

## Formulation and Evaluation of Paracetamol Effervescent Tablet:

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### ABSTRACT:

Oral dosage forms are a popular way of taking medication, but they have some disadvantages, such as slow absorption of medication and delayed onset of action. These drawbacks can be overcome by administering the drug in liquid form, but many APIs or drugs in liquid dosage form limit their use. Effervescent tablets have emerged as an alternative dosage form that can accelerate drug disintegration and dissolution. They are generally used in quick-release preparations. To use an effervescent tablet, it is added to a glass of water just before administration, and the drug solution or dispersion is to be drunk immediately. The tablet is instantly broken and separated by the internal release of CO<sub>2</sub> in water due to the interface between citric acid and tartaric acid with alkali metal carbonates or bicarbonates in the presence of water. Due to the release of CO<sub>2</sub> gas, the dissolution of API in water, as well as the taste-masking effect, is enhanced, along with the development of a new pharmaceutical technique. Effervescent tablets are increasingly used to adjust the behavior of drug release, such as in sustained and controlled release preparations, pulsatile drug delivery systems, and so on. In the present work, acids and bases in dissimilar concentrations were used to formulate an effervescent tablet containing an immediate release of paracetamol. The tablets were formulated using the wet granulation as well as dry granulation method by a single rotary tablet punching machine. The formulated tablets were then evaluated for hardness, friability, weight variation, disintegration/dissolution time, and in-vitro drug release. From the study, it was concluded that F3 showed better results than F1 and F2.

**Keywords:** effervescent tablet, sustained release, wet granulation method

### I. INTRODUCTION:

Oral drug delivery has been recognized for decades as the furthestmost broadly used route of administered amongst all the routes that have been

working for the systemic distribution of drug via numerous pharmaceutical products of diverse dosage forms. The motives that the oral route attained such approval may be in part accredited to its ease of administration. Oral sustained drug delivery system is difficult by partial gastric residence times (GRTs). Speedy GI transit can avoid comprehensive drug release in the absorption region and decrease the effectiveness of the administered dosage.[1]

Effervescence is described as exclusion of carbon dioxide gas from a fluid due to chemical reaction. This effect starts when preparation come in contact with water which works as catalyzing agent. Effervescent tablets need to be liquified in water before administration. The tablet is punctually broken down by releasing carbon dioxide in water. Carbon dioxide produces by effervescent reaction increases the penetration of active substance into the paracellular pathway and consequently their absorption. The effervescent formulation does not come in direct contact with the gastrointestinal tract and thus such dosage forms are useful for this kind of patient. It decreases the onset of action, due to faster absorption of formulation in liquid dosage form, as compared to tablet formulations.[2]

Effervescent tablets were designed to supply solutions that release greenhouse gas simultaneously. Usually, these tablets are prepared by compressing the active ingredients with mixture of bicarbonate of soda and organic acids like citric and hydroxy acid. Generally, these tablets are included drugs that are solved rapidly when entered to water and that they are recommended as a transparent and palatable solution. So, they'll be prescribed to patients who suffered from swallow capsules or tablets. The main advantages of effervescent tablets are quick production of solution. Thus, it's faster and better to soak up. As a source of acid, acid is that the most used acid. Also, other acids like tartaric, fumaric, adipic, malic acid and anhydrides and salts of

acid will be used. Potassium and washing soda, sodium and hydrogen carbonate, arginine carbonate are used as a sources of alkali. sodium hydrogen carbonate is one amongst the foremost used carbonate due to high solubility, severe reaction and low cost. So, excipients like water soluble lubricants (e.g. PEG 4000, 6000 and sodium benzoate), sweeteners, flavourings and water-soluble colours (Placeholder1) are applied. [3]

## **BENEFITS:**

### **1. Pleasant Taste Compared to Regular Tablets.**

Effervescent tablet can be liquified in a liquid such as fruit juice or water, which is the main cause of their approval. Due to which their taste gets way improved than regular tablet.

### **2. Distributed More Evenly.**

The dissolution of predictable tablet is gradually in sometime and can sometime be gateway causing there to the motive of irritation in some cases, in difference the dissolution of effervescent tablet is comprehensive and even through the stomach which stops the accumulation of component in local area. This makes effervescent tablet taste better and fewer irrigative and on effervescent method of ingestion of ingredient. Apart from providing nutritional benefit intended effervescent tablet also rise liquid consumption.

