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Formulation & Evaluation of Salbutamol Effervescent Tablets

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Abstract: Chronic Obstructive Pulmonary Disease (COPD) is one of the mostlong term pulmonary infection associated with difficulties in normal respiration process due to blocked airflow via bronchioles. Salbutamol is a commonly used bronchodilator that helps open the airways, but traditional oral tablets may work slowly because they take time to dissolve and absorb. This delay can be a problem for elderly patients or those who have trouble swallowing. This research aims to develop and test effervescent tablets containing Salbutamol to provide faster relief and easier administration for patients with COPD. Effervescent tablets dissolve quickly in water, forming a fizzy solution that is easy to swallow and allows for faster drug absorption. In this study, Salbutamol was combined with ingredients like sodium bicarbonate, citric acid, and tartaric acid using the wet granulation method. These ingredients were chosen for their ability to produce a fast-dissolving, stable, and effective tablet. The properties of Salbutamol, such as solubility and stability, were studied to ensure accurate dosage and proper function. The prepared tablets were tested for weight variation, thickness, hardness, friability, effervescence time, and disintegration time to confirm quality and performance. Some tablets were also designed to float in the stomach to improve absorption over time. The results showed that the effervescent tablets delivered Salbutamol quickly and effectively, offering a useful alternative for treating COPD symptoms. This type of tablet can improve patient comfort, compliance, and treatment outcomes, especially for those who have difficulty swallowing regular tablets.

Keywords: *COPD, Salbutamol, Effervescent Tablets.*

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I. INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is a long-term lung condition that makes breathing difficult due to airflow blockage. It is a major health problem worldwide and is expected to become one of the leading causes of death in the coming years. Managing COPD effectively requires medications that act quickly to relieve breathing difficulties and improve airflow. Salbutamol is a commonly used bronchodilator that helps to relax the airway muscles and ease breathing. It is also prescribed to patient suffering from COPD & asthma. However, traditional oral tablets of Salbutamol may have a delayed effect due to slow disintegration and absorption. They may also cause inconvenience for elderly patients or those who have trouble swallowing tablets.

Effervescent tablets are a suitable alternative to overcome these limitations. These tablets dissolve quickly in water, producing a solution that can be easily swallowed. The fast disintegration of effervescent tablets allows for quicker drug absorption and onset of action, which is beneficial in treating respiratory emergencies . Some effervescent tablets can also be designed to float in the stomach, which may increase the time the drug stays in the stomach and improve its absorption .

Previous research has explored different approaches to improve the effectiveness of Salbutamol tablets. Fast-disintegrating tablets have shown promise in enhancing the speed of action . Sublingual tablets have also been developed to increase drug bioavailability and provide faster relief . Other studies have looked into floating and effervescent tablets that offer prolonged drug release and better gastric retention . In addition, reviews on effervescent tablets have highlighted their advantages in improving patient compliance and therapeutic outcomes The aim of this research is to develop and evaluate effervescent tablets containing Salbutamol for the treatment of COPD.

➢ *Advantage of Effervescent tablets*

- Fast onset of action
- No need to swallow tablet
- Good stomach & intestinal tolerance.
- More portability
- Improved palatability
- Superior stability

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- More consistent response
- Accurate Dosing
- Improved Therapeutic effect

II. AIM & OBJECTIVE

➢ *Aim:*

To achieve fast action of salbutamol in the form of effervescent tablet for quick in treatment of Chronic Obstructive Pulmonary Disease.

➢ *Objective:*

First it dissolves in solution form which can administered and give direct absorption to the treatment of Chronic Obstructive Pulmonary Disease by bioavailable predicted dose material.

➢ *Why we Choose Effervescent tablet for Formulation*

The oral dose are simple to administer. The components (carbonate and acid) act as a pH buffer in the stomach. At 15 minutes, absorption occurs. They can be consumed in liquid form. Patients with swallowing difficulties can readily take these drugs. It is well tolerated in the stomach. Co2 is generated during the effervescent process, which promotes the penetration of active compound into the paracellular regions. The most common need of effervescent tablet are:

- *Rapid and Improved Absorption:*

It dissolves in liquid and the contents are quickly absorbed. Traditional tablet disintegrate slowly, resulting in decreased absorption while granules are comparatively faster.

