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Formulation and evaluation of effervescent tablet

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Abstract
Despite certain drawbacks as compared to alternative techniques, oral dose forms remain the most widely used way to dispense medications. One such drawback is the possibility of delayed drug absorption, which can be prevented by administering the drug in liquid form, thus enabling a lower dosage. However, the usage of many medications is restricted due to their volatility when taken in liquid dosage form. The effervescent method, which is commonly used in fast release preparations, can be used to create a dose form that can hasten the breakdown and disintegration of drugs. Ascorbic acid (vitamin C), a potent antioxidant, cannot be produced by the human body and must instead be obtained through external sources like food and drugs. Grape seed extract contains antioxidants that can help delay the aging process. As you age, your skin becomes less soft, thus anti-aging skincare products with calming and restorative active ingredients are essential. Numerous polyphenols can be found in grape seed extracts. Aloe vera is frequently used as an ingredient in pharmaceuticals due to its anti-inflammatory properties, which reduce pain, swelling, and redness. Because effervescent pills have a quicker beginning of action and faster absorption, they are suitable for conditions like pain or inflammation that need to be treated right away. Creams, on the other hand, are primarily used for localized skin diseases and provide customized treatment.

Keywords: Ascorbic acid, effervescent tablet, floating delivery system, grapes seeds

Introduction
Ascorbic acid, also known as vitamin C, is a water-soluble vitamin with potent antioxidant qualities. Vitamin C is found naturally in citrus fruits and the majority of other fruits and vegetables. It serves a variety of purposes, such as preventing respiratory tract infections and lowering the risk of cardiovascular illnesses and even cancer. Additionally, vitamin C increases the processes of collagen synthesis and iron absorption. Conversely, if vitamin C is not consumed, vitamin C deficiency diseases, such as scurvy, will develop. Scurvy symptoms include bleeding gums and an increased risk of hemorrhage because blood capillaries are fragile, as well as fatigue and psychological problems like depression, hysteria, and social introversion. Effervescent tablets are made to shatter when they come into touch with liquids like juice or water, which frequently results in the tablet dissolving into a solution. Carbon tablets, often known as effervescent tablets, are made to dissolve in water and release carbon dioxide. They are made by compressing powdered component materials into a dense mass and then packaging them in blister packs or in a hermetically sealed container with a desiccant built into the top. They are used by dropping them into water to create a solution. The powdered materials can also be granulated and marketed as effervescent granules, or they can be packaged and marketed as effervescent powders. Before being formed into tablets, powdered components are often first granulated. Effervescent tablets are made to shatter when they come into touch with liquids like juice or water, which frequently results in the tablet dissolving into a solution. Because of this, many people, including those taking pills for medical purposes and as dietary supplements, prefer effervescent tablets. Aloe vera is a great moisturizing agent for your dry, lifeless skin because it contains a significant amount of water. Aloe vera's salicylic acids help to clear your skin's pores, which is essential for acne treatment. Aloe vera's antibacterial and anti-inflammatory qualities help to prevent infections and lessen acne's redness and irritation [1].

Advantages of Effervescent Tablet

- Effervescent offers the following benefits. Effervescent pills' main benefit is their ease of dissolution, which allows patients to quickly get precise dosages.
- Those who are dehydrated will benefit most from efficiency tablets since they rapidly replenish electrolytes in the body.
- The consumer may find efficiency tablets more appealing than conventional dose forms.
- Compared to the tablet and capsule dosage form, it could have a higher concentration of active components.
- Effervescent tablets, on the other hand, dissolve rapidly and fully, ensuring that you receive the full benefit of the components distributed more equally, whereas conventional tablets dissolve slowly, which may result in decreased absorption rates.
- Once consumed, conventional tablets dissolve gradually in the stomach, often just partially dissolving, which can cause irritation.

Disadvantages of Effervescent Tablet

- The primary drawbacks of effervescent tablets are the requirement for bigger tablets, specialized packaging materials, a complicated production process, and costly excipients.
- Because it contains a lot of salt or potassium, it is not appropriate for individuals who have heart failure or cardiac insufficiency. It is also more expensive than traditional tablets because the majority of the elements are very pricey.
- It might be challenging to develop active pharmaceutical ingredients (API) with an undesirable taste and odor.
- Pleasant taste compared to regular tablets [2].