### **3. increased Liquid Intake**

Increased Liquid Consumption is more helpful during period of desiccation ill time and in less liquid ingestion.

### **4. Easy Alternative to Regular Tablets**

Effervescent tablet can use in residence of regular tablet. Which cause trouble in swallowing either due to sickness or age, old age people who administer medicine or supplement on daily basis reports problem associated to swallowing of tablet to overcome these difficulties effervescent tablets are of great significance and can be on relaxed way to swallow a tablet.

### **5. To Sum Up**

Effervescent tablets are receiving progressively popular and it's easy to work out why. They supply a way more effective way of taking supplements or medicines since being spread consistently and far faster than regular medicines. [4]

## **Reason For Selection Of Effervescent Tablets Of Paracetamol:**

### **Fast onset of action.–**

Effervescent tablet has main advantage that the drug product is already in solution on the time it is consumed. therefore, the absorption is earlier and further complete than with predictable tablet. earlier absorption means faster onset of action. effervescent drug is distributed to the stomach at a pH that is just correct for absorption. numerous medication portable slowly through the stomach or have absorption that is hindered by food or another drug.

**No need to swallow tablet** - effervescent tablets are administered in liquid form so they easy to take as International Journal of Pharmaceutical Research & Development ISSN: 0974 – 9446 Existing online on www.ijpr.com 78 associated to tablets or capsule. the number of persons who cannot gulp tablet or who dislike swallowing tablet and capsule is rising. through an effervescent dosage form, one dose can usually transport in just 3 or 4 ounces of water.

**Good stomach and intestinal tolerance** - effervescent tablet liquify completely in a buffered solution. Reduced localized contact in the upper stomach leads to fewer irritation and greater acceptability. buffering also prevent intestinal acids from interrelating with drug themselves, which can be a main cause of stomach tolerance.

**More portability** - effervescent tablet is more simply delivered than liquid medication because no water is added until it is complete to use.

**Improved palatability** - drugs transported with effervescent base, taste improved than most liquids, mixture and suspensions. greater taste masking is attained by limiting offensive characteristics and adding formulations with flavour and fragrances.

**More consistent response** - drugs delivered with effervescent technology have expectable and reproducible pharmacokinetics profile that are considerably more consistent than the tablets or capsule.

**Accurate dosing** - researchers have been revealed that effervescent tablets improve the absorption of number of active constituents compared to predictable formulations. this is because the carbon dioxide formed by the effervescent reaction can increase active ingredient penetrability due to an change of paracellular pathway. [5]

**Table:1: Excipients used in Formulation**

Sr.No.	Category	Use	Example
1.	Diluents	Used to make up volume of tablet.	Lactose, Microcrystalline cellulose.
2.	Glidant	Helps in free flowing of granules from hopper to die cavity.	Colloidal silicon dioxide, starch, Talc.
3.	Binder	Used as binding agent in tablets.	Glucose, Lactose, Gelatin.
4.	Lubricant	Used to reduce the friction between die wall and tablet.	Stearic acid, Magnesium stearate, Talc, SLS.
5.	Disintegrant	Generally, not used in Effervescent tablet.	Sodium starch glycollate, Starch.
6.	Antiadherent	Prevents sticking of tablets	talc

**AIM & OBJECTIVES:**

The aim of this study was to formulate effervescent tablet with sufficient mechanical integrity and to achieve faster disintegration in the water.

**OBJECTIVES:**

- To optimize formulation for effervescent tablet.
- To prepare effervescent tablet
- To evaluate various parameter for effervescent tablet.
- To generate information useful to the formulation in developing desired, stable and bioavailable dosage form.

- fast onset of action.
- rapid and enhanced absorption.

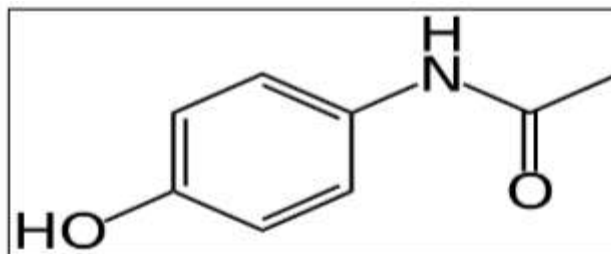
**II. MATERIAL AND METHOD:**

**Ingredients:** paracetamol, citric acid, Sodium Bicarbonate, starch, talk, lactose.

**Paracetamol;**

Paracetamol / acetaminophen is one of the greatest prevalent and most usually used analgesic