- *Excellent Compatibility:*

In case of effervescent granule the ratio of acid & carbonates is in balanced which makes a buffer. This is more compatible

- *Increased Liquid intake:*

Effervescent granules give better medical benefits as well as extra liquid intake in absorption regions.Benefits for patients with swallowing difficulties : effervescent tablet provide an alternative for these people.

- *Easy Handling and Precise dosing:*

Effervescent tablet dissolve fast, allowing patients to achieve precise dosing so we selected formulation of effervescent tablet from given formulation tablet given below.

III. MATERIAL AND METHOD

Effervescent tablet is the formulation made from synthetic ingredients which are easily available in market. Wet granulation technique used in Effervescent tablets preparation) Salbutamol purchase in local market and other excipients are like citric acid, tartaric acid, sodium bicarbonate, magnesium stearate , camphor powder, sodium citrate, Maize Starch , saccharin sodium, orange oil are obtained in pharmaceutical lab from KBIPER. salbutamol are effect of increasing doses of short-acting β2 -agonists (SABA) in patients with stable COPD during long-term treatment with long-acting β2 -agonists (LABA) is presently unknown. Sodium bicarbonate is the major source of carbon dioxide in effervescent systems. Tartaric acid is also used in many effervescent preparations, being readily available commercially. It is more soluble than citric acid and is also more hygroscopic. It is as strong an acid as citric acid. Eucalyptus oil known for its respiratory benefits, can be used in effervescent tablets to help alleviate symptoms associated with Chronic Obstructive Pulmonary Disease. Cetirizine , an antihistamine commonly used for allergies.

➢ *Material Collection:*

Salbutamol purchase in local market and other excipients are like citric acid, tartaric acid, sodium bicarbonate, magnesium stearate, camphor powder, sodium citrate, Maize Starch , saccharin sodium, orange oil are obtained in pharmaceutical lab from KBIPER college.

Table 1 Application of ingredients

Ingredients	Role
Salbutamol	Bronchodilator
Sodium Citrate	Bronchial secretion enhancer
Eucalyptus oil	Loosen phlegm
Diphenhydramine	To relieve cough
Citric acid	Effervescent agent
Salicyclic Acid	Analgesic
Microcrystalline cellulose	Disintegrant agent
lactose	Flowability, wettability
Magnesium stearate	Lubricant
Sodium Bicarbonate	Effervescent agent
Tarteric acid	Effervescent agent
Talc	Lubricant
Starch	Binding agent
Camphor	Relieve cough , pain
Sodium saccharin	Sweetening agents

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IV. DRUG PROFILE: SALBUTAMOL

➢ *Structure:*

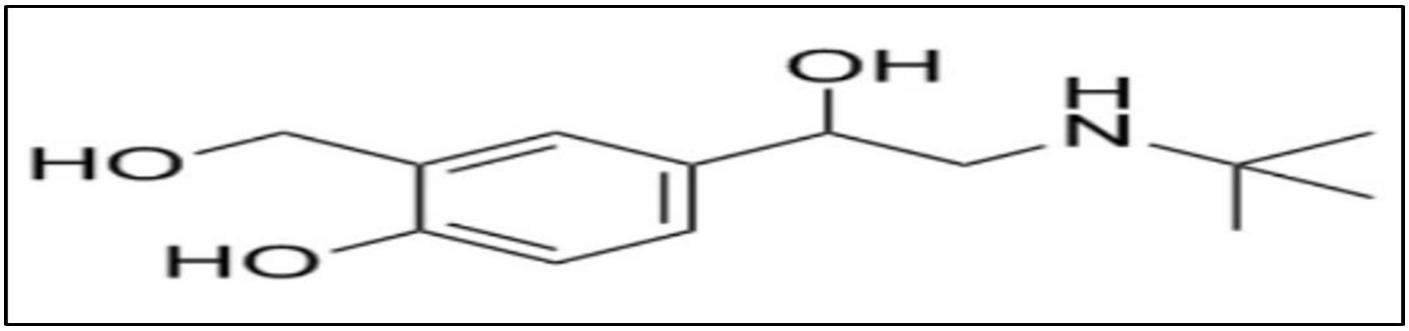

Fig 1 IUPAC Name [1-(4-hydroxy-3-hydroxymethylphenyl)-2- (Tbutylamino) Ethanol]