Materials and Methods

Materials

Grapes seed extract were manufactured at Indian Agri Farm 9 -70, church street, Chettikulam, Tirunelveli, Kanaykumari, Tirunelveli - 627120, Tamil Nadu, India. other excipients use from as ascorbic acid, alovevera, citricacid, sodium bicarbonate, Mannitoi, Saccharrin, polyvinylpyrrolidone.

Methods

Preparation of Effervescent Tablet Dry Granulation Methods

Effervescent granules were made using the dry granulation process. After the API and excipients were weighed as shown in table no. 1 and triturated using a mortar and pestle, materials such as sodium saccharine were added, mixed, and run through sieve number 80.

Tablet punching

About 400 mg of powder should be weighed before being placed in a punching mold and the necessary number of tablets punched using a manually operated tablet punching machine [3].

Materials

Table 1: After the API and excipients were weighed

	Ingredients	Mg/tablet			Role
		F 1	F 2	F 3	
1	Ascorbic Acid	133	133	133	Antioxidant
2	Grapes Seed Extract	106	106	106	Skin Conditioning
3	Alovera	94	94	94	Anti-Inflammatory
4	Citric Acid	30.5	26.5	20.2	Exfoliating Agent
5	Sodium bicarbonate	22.5	26.5	32.5	Diluent
6	Mannitol	7	7	7	Disintegrant
7	Sodium Saccharin	3	3	3	Sweetener
8	Polyvinylpyrrolidone	4	4	4	Binder

Evaluation of Effervescent Tablet

Untapped bulk density

Untapped bulk density analysed using volumeter by the method mentioned in United States Pharmacopoeia: General Chapter on bulk density <616> [4].

Tapped bulk density

Tapped bulk density is determined by placing a graduated cylinder by the method mentioned in United States Pharmacopoeia: General Chapter on tapped density <616> [5].

Hausner's ratio

It is an indirect index of measuring granules flow by the method mentioned in United States Pharmacopoeia: General Chapter on powder flow <1174>. Lower Hausner's ratio (<1.25) indicates good flow property of granules [6].

Compressibility (Carr's index)

It is an indirect index of measuring granules flow by the method mentioned in United States Pharmacopoeia: General Chapter on powder flow <1174> [6]. Lower Carr's index (between 15 and 20%) indicates fair compressibility property of the granules.

Angle of repose

It was determined by the method mentioned in United States Pharmacopoeia: General Chapter on powder flow <1174>. [6] Table 3 below mentions the flow of the granules based on angle of repose measurements.

Weight variation

Weight variation was determined to know if different batches of tablets have uniformity. It was determined by the method mentioned in United States Pharmacopoeia: General Chapter on uniformity of dosage units <905> [7]. Weight variation specification as IP/BP &USP

Measurement of effervescent time

A single tablet is placed in a beaker containing 200 mL of DM water at 20 °C±1° temperature. When a clear solution without particles is obtained the effervescence time has

finished. Note down the time of effervescence. The mean of three measurements of each formulation is to be reported [8].

pH

pH of solution was determined with one tablet in 200 mL of DM water at 20 °C±1 °C by using pH meter (Make: Toshniwal India, Model: CL54+), immediately after completing the effervescent (n= 3)

Thickness

For tablets to have consistent sizes, their thickness was crucial. A computerized tablet
thickness tester was used to measure thickness.

Tablet strength

The resistance of tablets to shipping or breakage under conditions of storage, transportation and handling before usage depends on its hardness. The hardness of tablet of each formulation was measured by digital tablet hardness tester. The hardness was measured in terms of [Kp(kgf)]. Hardness or tablet crushing strength is the force required to break a tablet in a diametric compression. The force is measured in [Kp(kgf)] and tablet hardness of about 5.0 -10.0 [Kp(kgf)] is considered to be satisfactory for uncoated tablets [2].

