Research article

Formulation and In-vitro evaluation of electrolyte effervescent tablet

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ABSTRACT

Effervescence is the formation of gas bubbles from a liquid as a result of a chemical reaction. Effervescent tablets have special properties for medicinal use, allowing for fast absorption of the required drug. If a drug dissolves quickly in water and is present in a suitable amount, it can be absorbed rapidly and effectively in this way. Acids used in effervescent processes include citric, malic, tartaric, adipic, and fumaric acids. Citric acid is the most often utilized acid for this purpose, and it gives the products a citrus flavor. Tartaric, adipic, and fumaric acids are commonly implemented in small doses due to their low water solubility. Electrolytes Effervescent tablets are used to make dosing easier, assure optimal compatibility, increase a patient's liquid intake, and avoid swallowing large tablets.

Keywords: Effervescent, Tablets, Electrolytes, Effervescent system.

INTRODUCTION

The oral dosage forms are the most common route of drug administration despite having some disadvantages like slow absorption, and thus the onset of action is prolonged. This will be overcome by administrating the drug in liquid form but, many APIs have a limited level of stability in liquid form. So, Effervescent tablets act as an alternative dosage form. Oral dosage forms are the most common route of delivery of the drug, despite some difficulties such as poor absorption, which delays the onset of action. This can be avoided by administering the medicine in liquid form, although many APIs have limited stability in liquid form. As an end result, effervescent tablets offer a supplement to traditional tablets[1,2].

Effervescent tablets are tablets that are meant to be dissolved or dispersed in water before administration, according to the FDA's revised definition. In addition to the ingredient that is active, it usually contains a mixture of acids / hydrochloric acids (citric, tartaric, malic, or other suitable acids or acid anhydrides) and carbonates and bicarbonates (sodium, potassium, or other suitable alkali metal carbonates or bicarbonates)[3,4]. When mixed with water, carbon dioxide is released. Sometimes the active ingredient itself can act as an acidic or basic metal compound required for the foaming reaction. Effervescent pills are commonly uncoated tablets containing acids, carbonates, or bicarbonates, which respond quickly with water to release CO2. It must be dissolved or diluted in the water earlier than use. Some medicines are beneficial for pharmaceuticals that cause stomach damage or are sensitive to stomach pH, as well as drugs that are regularly given in high quantity and can be taken as effervescent tablets. Moreover, due to the fact that effervescent tablets are given in liquid form, for many reasons, they are easier to swallow than pills or capsules with a difficult absorption [5,6]. One dose of an effervescent tablet, on the other hand, in 3-4 ounces of water, it's usually dissolved. The gastrointestinal tract does not come into direct touch with effervescent products. Because they have been pre-dissolved in a buffer solution. As a result of the reduced gastrointestinal irritation in the stomach and intestine, they are well tolerated.

The following diagram depicts the carbon dioxide liberation reaction between citric acid and sodium bicarbonate, as well as tartaric acid and sodium bicarbonate[7,8].

Figure 1: Effervescence effect of tablet
Citric acid + Sodium bicarbonate → Sodium citrate + Water + Carbon dioxide
\[ C_6H_8O_7 + 3NaHCO_3 \rightarrow Na_3C_6H_5O_7 + 4H_2O + 3CO_2 \]

Tartaric acid + Sodium bicarbonate → Sodium tartarate + Water + Carbon dioxide

Electrolytes

Electrolytes play a critical role in the body's maintenance of homeostasis. They will have essential functions such as physiologic functions as maintaining intracellular and fluid that is extracellular; power production and utilization; electric conductivity and muscular contraction in cardiac, skeletal, and vascular smooth muscle tissue; and clot development. Many infection processes could cause electrolyte abnormalities including infection that is gastrointestinal, endocrine diseases like diabetic issues, hyper are, hypoadrenocorticism, and thyroid disorders; renal and urinary illness; numerous neoplasms; sepsis; and epidermis conditions. Treatment treatments in critical creatures that are ill precipitate electrolyte problems or medically considerable shifts in electrolyte distribution and amounts in the body. Electrolyte abnormalities can be treated effectively, resulting in lower morbidity and death⁹,¹⁰.

An imbalance in these electrolytes can occur in either high or low amounts. Electrolyte levels that are too high or too low might interfere with normal biological functions and lead to life-threatening complications¹¹. Electrolytes are charged minerals found in your blood and other biological fluids. Electrolytes have a variety of effects on how your body works, including:
- Your body's water content
- Your blood's acidity (pH)
- Your muscular performance
- Other critical activities

When you sweat, you lose electrolytes. Electrolyte-containing drinking fluids must be substituted. Electrolytes are not found in water. Electrolytes that are commonly used include:
- Calcium, Chloride, Magnesium, Phosphorus, Potassium, Sodium, Calcium, Chloride, Magnesium, Phosphorus, Potassium, Sodium Acids, bases, and salts are all examples of electrolytes.