- Drug Bank ID: DB01001
- Generic Name: Albuterol
- Brand Name: Airomir, Airsupra, Combivent, Proair, Proventil,
- Ventolin Weight: 239.3107 g/mol
- Monoisotopic: 239.152143543
- Melting Point: 157-158°C
- Chemical Formula: C13H21NO3
- PUBCHEM ID: CID 91531784

➢ *Description:*

A white or almost white, crystal clear solution in methanol, very pale clear yellow solution.

➢ *Mechanism of Action:*

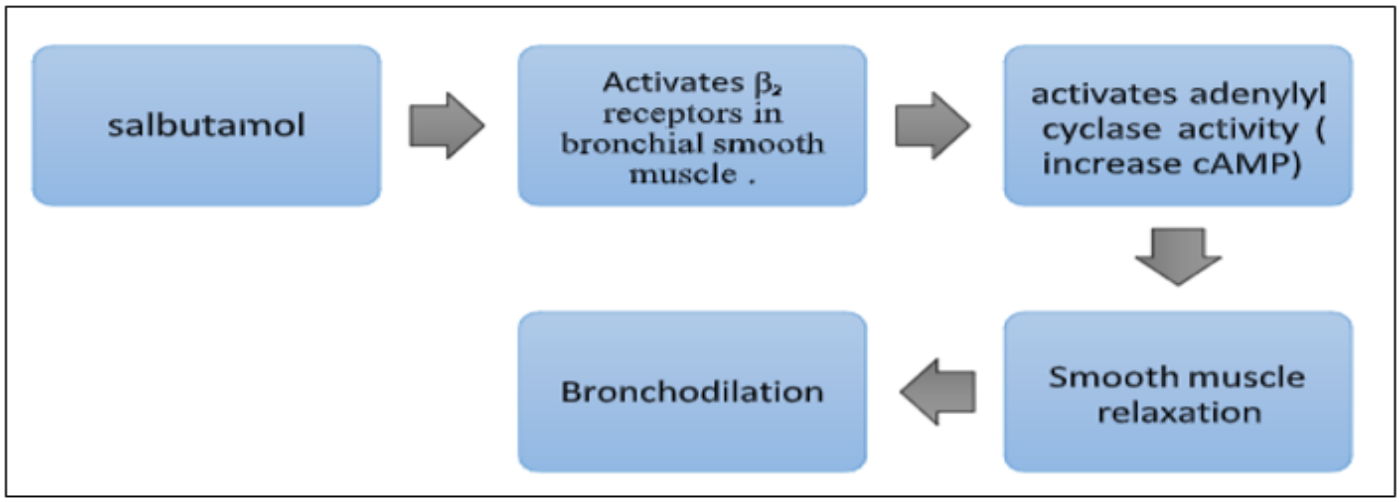

Fig 2 Mechanism of Action

➢ *Adverse Drug Effects:*

- Seizures, angina, fluctuations in blood pressure.
- Tachycardia reaching rates of up to 200 beats per minute, arrhythmias.
- Feelings of nervousness, headaches, tremors, muscle cramps,
- Dry mouth, palpitations, nausea, dizziness.
- Hyperglycemia, hypokalemia, and metabolic acidosis.

➢ *Salbutamol Physicochemical Properties*

- Appearance of salbutamol powder: White and crystalline powder.
- Solubility: salbutamol soluble easily in organic solvents such methanol, ethanol and chloroform but Sparingly soluble in water.

