standards

In the past, the only release index required for a tablet is its disintegration time, which does not necessarily measure the physiological availability of the drug in a patient. Studies have shown that the agitation of the gastric contents during normal contractions is quite mild in contrast to the turbulent agitation produced in the disintegration test apparatus. The low order of magnitude of agitation in the stomach produces substantially higher disintegration in vivo than those obtained using the USP apparatus. Furthermore, the particles of the disintegrated tablets are not dispersed throughout the stomach but remain as an aggregate.Thus, the tablet disintegration test is limited to manufacturing control of lot-to-lot variations in individual products and is not a measure of bioavailability. Nevertheless, it is used to provide a simple and useful means for monitoring and controlling the quality of tablets.Research has established that one should not automatically expect a correlation between disintegration and dissolution. However, since the dissolution of a drug from the fragmented tablet appears to control partially or completely the appearance of the drug in the systemic

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circulation, disintegration is still used as a guide by the formulator in the preparation of an optimum tablet formula and as an in-process control test to ensure batch-to-batch uniformity.Factors affecting disintegration of tablets include:
-Medium used.
-Temperature of the test media.
Operator's experience.
-Nature of the drug.
-The diluent used in the formulation.
-The type and concentration of binder used.
-Type and amount of disintegrant used, including method of incorporation.
-The presence of excessive lubricants and overly mixed lubricants.
-Compressional force used.

8. pH Test:
Measures the acidity or alkalinity of a solution.
pH range: 0-14
pH 7: Neutral
pH <7: Acidic
pH >7: Alkaline/Basic

9. Weight variation :
The weight variation test is a critical quality control measure used to assess the uniformity of dosage units, such as tablets or capsules. This test involves randomly selecting a specified number of units from a batch and individually weighing them to determine if the weights fall within acceptable limits. The weight variation is calculated and compared to established standards or specifications

10. Friability Test:-
The test involves selecting a specified number of tablets, typically 10-20, which are then weighed accurately. The tablets are placed in a friability tester, a device designed to simulate the mechanical stresses encountered during handling, packaging, and transportation.The tablets are tumbled or rotated in the tester for a predetermined number of revolutions, usually 100 or 200 times. After the test, the tablets are re-weighed, and the percentage weight loss is calculated.The friability value is expressed as a percentage, with lower values indicating greater tablet strength and durability. The test helps identify potential issues with tablet formulation, manufacturing, or packaging, ensuring that tablets can withstand handling and storage without significant degradation Tablets tumbled in a drum, then weighed
% weight loss calculated
Low %: Tablets are robust
High %: Tablets are fragile

11. n-vitro dissolution profile: Using a dissolution test:
Testing Ascorbic Acid Release from Effervescent Tablets- Equipment: Labindia
DS8000 dissolution tester Method: USP 44 compendial method
Conditions: 900 mL de-mineralized water Temperature: 37°C ± 0.5°C
Paddle speed: 50 RPM -
Time: 60 minutes- Samples: 6 tablets in each dissolution jar (total 3 jars) Sampling: 5 mL aliquots taken at 5, 15, 30, 45, and 60 minutes
Analysis: UV spectrophotometer (Shimadzu UV-1900) at 258 nm
Calculation: - Amount of ascorbic acid released (mg) = (medication concentration × dilution factor × dissolution medium volume) / 1000 % Drug released = (Amount of drug released / label claim) × 100
This test measures how much ascorbic acid is released from the effervescent tablets over time

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Improving Ascorbic Acid Tablets:

To create better ascorbic acid tablets with improved properties like density, flow, and compressibility, different formulation approaches were tried (F1-F3). These involved mixing ascorbic acid with other ingredients and effervescent granules.The study evaluated two sets of parameters 1. Pre-compression parameters: These are properties of the powder blend before compressing it into tablets.

2. Post-compression parameters: These are properties of the tablets after compression.

The goal was to compare these parameters for different formulations (F1-F3) and see which one works best.