MATERIAL AND METHODS

Sodium Citrate, Sodium Chloride, Potassium Chloride, Dextrose Anhydrous, sodium bicarbonate, citric acid, tartaric acid, polyvinyl pyrrolidone, Mannitol, Polyethylene glycol-6000.

Direct compression

To obtain a free-flowing, non-segregating, compressible combination, direct compression usually requires a careful selection of raw components. Direct compression was used to make effervescent tablets with various amounts of different grades of polymers, sodium bicarbonate, and citric acid. All of the ingredients were precisely weighed and sieved using different mesh sizes. The other components were then uniformly mixed in a glass mortar. After the drug and other components had been thoroughly combined, a post-lubricant was added and blended for another 2-3 minutes. A tablet press machine was used to compress the powder mixture into tablets. For all formulations, the weights of all tablets were kept consistent.

Wet method

The wet method differs from the fusion method in that the binding agent is not the citric acid crystallization water, but rather ethanol, which is used to moisten the flexible mass for granulation. All of the powders (anhydrous) were weighed and placed in a mortar, and then ethanol was added drop by drop until a moist mass was obtained to pass the ball test. The wet mass was then sieved, and the granules were dried in a 40°C oven for 10 minutes; finally, the granules were compressed into tablets using a tablet press machine, and the granules were placed in containers and carefully sealed.¹¹-¹²

Fusion method (dry method)

The one molecule of water present in each citric acid (monohydrate) works as a binding agent for the powder combination in the fusion technique. In a mortar, the needed amount of citric acid monohydrate was placed on a hot plate. The heat released the water of crystallization from the citric acid during the heating process, and then all of the other materials were added with continuous mixing. The mixture was sieved and allowed to dry at room temperature before being compacted into tablets with a tablet press machine¹³-¹⁴.

EVALUATION OF EFFERVESCENT TABLET

Pre-compression evaluation

Angle of repose (θ)

The direction of repose is described as the direction that is optimum can be made involving the powder pile's area and its particular horizontal airplane. The perspective of repose can help calculate the force this is certainly frictional loose dust or granules. It is an example of the dust's movement properties.

\[
\tan \theta = \frac{H}{R} \\
\theta = \tan^{-1} \left( \frac{H}{R} \right)
\]

Where θ is the angle of repose.
H represents the pile's height.
R denotes the pile's base radius. The blend is certainly powdered allowed to flow via a funnel that has been attached to a stand (H). The radius and height regarding the powder heap produced had been then assessed to determine the rest direction. It was carefully observed that the powder particles didn't fall and roll over each other because they passed through the funnel's sides.

<table>
<thead>
<tr>
<th>The angle of repose (degrees)</th>
<th>Type of flow</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 20</td>
<td>Excellent</td>
</tr>
<tr>
<td>20-30</td>
<td>Good</td>
</tr>
<tr>
<td>30-34</td>
<td>Passable</td>
</tr>
<tr>
<td>&gt; 40</td>
<td>Very poor</td>
</tr>
</tbody>
</table>

Table 1: Angle of repose as an indication of powder flow properties
The hardness of tablets

**Post-compression evaluation**

**Hausner's Ratio**

Hausner showed that the tapped-density-to-bulk-density ratio was connected Friction between particles could be used to identify the properties of powder flow. He discovered that the powder with reduced inter-particle friction had a ratio of about 1.2, where Hausner's ratio exceeds 1.6 as more cohesive, less free-flowing powders. If the Hausner's ratio is less than 1.25, the flow is great. Where M = Mass of powder taken. V0 = Apparent unAPPED volume.

**Tapped Mass**

Many precisely considered powder from each formulation had been introduced right into a measuring cylinder. The cylinder was hit from the level of 2.5 cm per 2 s, as much as amount plateau. Tapped thickness had been determined from the formula that is following.

The density of tapping was measured by the formula as given below:

\[ \text{Tapped density} = \frac{M}{V_2} \]

Where M = Weight of powder. V2 = Tapped volume.

**Carr's Index**

Carr developed an indirect method of calculating powder flow from bulk densities. A direct measure of the percentage compressibility of a powder was a measure of the Power and stability of the potential powder arch or bridge.

The Carr index of each formulation was calculated using the equation below:

\[ \% \text{ Compressibility} = \frac{D_f - D_o}{D_f} \times 100 \]

Where, \(D_f\) = Fluff, poured bulk, and bulk density, \(D_o\) = Bulk density: Tapped or Consolidated.