Fig 3 solubility test of drug

- Melting Point: The melting point of salbutamol isaround 157 o C . Fig no.2 : melting point test

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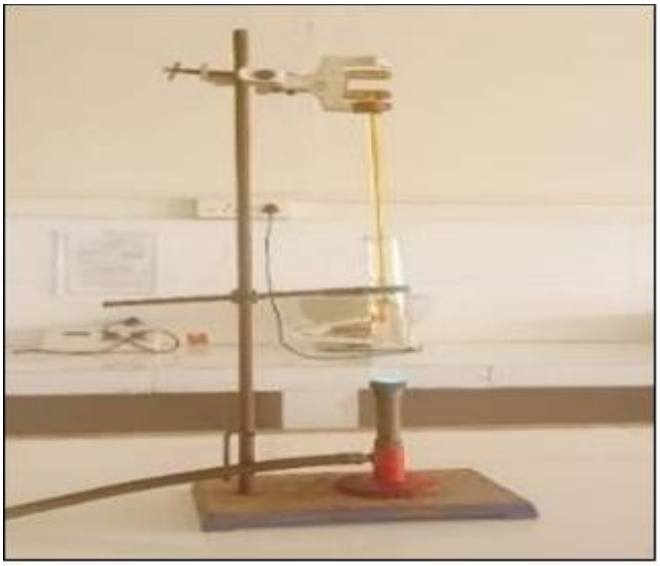

Fig 4 Melting Point Assembly

Fig 5 Litmus test

- Stability: While salbutamol is stable when store protected fromlight or moisture. Store between 15^0C and 25^0C.Keep out of reach of children.
- pH of Drug: salbutamol is acidic in form.
- Standard calibration curve for Salbutamol: Initially the pure Salbutamol was scanned in between UV-range such as 250-350 nm.The maximum absorbance for salbutamol was found at 276nm. A standard concentration of salbutamol in the range of 5 µg/ml was prepared in 0.1N NaoH and the absorbance were measured at 276nm.

Table 2 Standard values of Salbutamol

Sr. No	Concentration µg/ml	Absorbance at 276 nm
0	0	0
1	1	0.150
2	2	0.25
3	3	0.405
4	4	0.496
5	5	0.664