Structure:



Name	Paracetamol
IUPAC name	N-(4- hydroxyphenyl) ethanamide
Molecular formula	C <sub>8</sub> H <sub>9</sub> NO <sub>2</sub>
Molecular mass	151.163 gm/mol
Density	1.263 g/cm <sup>3</sup>
Melting point	169° c
Boiling point	420° c
Solubility in water	7.21g/kg (0°c)

**Table 2: Formula for preparation of effervescent tablet:**

Sr No:	Ingredient	F1 (mg)	F2 (mg)	F3 (mg)
1.	Paracetamol	300	300	300
2.	Sodium bicarbonate	92	110	128
3.	Citric Acid	112	120	128
4.	Lactose	92	92	92
5.	Gelatin	18	18	18
6.	Starch	12	12	12
7.	Talc	22	22	22

#### Method:

Drug (Paracetamol) , sodium bicarbonate were sieve through sieve No: 40#.Granules prepared with ethanol to form damp mass and it was passed through sieve no. 40#.

Citric acids, sodium bicarbonate, spray dried lactose, starch, gelatine was blended & passes through sieve no: 40#. Granules prepared by using binding agent (ethanol) & dry at 60°c for 30 minutes.Both granules mix & dry at 60°c for 15 minutes. Granules were compressed into tablet by using single rotary tablet punching Machine.

#### EVALUATION OF PRECOMPRESSED BLEND:

##### 1.Angle of Repose (θ):

The dry mixture powders were permitted to flow through the funnel immovable to a stand at certain height (h). The angle of repose was then considered by measure the height and radius of the heap of powders formed.

$$\tan \theta = h / r$$

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

Where θ called as angle of repose, h and r were height and radius of the powder heap pleasingly. According to the conditions the angle of repose value less than 250 shows excellent flow whereas angle greater than 400 indicates poor flow.[6]

##### 2.Bulk Density:

Apparent bulk density was resolute by pouring presieved drug excipient mixture into a graduated cylinder and measure the volume and weight “as it is”. It is expressed in g/ml and is specified by

$$D_b = M / V_0$$

Where, M is mass of powder and V<sub>0</sub> is the Bulk volume of powder.[7]

##### 3. Tapped density:

It is weight of granules divided by its tapped volume.

$$D_t = M / V_t$$

Where, M is mass of powder and V<sub>t</sub> is the tapped volume of the powder.[8]

**4. Compressibility index:**

The % compressibility is determined by Carr's compressibility index.

The % Carr's index is calculated by means of the following formula;

$$\% \text{Carr's Index} = \frac{\text{TD} - \text{BD}}{\text{TD}} \times 100$$

Where, TD is tapped density and BD is bulk density.[9]

**5. Hausner's Ratio:**

It was calculated by following formula-

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

Hausner's ratio from 1.25 to 1.6 show moderate flowing properties. If ratio is more than 1.6 will show more cohesive powders.[10]

**III. EVALUATION OF TABLET:**

**Average thickness:**

The thickness of the tablets were determined using vernier Calliper. According to report tablet thickness would be precise within a ± 5% variation of average value.

**Hardness and friability:**

For each formulation, the hardness and friability of 20 tablets were determined using the Monsanto Hardness Tester and Roche Friabilator resp. Percentage friability of tablets was measured by using following formula,[11]

$$\text{Percentage friability} = \frac{\text{initial weight} - \text{Final weight}}{\text{initial weight}} \times 100$$

**Disintegration time:**

This test performed on 6 tablets. For disintegration time, one tablet was positioned in the centre of the Petri dish (internal diameter 10 cm) comprising 10 ml of water and the time taken by the tablet to disintegrate totally was noted.[12]

**Weight Variation:**

Twenty tablets were selected casually. Tablets were weighed individually and mean weight was calculated. Then deviation of each tablet from average weight was calculated and percent deviation was calculated.