**Table 2: Carr's Index as an indication of powder flow**

<table>
<thead>
<tr>
<th>Carr's index (%)</th>
<th>Type of flow</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-15</td>
<td>Excellent</td>
</tr>
<tr>
<td>12-16</td>
<td>Good</td>
</tr>
<tr>
<td>18-21</td>
<td>Fair to passable</td>
</tr>
<tr>
<td>23-35</td>
<td>Poor</td>
</tr>
<tr>
<td>33-38</td>
<td>Very poor</td>
</tr>
<tr>
<td>&gt;40</td>
<td>Extremely poor</td>
</tr>
</tbody>
</table>

**Hausner's ratio**

Hausner showed that the tapped-density-to-bulk-density ratio was connected Friction between particles could be used to identify the properties of powder flow. He discovered that the powder with reduced inter-particle friction had a ratio of about 1.2, where Hausner's ratio exceeds 1.6 as more cohesive, less free-flowing powders. If the Hausner's ratio is less than 1.25, the flow is great.

Hausner's Ratio = Tapped density/bulk density.

**Post-compression evaluation**

**The hardness of tablets**

In manufacturing, packaging, and shipping, to withstand mechanical shock, tablets must have a particular level of strength or hardness and resistance, from handling. Force on the anvils and the crushing pressure the tablets will break as a result. Were observed between two anvils to perform this test tablet. To measure the hardness of tablets, the Monsanto Hardness Tester was used. The results were given in kilograms per square meter.

**Weight variation**

Twenty tablets were individually weighed, with the average weight determined and the individual tablet weights compared to the average. If no more than two tablets differ by more than twice the percentage limit, the tablets pass the test.

**Thickness of tablet**

During counting and shipping, variations in tablet thickness can cause problems. The thickness of the tablets was measured with Vernier calipers.

**Friability**

This test ended up being done with a Roche friabilator. Examples of ten preweighed tablets had been put throughout a friabilator that has been operated for 100 revolutions. The tablets were then being reweighed and dusted. Tablets that lose but 0.5–1.0% of these weights were considered appropriate. Also, if capping occurs during friability examination, the tablets have been refused.

\[ F = \frac{W_{\text{initial}} - W_{\text{final}}}{W_{\text{initial}}} \times 100 \]

**Formulation table**

**Table 3: Weight variation specification**

<table>
<thead>
<tr>
<th>IP/BP</th>
<th>Limit</th>
<th>USP</th>
</tr>
</thead>
<tbody>
<tr>
<td>80 mg or less</td>
<td>1.0%</td>
<td>130 mg or less</td>
</tr>
<tr>
<td>More than 80mg or Less than 250mg</td>
<td>7.5%</td>
<td>130mg to 324mg</td>
</tr>
<tr>
<td>250mg or more</td>
<td>5%</td>
<td>More than 324mg</td>
</tr>
</tbody>
</table>

**Table 4: Formulation design for Electrolyte Effervescent tablet**

A desiccator containing silica gel was used to dry ten tablets for four hours. The % of the content of water was calculated.

**Solution PH**

In filtered water, one tablet was dissolved. A pH meter was used to determine the pH of the solution after it had completely
dissolved. For each formulation, the test was carried out three times [30].

Water content
A desiccator containing silica gel was used to dry ten tablets for four hours. The % of the content of water was calculated [31].

Co2 content
In 3 different beakers, three pills were placed in 100 mL of 1N sulphuric acid solution. The variation in weight before and after the dissolution of the tablets was calculated to assess the amount of CO2 released (mg) [32].

Disintegration time measurement
At 15-25 °C, the effervescent time was measured using a stopwatch after one tablet was dissolved in 200 mL filtered water. The effervescence time is over when a clear, particle-free solution is obtained. For each approach, the average of six measurements was calculated [34].

RESULT AND DISCUSSION

Precompression parameters of the blend: The bulk density of precompression blends was found to be in the range of 0.540 to 0.625 gm/ml, tapped density in the range of 0.625 to 0.715 gm/ml, Carr's index value was in the range of 1.093 to 1.162%, Hausner's ratio in the range of 8.567 to 13.95, and angle of repose between 26.67 to 28.88. All the values were found to be within the prescribed limits according to the i.p., thus ensuring good flow properties of the formulation blends.

Post Compression Parameters: Hardness and friability: The tablet formulations were found to have a hardness ranging from 1.27 to 2.5.kg/cm. The friability and thickness values were determined to be in the range of 6.8 and 0.5 to 0.9 percent, respectively, which were found to be within the prescribed IP limits, assuring that all of the formulations had good mechanical strength. Solution time: Among the tablets prepared F3 formulations were found to be promising and have shown wetting time of 57.14 to 1.47min. Ph of the solution: Among the tablets prepared F6 formulations was found to be promising and has shown the ph. of 6.58 to 7.20. Uniformity of weight: The weight variation of all the prepared effervescence pills was assessed. All of the tablets' weights were confirmed to be consistent, with modest standard deviations and within the allowed limits.