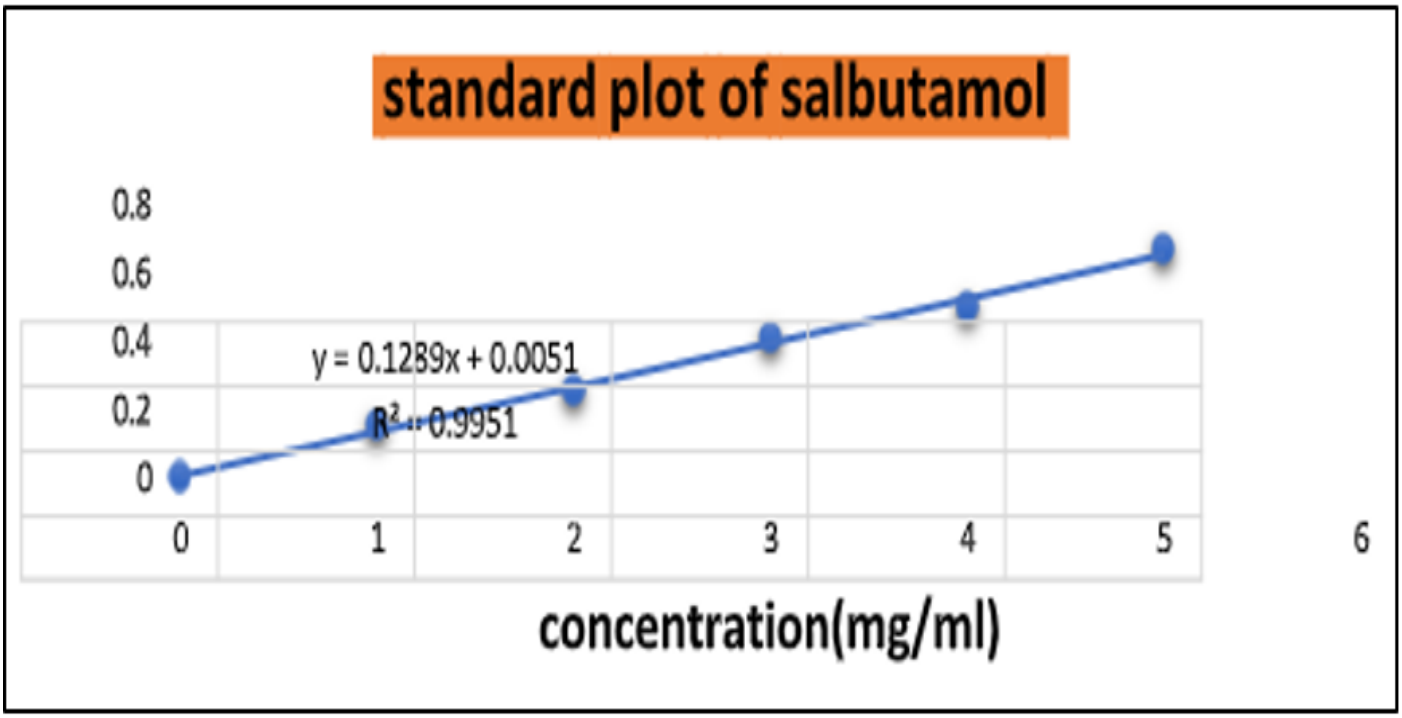

Fig 6 Calibration curve of salbutamol pure drug

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Fig 7 Different dilution of drug

➢ *Formulation of Effervescent Tablet*

Effervescent tablet are a type of pharmaceutical dosage form that rapidly dissolves in water, releasing carbon dioxide and resulting in an effervescent solution. This formulation is designed to deliver active ingredients quickly and efficiently.

V. FORMULATION STUDIES

Table 3 Formulation F1, F2, F3 and their Role in Formulation

Sr .No	Ingredients	Composition			Role
		F1	F2	F3	
1	Salbutamol	2 gm	2 gm	2 gm	Bronchodilator
2	Sodium Citrate	1 gm	1 gm	1 gm	Bronchial secretion enhancer
3	Eucalyptus oil	3%	5%	2%	Loosen phlegm
4	Diphenhydramine	0.5 gm	0.5gm	0.5 gm	To relieve cough
5	Citric acid	3 gm	4gm	3 gm	Effevescent agent
6	Salicyclic Acid	1 gm	1 gm	1gm	Analgesic
7	Microcrystalline cellulose	2 gm	3gm	2 gm	Disintegrant agent
8	lactose	2 gm	1 gm	1.5 gm	Flowability,wettability
9	Magnesium stearate	2.5gm	2.5gm	2.5gm	Lubricant
10	Sodium Bicarbonate	7gm	7gm	7gm	Effevescent agent
11	Tarteric acid	4 gm	3gm	4 gm	Effevescent agent
12	Talc	1 gm	1 gm	1 gm	Lubricant
13	starch	2gm	2 gm	2 gm	Binding agent
14	camphor	0.5 gm	0.5gm	0.5gm	Relieve cough , pain

Fig 8 Excipients use in preparation of tablet

VI. PROCEDURE

Fig 9 Fine Granules

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Fig 10 Sieving the Granulation