Friability

15 tablets were weighed accurately. These tablets were subjected to combined effect of attrition and impact by using a friabilator (Make: Labindia India, Model: FT1020) 100 and 200 revolutions at 25 rpm. The tablets were reweighed after the test. The percentage friability was calculated by below mentioned formula, which should not be more than (NMT) 1.0% as mentioned in the USP.

n-vitro **dissolution profile:** Using a dissolution test apparatus (Make: Labindia India, Model: DS8000), the ascorbic acid dissolution profile in an effervescent tablet was determined using the USP 44 compendial method (n=3), apparatus No. II (paddle), and a speed of 50 RPM for 60 minutes in 900 mL of de-mineralized water at a medium temperature of 37±0.5 °C. Six randomly chosen pills were added to each dissolving jar. Five milliliter sample aliquots were taken out of each dissolving jar at various intervals, including five, fifteen, thirty, forty-five, and sixty minutes.
Samples were filtered using Whatman filter paper (No. 42) following withdrawal. After transferring 1 mL of the beaker's filtrate into a 10-mL volumetric flask, it was diluted with 10 mL of dissolving medium. For the remaining five tablets, the identical process was carried out. The absorbances of the standard and sample were measured at λ= 258 nm using a UV visible spectrophotometer (Make: Shimadzu Japan, Model: UV-1900). The formula below was used to calculate the amount of ascorbic acid medication released from the tablet formulations [9].
medication concentration × dilution factor × dissolution medium volume / 1000 equals the amount of medication released (mg).
Drug released (%) = Amount of drug released (mg) / label claim (mg) x 100

Results and Discussion

Characterization of effervescent granules Drug excipients compatibility studies

FT-IR spectra of the formulation and ascorbic acid were found to be superimposable. There were no additional peaks observed in the functional group and fingerprint regions in the spectra of formulations. This indicated that there was no alteration in the molecular structure and functional groups in the effervescent granules. This study proposed that ascorbic acid was chemically intact in presence of mannitol, sodium bicarbonate and citric acid.

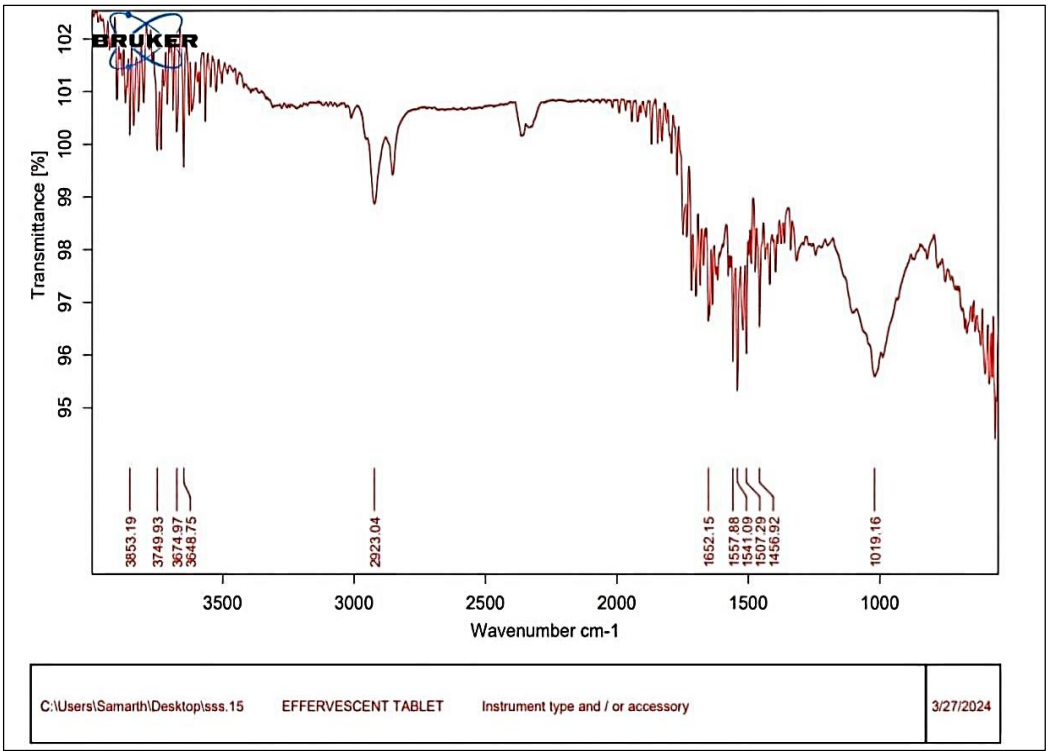

Fig 1: FTIR

Evaluation of pre-compression and post compression parameters

In an effort to obtain ascorbic acid formulations with improved density, flow and compressibility properties compared with ascorbic acid and to discriminate one from the other, different formulation approaches were designed (i.e. Formulation F1- F3) as mentioned in Table 2. These involved blends obtained by physical mixing individual excipients (with and without ascorbic acid) and mixing ascorbic acid with effervescent granules. The results for the pre-compression parameters of ascorbic acid and various formulation (F1- F3) are listed in Table.