CONCLUSIONS
The action of an effervescent formulation was accelerated. Effervescent tablets were made using the Dry, Wet, or Compression methods, with the Wet approach being the most common. Effervescent granules were made using a wet process, such as the Fusion method, or a dry way with the Fusion method being the most important. As a result, electrolyte effervescent tablets be used in the case of dehydration. This formulation is convenient to store, transport, and carry. Also, provide an accurate dose. Electrolyte Effervescent tablet prepared by using various super disintegrates like sodium bicarbonate, citric acid, Polyethylene glycol-6000, PVP, Mannitol, Tartaric Acid by prepared effectively by the direct compression method, wet method, and Fusion Method. The prepared formulation was evaluated for the results were within the prescribed ranges for the pre-compression parameters and which indicates good free-flowing properties the physical parameters were found satisfactory and within the limits, this method was shown good results for given limits and This shows that the material has good free-flowing properties. The physical parameters were found satisfactory & within the limits. This method was showed good results The tablets prepared with sodium bicarbonate, citric acid,

<table>
<thead>
<tr>
<th>Concentration (µg)</th>
<th>Absorbance (nm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.032</td>
</tr>
<tr>
<td>2</td>
<td>0.064</td>
</tr>
<tr>
<td>3</td>
<td>0.098</td>
</tr>
<tr>
<td>4</td>
<td>0.129</td>
</tr>
<tr>
<td>5</td>
<td>0.166</td>
</tr>
<tr>
<td>6</td>
<td>0.193</td>
</tr>
</tbody>
</table>

Figure 2: Standard calibration curve

<table>
<thead>
<tr>
<th>Formulation code parameters</th>
<th>Thickness (mm)</th>
<th>Hardness (kg)</th>
<th>Weight variation</th>
<th>Friability</th>
<th>Disintegration Time (sec.)</th>
<th>Ph of solution</th>
<th>Water content</th>
<th>CO2 content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Compression (F1)</td>
<td>6.8</td>
<td>1.27</td>
<td>pass</td>
<td>0.9</td>
<td>57.41</td>
<td>6.39</td>
<td>0.062</td>
<td>0.39</td>
</tr>
<tr>
<td>Wet Granulation Method (F2)</td>
<td>6.8</td>
<td>1.52</td>
<td>pass</td>
<td>0.6</td>
<td>1.35</td>
<td>6.58</td>
<td>0.046</td>
<td>0.45</td>
</tr>
<tr>
<td>Fusion Method (F3)</td>
<td>6.8</td>
<td>2.5</td>
<td>pass</td>
<td>0.5</td>
<td>1.46</td>
<td>6.79</td>
<td>0.024</td>
<td>0.63</td>
</tr>
<tr>
<td>Fusion Method (F4)</td>
<td>6.8</td>
<td>2.21</td>
<td>pass</td>
<td>0.5</td>
<td>1.47</td>
<td>7.20</td>
<td>0.035</td>
<td>0.75</td>
</tr>
</tbody>
</table>

Table 7: Post evaluation parameters

Table 6: Pre-evaluation parameters

<table>
<thead>
<tr>
<th>Formulation code parameters</th>
<th>Bulk density (g/ml)</th>
<th>Tapped density (g/ml)</th>
<th>Angle of repose(Ø)</th>
<th>Hausner's ratio</th>
<th>Carr's index (%)</th>
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<tbody>
<tr>
<td>Direct Compression (F1)</td>
<td>0.5714</td>
<td>0.625</td>
<td>26.67</td>
<td>8.567</td>
<td>1.093</td>
</tr>
<tr>
<td>Wet Granulation Method (F2)</td>
<td>0.625</td>
<td>0.715</td>
<td>27.83</td>
<td>12.58</td>
<td>1.144</td>
</tr>
<tr>
<td>Fusion Method (F3)</td>
<td>0.555</td>
<td>0.645</td>
<td>28.88</td>
<td>13.95</td>
<td>1.162</td>
</tr>
<tr>
<td>Fusion Method (F4)</td>
<td>0.540</td>
<td>0.625</td>
<td>28.80</td>
<td>13.6</td>
<td>1.157</td>
</tr>
</tbody>
</table>

{| concentration (µg) | absorbance (nm) |
<table>
<thead>
<tr>
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<td>0.166</td>
</tr>
<tr>
<td>6</td>
<td>0.193</td>
</tr>
</tbody>
</table>

Figure 2: Standard calibration curve

Standard calibration curve for electrolyte

Standard calibration curve

Standard calibration curve for electrolyte

y = 0.0325x

R² = 0.999


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Polyethylene glycol-6000, PVP, Mannitol, Tartaric Acid, and F3 by Fusion method was found to be the best formulation as it exhibited satisfactory physical parameters, least solution time (1mins 46sec.), pH of solution (6.79), Hardness 2.5kg/cm3, thickness 6.8mm.

ACKNOWLEDGEMENT

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REFERENCES


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