Evaluation of Marketed Effervescent Tablets

Bharat sagare[1], Vishal Pawar[2], Mansi Patilghote[3], Shamlila B Bavge[4], Nandkishor B Bavge[5], Wasmate sir[6]

[1]*B pharmacy final year student ,Latur College of Pharmacy Hasegaon, Tq. Ausa, Dis. Latur ,413512 Maharashtra, India*

[2]*Department of pharmaceutical analysis ,Latur College of Pharmacy Hasegaon, Tq. Ausa, Dis. Latur ,413512 Maharashtra, India*

[3]*Department of pharmacognosy , Latur College of Pharmacy Hasegaon, Tq. Ausa, Dis. Latur ,413512 Maharashtra, India*

[4]*Department of pharmaceutics ,Latur College of Pharmacy Hasegaon, Tq. Ausa, Dis. Latur ,413512 Maharashtra, India*

Abstract **- The aim of this study is to evaluation of Effervescent tablet with sufficient mechanical integrity and to achieve faster disintegration in the water. Effervescent tablets are uncoated tablets that generally contain acid substances and carbonates or bicarbonates and which react rapidly in the presence of water by releasing carbon dioxide. They are intended to be dissolved or dispersed in water before use. Effervescent compositions in the form of tablets comprising a therapeutic agent, a granulating agent, a micro particulate effervescent component and an effervescent system which dissolve rapidly in water to yield an effervescent solution containing a completely dissolved therapeutic agent and a process for their preparation.**

Index Terms **- Effervescent Tablets.**

INTRODUCTION

"Effervescent tablet is a tablet intended to be dissolved or dispersed in water before administration". It generally contains in addition to active ingredients, mixture of acids/acid salts (citric, tartaric, malic acid or any other suitable acid or acid anhydride) and carbonate and hydrogen carbonates (sodium, potassium or any other suitable alkali metal carbonate or hydrogen carbonate) which release carbon dioxide when mixed with water. Occasionally, active ingredient itself could act as the acid or alkali metal compound necessary for effervescent reaction. Effervescent tablets are uncoated tablets that generally contain acid substances and carbonates or bicarbonates and which react rapidly in the presence of water by releasing carbon dioxide. They are intended to be dissolved or dispersed in water before use. The aim of this study is to develop and physico-chemically evaluate the Effervescent Tablets of Effervescent. To enhance the onset of action of Effervescent and increase the solubility of Effervescent. To enhance the bioavailability of drug. To achieve better patient compliance, To Avoid the First Pass Effect, they should have satisfactory property, Tablet having the greater bioavailability than other dosage form, The stability of Effervescent tablets can be increased, the effervescent tablets require strictly humid control area. The Effervescent tablets cannot be made in a normal area where the humidity and temperature condition not maintained.

Fast onset of action. - Effervescent tablets have major advantage that the drug product is already in solution at the time it is consumed, thus the absorption is faster and more complete than with conventional table faster absorption means faster onset of action effervescent drug are delivered to the stomach at a pH that is just right for absorption many medications travel slowly through the gastrointestinal tract or have absorption that is hampered by food or other drug. No need to swallow tablet - effervescent medications are administered in liquid form so they easy to take as compared to tablets or capsule the number of people who cannot swallow tablet or who dislike swallowing tablet and capsule is growing with an effervescent dosage form, one dose can usually be delivered in just 3 or 4 ounces of water. Good stomach and intestinal tolerance - effervescent tablet dissolve fully in a buffered solution. Reduced localized contact in the

upper gastrointestinal tract leads to less irritation and greater tolerability buffering also prevent gastric acids from interacting with drug themselves, which can be a major cause of stomach. More portability - effervescent tablet is more easily transported than liquid medication because no water is added until it is ready to use. Improved palatability - drugs delivered with effervescent base, taste better than most liquids, mixture and suspensions superior taste masking is achieved by limiting objectionable characteristics and complementing formulations with flavor and fragrances. The effervescent tablet essentially include flavoring so they taste much better than a mixture of non-effervescent powder in water moreover, they produce fizzy tablets, which may have better consumption appeal than the traditional dosage form. More consistent response - drugs delivered with effervescent technology have predictable and reproducible pharmacokinetics profile that are much more consistent than the tablets or capsule. Accurate dosing - researchers have been shown that effervescent tablets enhance the absorption of number of active ingredients compared to conventional formulations. This is because the carbon dioxide created by the effervescent reaction can enhance active ingredient permeability due to an alteration of paracellular pathway. the paracellular pathway is the primary route of absorption of hydrophilic active ingredients in which the solutes diffuse into the intercellular space between epithelial cells. it is postulated that the carbon dioxide widens the intercellular space between cell which leads to greater absorption of active ingredients (both hydrophilic and hydrophobic).the increased absorption of hydrophobic active ingredients could be due to the non-polar carbon dioxide gas molecules partition into cell membrane, thus creating an increased hydrophobic environment, which would allow the hydrophobic active ingredients to be absorbed. Conventional tablets are often associate with slower onset of action and also undergoes first pass metabolism. Effervescent tablets avoid the first pass metabolism and also produce rapid onset of action. Oral liquid also provides rapid onset of action but required carefully handling.

MATERIALS AND METHODS

Effervescent is procured by om medical ,Citric acid, Fumaric acid, Sodium Citrate, Sodium benzoate is, Tartaric acid ,Sodium Bicarbonate , Polyethlenglycol-6000 Polyvinylpyrolidone-K- 30, Simethicone Acesulfame given by college(Maharashtra college of pharmacy,nilanga).