**Content Uniformity:**

Used to ensure that every tablet contains the amount of drug substances certainly with little variation between tablets with in batch.[13]

**In vitro drug release studies:**

In vitro drug release studies were started using USP apparatus I (basket method). The dissolution media was 1000 mL of 0.1 N HCl at 37 °C for 30 minutes to signify the gastric medium where the tablets will disintegrate. In all experiments, 5 mL of sample was withdrawn at 5 min interval and replaced by means of fresh medium to keep sink condition. Samples were filtered and examined spectrophotometrically at 230 nm.[14]

**IV. RESULT AND DISCUSSION:**

**Table:3: Evaluation of Granules:**

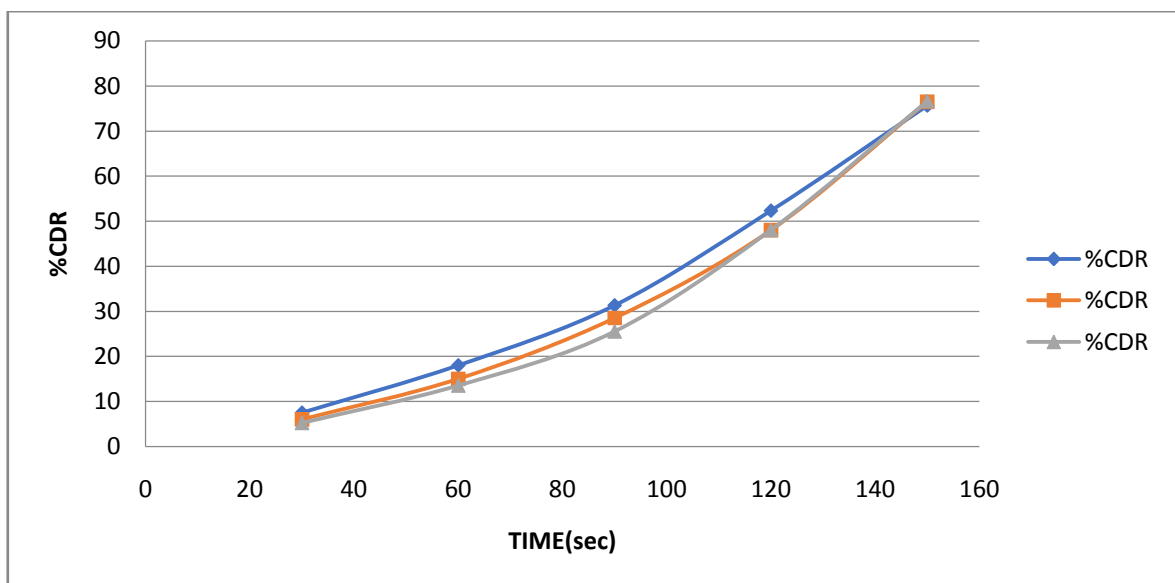
property	F1	F2	F3
Bulk density G/cm <sup>3</sup>	0.75	0.72	0.73
Tapped density G/cm <sup>3</sup>	0.86	0.81	0.85
Angle of repose (Degree)	25.17	28.81	27.47
% Compressibility	11.63	11.11	14.11
Hausner's Ratio	1.13	1.12	1.18

**Table:3: Evaluation of Tablets:**

Property	F1	F2	F3
Thickness (MM)	7.2	8.3	7
Disintegration Time (sec)	91±3	82±2	75± 3
Hardness (kg/cm <sup>3</sup> )	2.3	2.1	1.8
Friability test(%)	Pass	Pass	Pass
Amount of drug content	76.5%	75%	76.6%
Weight variation	NMT 2 tablets out of range	NMT 2 tablets out of range	NMT 2 tablets out of range

From the evaluated data it has been observed that the F3 Shows the better result than F1 & F2.

**Table: 4:Dissolution Test Result:**



**Fig: a. In vitro release of paracetamol effervescent tablet.**

From above graph (Fig: a) F3 shows the more drug release as compared to F1 & F2. therefore, it has been concluded that F3 shows better result.

**V. SUMMARY AND CONCLUSION:**

The study was under taken with an aim to formulate effervescent tablets of analgesic and antipyretic drug (paracetamol).

The literature review showed that paracetamol having similar mechanism of action to aspirin because similarity in structure. Paracetamol act by reducing production of prostaglandin which

involved in pain and fever process, by inhabiting the cyclo-oxygenase enzyme.

In present work an attempt has been made to formulate an effervescent tablet containing immediate release paracetamol using various acids and base. the effervescent tablets were prepared by wet granulation technique. Lactose as a binder and talc as lubricant were used. There are three formulations that content the citric acid and sodium bicarbonate were formulated.

These three formulations were evaluated for hardness, friability, weight variation,

disintegration time and in-vitro drug release. From above study it was concluded that F3 shows the better result than the F1 & F2.

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