Fig 13 Granule compression

Fig 12 Tray Dried

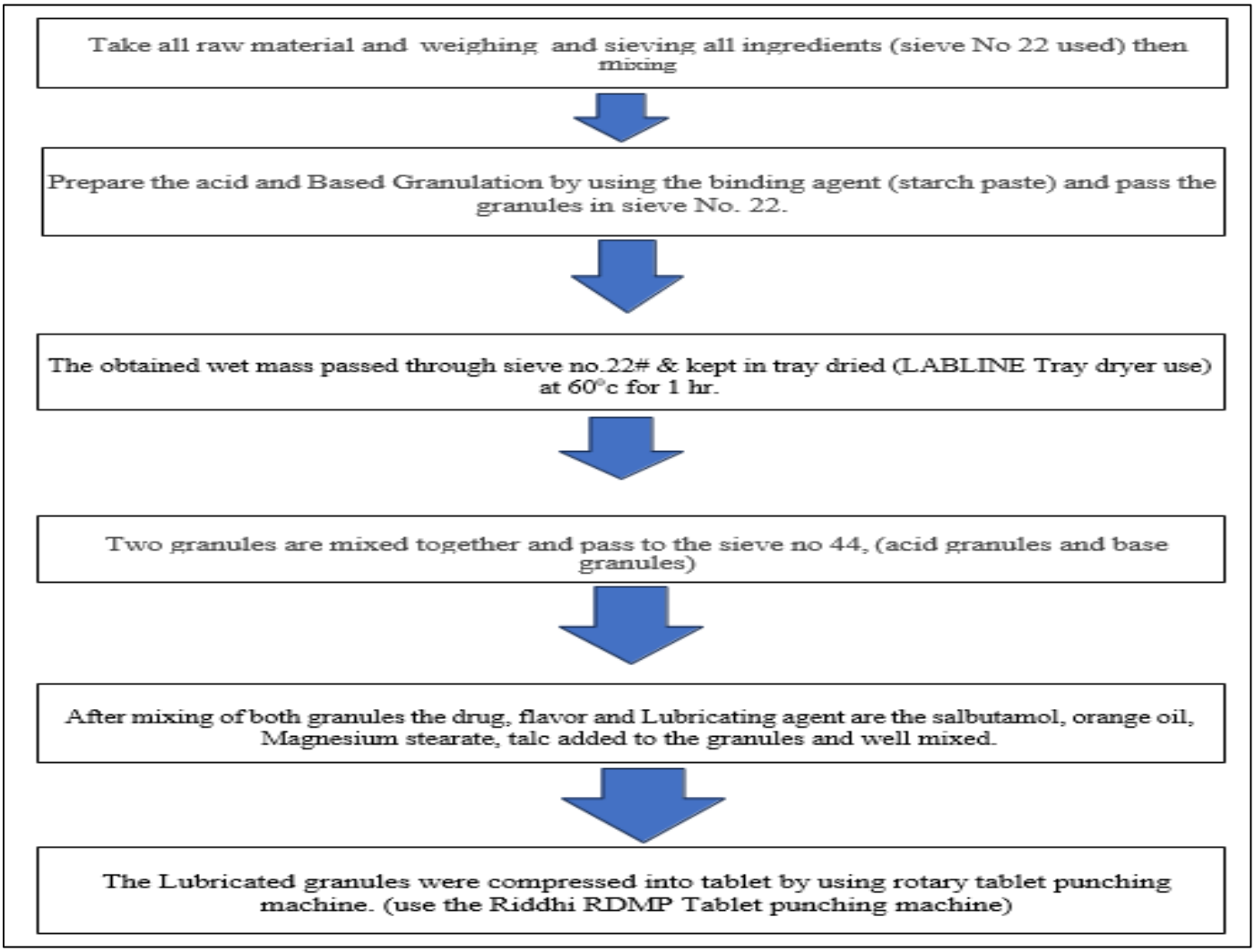

Fig 14 Preparation of tablet formulation (F1, F2, F3)

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Fig15 (A) Formulation: Fig16 (B)Formulation: Fig17 (C) Formulation:3

VII. EVALUATION OF EFFERVESCENT TABLETS

➢ *Weight variation:*

Weight variation was determined to know whether different batches of tablets have uniformity. Weighed 20 tablets individually, calculated the average weight and compared the individual tablet weights to the average. The tablets meet the test if not more than two tablets are outside the % limit and none of the tablet differ by more than two times the % limit.