Preformulation:-

Preformulation is a branch of pharmaceutical sciences that utilizes biopharmaceutical principles in the determination of physicochemical properties of a drug substance. The goal of pre- formulation studies is to choose the correct form of the substance, evaluate its physical properties and generate a thorough understanding of the material's stability under various conditions, leading to the optimal drug delivery system. The pre formulation study focuses on the physiochemical parameters that could affect the development of efficacious dosage form. These properties may ultimately provide a rationale for formulation design. Also, it will help in minimizing problems in later stages of drug development, reducing drug development costs and decreasing product's time to market. It gives the information needed to define the nature of the drug substance and provide framework for the drug combination with pharmaceutical excipients in the dosage form.

Objective: -The overall objective of Preformulation testing is to generate information useful to the formulation in developing desired, stable and bioavailable dosage forms

Scope: -The use of pre formulation parameters maximizes the chances in formulating an acceptable, safe, efficacious and stable product.

Pre formulation encompasses at least following tests:
Determination of melting point

The melting point of Effervescent is determined by using Thermocal melting point apparatus.

Solubility

Effervescent is practically insoluble in water, freely soluble in acetone, soluble in alcohol.

Angle of Repose (0)

The frictional force in a loose powder or granules can be measured by angle of repose. Angle of repose is

defined as the maximum angle possible between the surface of a pile of the powder and horizontal plane.

tan 0 = h / r

0 = tan-1 (h/r)

Where, 0 is the angle of repose h is height of pile

Angle of repose (0) (degrees)	Flow
<25	*Excellent*
25-30	*Good*
30-40	*Passable*
>40	*Very poor*

Table1:Relationship between Angle of Repose (0) and flow properties

METHOD

A funnel is filled to the brim and the test sample is allowed to flow smoothly through the orifice under gravity. From the cone formed on a graph sheet is taken to measure the area of pile, thereby evaluating the flowability of the granules. Height of the pile is also measured.

Bulk Density

Bulk density is defined as the mass of a powder divided by the bulk volume. The bulk density of a powder depends primarily on particle size distribution, particle shape, and the tendency of the particles to adhere to one another.

Tapped Density

After measuring the bulk volume the same measuring cylinder was set into tap density apparatus. The tap density apparatus was set to 300 taps drop per minute and operated for 500 taps. Volume was noted as (Va) and again tapped for 750 times and volume was noted as (Vb). If the difference between Va and Vb not greater than 2% then Vb is consider as final tapped volume. The tapped density is calculated by the following formula.

Tapped density = Weight of powder / Tapped volume

CARS INDE X TABALE

Consolidation Index (Carr %)	Flow
5-15	Excellent
12-16	Good
18-21	Fair to passable
23-35	Poor
33-38	Very poor
>40	Very Very poor

Table. Composition of effervescent Tablets Effervescent (Dry granulation)

Ingredients	F1	F2
Effervescent		
Citric acid (anhydrus)		
Tartaric acid		
Ascorbic acid		
Sodium bicarbonate		
Sodium carbonate		
Sodium citrate		
Sodium benzoate		
Mannitol		
PEG-6000		
PVP-K-30		
Simethicone		
Acesulphum potassium		

EVALUATION OF EFFERVESCENT TABLETS TO BE PERFORMED

Uniformity of thickness Test

The maximum thickness of the formulation the minimum thickness of the formulation

Hardness test

The hardness of the tablet

Friability test

The maximum friability of the formulation is found to be. The minimum friability of the formulation is founding to be done by the test. The % friability is less than in all the formulations ensuring that the tablets were mechanically stable.

Test

All the evaluationd (F1 & F2) tablets were passed weight variation test as the % weight variation is within the IP limits of the weight. The weights of all the tablets were founding to be done by uniform with low standard deviation values. The prepared formulation complies with the weight variation test.

Tablet Disintegration Test

Disintegration time is founding to be done by from all formulations, F1 has minimum in vitro Effervescent time, but its hardness is not good so we select formula F2.

Weight Variation Test

All the evaluationd (F1 & F2) tablets were passed weight variation test as the % weight variation was within the IP limits of ± 5.0% of the weight. The weights of all the tablets were founding to be done by uniform with low standard deviation values.

PH of the solution Test

PH of solution prepared putting tablets into water is affected by storage condition due to liberation of CO2

Evavaluation of the powder blend

Batch code	Bulk density	Tapped density	Angle of repose	Percent Compressibility
F1				
F2				

Table Evaluation of Effervescent Tablet Parameter

Batch code	Thickness (mm)	Hardness (kg)	Friability	Weight variation	Disintegration Time(sec)	ph of solution
F1						
F2						

Table Observation of Effervescent Tablet

	Dry granulation	Wet granulation
	Only half of the tablet is showing effervescence and sticking problem also occurred.	Capping problem and less effervescence
	Sticking problem, less effervescence	Capping problem and less effervescence
	Sticking problem, less effervescence	Capping problem and less effervescence
	Sticking problem, less effervescence	Very quick effervescence, the tablet surface is rough
	Tablet gives good effervescence, but some particles settle at the bottom of the solution, sticking problem also occurred.	Tablet gave good effervescence solution become somewhat clear and with less capping problem
	Tablet gives good effervescence, but the tablet surface found rough and sticking problem also occur	Tablet gives good effervescence but the capping also as such.
	The tablet gives good effervescence, capping problem but some particles become settled down, the hardness also not good	The tablet gives good effervescence, no capping problem and the solution become founding to be done by clear, hardness of tablet not good
	The tablet founding to be done by good hardness, but the capping problem somewhat occurs, solution founding to be done bynot clear	The tablet gives good effervescence; no capping problem and the solution become founding to be done byclear, hardness of tablet also good compared to other batches.
	Tablet gives good effervescence, but some particles settle at the bottom of the solution, sticking problem also occurred.	Tablet gives slow effervescent. The other properties like hardness, appearance is satisfactory.

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