Batches	Angleof repose	Bulk density (g/ml)	Tapped density 9g/ml)	Caars index(%)	Hausners ratio
F1	36.48	0.40	0.68	32.80	1.40
F2	30.4	0.49	0.65	24.55	1.30
f3	33.07	0.43	0.69	29.4	1.2

Table 4: **Different formulation approaches were designed (i.e.Formulation F1- F3)**

12. Loss on drying:

-loss on Drying (LOD): Measures moisture content

1. **Ash Values:**

Total Ash: Measures total mineral content

Acid-insoluble Ash: Measures mineral content not soluble in acid

Water-soluble Ash: Measures mineral content soluble in water

2. **Extractive Values:** Ethanol-soluble Extractive: Measures compounds soluble in ethanol

- Water-soluble Extractive: Measures compounds soluble in water

lod	8.3%w/w

Table no :5 **extractive value:**

Extract	Result
Ethanol soluble extractive	0.20
Aqueous soluble extractive	0.13

Table no :6

Ash value(%w/w):

Sr no	Physical constant	Result
1	Total ash	5.6%w/w
2	Water soluble ash	0.56%w/w
3	Acid soluble ash	1.12%w/w

Table no:- 7

Post compression study :

Tablet weight:

Weight variation is a crucial parameter that ensures each tablet contains the correct amount of active ingredient. According to the United States Pharmacopeia (USP), tablets weighing over 400mg should have a weight variation within ±5%. This tight tolerance ensures that patients receive the intended dose of the medication.

pH of Effervescent Solution

The pH of the solution after disintegration is crucial, especially for sensitive active ingredients. Typically, the pH range is between 4.5 and 6.0, depending on the acid-base ratio and active ingredients. The solution should not be highly acidic

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or alkaline to ensure stability and efficacy of the medication. A pH range that is too far outside this range could potentially affect the stability or bioavailability of the active ingredient.

Tablet Hardness

Effervescent tablets require a delicate balance of hardness and disintegration properties. They need to be hard enough to withstand handling and storage but still disintegrate rapidly when added to water. Typical hardness values for effervescent tablets range from 4-8 kg/cm². This balance is critical to ensure that the tablets can withstand the rigors of packaging and transportation while still providing the desired effervescent properties.

Tablet Thickness

The thickness of effervescent tablets can vary depending on the formulation, but it is typically between 4-10 mm for large tablets. Minimal variation (±5%) is essential to ensure consistent quality and to prevent issues during packaging and storage. Uniform thickness also ensures that the tablets disintegrate consistently in water.

Friability

Friability is a measure of the tablet's ability to withstand abrasion and breakage. According to USP and British Pharmacopoeia (BP) standards, effervescent tablets should have a friability of less than 1% weight loss. Due to their fragile nature, specialized coating or packaging may be necessary to prevent breakage and ensure that the tablets remain intact during handling and storage.

Effervescent Time

Effervescent tablets are designed to disintegrate quickly in water, releasing their active ingredients. According to the USP, complete disintegration should occur within 5 minutes in 200mL of water at a temperature between 20-30°C. This rapid disintegration is critical to ensure that the medication is released quickly and consistently.

Parameter	Observation (f3)
Tablet weight(mg)	400
Tablet hardness(kp(kgf)	5.9
Thikness(mm)	3.2
Friability(%)	0.4
Effervesant time(seconds)	135
Effervescent solution ph	6.2

***Table no :-8* stability parametes:**

No change in appearance (color, odor, texture, smoothness)
Slight change in pH at high temperature (40°C)

Sr no	parameter	At room temp	At 400c
1	colour	No change	No change
2	Odour	No change	No change
3	Texture	Good	Good
4	Smoothness	Smooth	Smooth
5	Ph	5.8	5.7

Table no:-9

II. CONCLUSION

Dry granulation process Works well for making tablets Key ingredients Sodium bicarbonate and citric acid greatly affect the quality of effervescent granules with ascorbic acid, grape seed extract, and aloe vera extract Herbal dosage

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form: Formulating plant extracts into a suitable dosage form is more effective than using raw plant materials or isolated compounds.

The study evaluated the quality of effervescent tablets prepared with a combination of ingredients, including ascorbic acid (vitamin C), citric acid, tartaric acid, sodium bicarbonate, calcium carbonate, sodium saccharin, and aspartame. The results showed that these tablets met the required standards for various quality parameters.Key Findings- pH Level The tablets had a suitable pH level, which is essential for ensuring the stability and effectiveness of the active ingredients.-Disintegration Time: The tablets dissolved quickly, releasing their active ingredients in a timely manner. This is important for ensuring that the tablets are easy to consume and provide the desired benefits.Carbon Dioxide Release: The tablets released the right amount of carbon dioxide, which is essential for creating the fizzing effect that is characteristic of effervescent tablets. Overall Outcome The study found that the effervescent tablets met all the required standards for quality, indicating that they are suitable for consumption and can provide the desired benefits. The results of this study can be useful for manufacturers of effervescent tablets, as well as for researchers and developers who are working on similar products.

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