Fig 18 Weight Variation

Table 4 Weight of formulated effervescent Tablets

Tablet .No	Weight of tablet (in gm)	Tablet. No	Weight of tablet (in gm)
1	0.27	11	0.27
2	0.26	12	0.27
3	0.27	13	0.27
4	0.26	14	0.26
5	0.27	15	0.26
6	0.27	16	0.27
7	.029	17	0.27
8	0.27	18	0.27
9	0.27	19	0.28
10	0.26	20	0.29

Total weight of 20 tablet = 5.4 gm

$$\text{Average weight} = \frac{\text{total weight}}{20} = \frac{5.4}{20} = 0.2705$$

$$\text{Limit} = \frac{\%\ \text{deviation allowed}}{100} \times \text{Avg weight} = \frac{5}{100} \times 0.270 = 0.0135$$

- Upper limit = Average weight+ limit = 0.2705 + 0.0135 = 0.2835 Lower limit = Average weight - limit = 0.2705-0.0135= 0.2565
- There are tablet weight given between the 0.256-0.2835 are present the passed the weight variation test as per IP .

➢ *Tablet Thickness and Diameter:*

Thickness and diameter of tablets were important for uniformity of tablet size. Thickness and diameter were measured using Vernier Calipers. The tablet diameter are 8.49 mm.

Fig 19 Vernier Calipers test

➢ *Tablet Hardness Test:*

The hardness of tablet of each formulation was measured by Pfizer hardness tester. Three reading are taken 3,4,4 respectively so that the average was 3.6 kg/cm^2

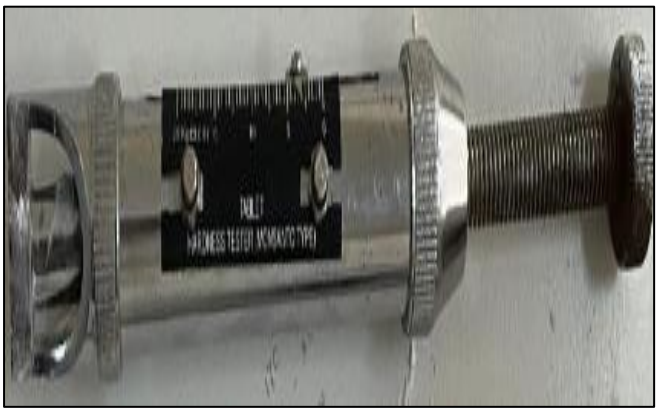

Fig 20 Pfizer hardness tester

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➢ *Friability (F):*

Friability of the tablet determined using Roche friabilator. Total weight of tablet = 5.60 gm(w1) After friability test the weight of tablet = 5.55gm (w2) $F = \frac{W\ Initial - W\ final}{W\ initial} \times 100 = \frac{5.60 - 5.55}{5.60} * 100 = 0.89\ \%$

Fig 21 Roche Friabilator

➢ *Determination of Effervescent time:*

A tablet was placed in a glass containing purified water and effervescent time was measured by a stopwatch. The effervescent of the tablet were observed and time noted was 20 second.

Fig 22 Effervescent time measure

➢ *In-vitro disintegration time:*

The process of breakdown of a tablet into smaller particles is called as disintegration. The in-vitro disintegration time of a tablet was determined using disintegration test apparatus as per I.P. Place one tablet in each of the 6 tubes of the basket. Add a disc to each tube and run the apparatus using phosphate buffer (pH-6.8) maintained at37°±2°C as the immersion liquid. In- vitro disintegration time was found to be 20 second.

Fig 23 In-vitro disintegration time measure

VIII. RESULT & CONCLUSION:

After a long time salbutamol prefer for oral formulation. It mostly applicable for treatment of pulmonary infection . In case of aerosols salbutamol prefer but manufacturing cost is very higher . In our project we made effervescent tablets not only reduce the manufacturing cost also provide fast relief against pulmonary action. Here, we use upgraded material , validated equipment & efficient methods to make formulation of effervescent tablets. After evaluation parameters like weight variations, thickness, disintegration , we concluded that salbutamol effervescent tablets provide a better option to treat the (COPD)Chronic Obstructive Pulmonary Disease.

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