Table 2: Different formulation approaches were designed (i.e. Formulation F1- F3)

Batches	Angle of repose (℃)	Bulk Density (g/ml)	Tapped Density(g/mL)	Carr's index (%)	Hausner's ratio
F 1	35.26	0.43	0.65	33.84	1.51
F 2	31.48	0.47	0.60	21.66	1.27
F 3	34.02	0.45	0.63	28.57	1.4

Loss on Drying

The Loss on Drying, Ash Values likes (Total Ash, Acid insoluble ash, and Water-soluble ash), Ethanol soluble extractive and Water-soluble extractive of seed powder are given in Table No.- 2,3,4.

Table 3

LOD	8.0%w/w

Extractive Value

Table 4

Extract	Results
Ethanol soluble extractive	0.25
Aqueous soluble extractive	0.15

Ash value (%w/w)

Table 5

Sr. No.	Physical Constant	Results
1.	Total Ash	6.3%w/w
2.	Acid insoluble ash	1.02%w/w
3.	Water soluble ash	0.24%w/w

Physical analysis of grape seeds

Powder property (physical evaluation)

The herbal effervescent tablet was assessed based on the powder property (physical characteristics) listed in Table 5. Rheological results confirmed the herbal face pack's flow (powder) properties. It was discovered to be non-sticky and free-flowing.

Washability

Washability Test

Table 6

Sr. No.	Parameters	Observation
1	Washability	Easily Washable

Post compression parameters of effervescent tablet.

1. Tablet Weight

Weight variation should be within ±5% for tablets weighing more than 400mg (as per USP). Typical effervescent tablets weigh between 1 g to 5 g depending on the formulation.

2. Tablet Hardness

Typically, 4-8 kg/cm² for effervescent tablets (may vary). Must be hard enough to resist breakage but still disintegrate rapidly.

3. Tablet Thickness

Depends on formulation, usually 4-10 mm for large effervescent tablets. Variations should be minimal (±5%).

4. Friability

Should be <1% weight loss (USP/BP standard). Effervescent tablets are more fragile, so specialized coating or packaging may be used.

5. Effervescent Time

as per USP, complete disintegration should occur within 5 minutes in 200 mL of water at 20 - 30 °C.

6. pH of Effervescent Solution

Typically, between 4.5 and 6.0, depending on active ingredients and acid-base ratio. Should not be highly acidic or alkaline.

Table 7

Parameters	Observations (F 2)
Tablet Weight (mg)	400
Tablet Hardness [kp(kgf)]	5.6
Thickness(mm)	3.4
Friability (%)	0.5
Effervescent Time(seconds)	140
Effervescent solution pH	6.3

Fig 2: Formulation of Tablet

Stability Studies

The results of stability were shown in Table. No change in colour, odour, texture and smoothness were observed. The stability studies showed a slight change in pH of formulation at 40 °C.

Table 8

Sr No.	Parameters	At Room Temperature	At 400C
1	Colour	No change	No change
2	Odour	No change	No change
3	Texture	Good	Good
4	Smoothness	Smooth	Smooth
5	pH	5.82± 0.04	5.78± 0.05

Conclusion

In order to ascertain and understand how significant formulation parameters impact the desired product quality attributes for a selected formulation, the current study may be considered a model study. We deduce from the aforementioned investigation that the tablets were made by the dry granulation process and yielded outcomes that were both acceptable and satisfactory. The qualitative attributes, such as DT, PH, TP, and CO_2 quantity of effervescent granules API, like ascorbic acid, grape seed extract, and aloe vera extract, used in formulation, were found to be most critically affected by sodium bicarbonate and citric acid (anhydrous).

According to the current study, it may be more desired, advantageous, and therapeutically effective to formulate plant extracts into a suitable and acceptable herbal dosage form rather than adding the direct plant materials or isolated phytoconstituent.

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