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FORMULATION AND EVALUATION OF FLOATING TABLET OF RIZATRIPTAN BENZOATE

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ABSTRACT

Rizatriptan Benzoate is potent anti-migraine drug having agonist activity at the 5-hydroxytryptamine (5-HT) 1B & 5-HT 1D receptor. It commonly used for relief of headaches in treatment of migraine. Conventional tablets of RZT are not capable of rapid action, which is required for immediate relief from migraine pain. The aim of present work is to formulate & evaluate floating tablets of Rizatriptan Benzoate prepared by wet granulation methods using effervescent agents like sodium bicarbonate, super disintegrates like HPMC, HPMC K15M and Ethyl Cellulose as diluents & Alcohol was utilized as granulating medium, which increased rate of dissolution may leads to increase in oral bio availability. The prepared tablets were evaluated for uniformity of weight, thickness, friability, content uniformity, hardness, disintegration time, wetting time & for in vitro drug release. Further the tablets were characterized by Fourier transform infrared spectroscopy & differential scanning calorimetry. The correct formulation was subjected to stability at 40±2°C/75±5% RH for 30 days. In-vitro floating studies were carried out which increased the gastric residence time & improved bioavailability of the drug. Rizatriptan Benzoate is potent anti-migraine drug having agonist activity at the 5-hydroxytryptamine (5-HT) 1B & 5-HT 1D receptor. It commonly used for relief of headaches in treatment of migraine. Conventional tablets of RZT are not capable of rapid action, which is required for immediate relief from migraine pain.

KEYWORDS: Rizatriptan Benzoate effervescent agents like sodium bicarbonate, super disintegrants like HPMC, HPMC K15M and Ethyl Cellulose as diluents & Alcohol was utilized as granulating medium.

INTRODUCTION

Oral routes of drug administration have wide acceptance up to 50-60% of total dosage forms. Solid dosage forms are popular because of ease of administration, accurate dosage, self-medication, pain avoidance and most importantly the patient compliance. The most popular solid dosage forms are being tablets and capsules; one important drawback of this dosage forms for some patients, is the difficulty to swallow. Drinking water plays an important role in the swallowing of oral dosage forms. Often times people experience inconvenience in swallowing conventional dosage forms such as tablet when water is not available, in the case of the motion sickness (kinetics) and sudden episodes of coughing during the common cold, allergic condition and bronchitis[1]. Oral administration is the most versatile, convenient and commonly employed route of drug delivery for systemic action. Oral controlled release drug delivery have recently been of increasing interest in pharmaceutical field to achieve improved therapeutic advantages, such as ease of dosing administration, patient compliance and flexibility in formulation. A controlled drug delivery system with prolonged residence time in the stomach is of particular interest for drugs that are locally active in the stomach, have narrow absorption window in gastrointestinal tract, are primarily absorbed from stomach and upper part of GIT, are unstable in the intestinal or colonic environment, disturb normal colonic bacteria and exhibit low solubility at high pH values. Gastro retentive dosage form can remain in the gastric region for several hours and hence significantly prolong the gastric residence time of drugs. Prolonged gastric retention improves bioavailability, reduces drug waste, and improves solubility of drugs that are less soluble in a high pH environment[2-5]. Gastro retention helps to provide better availability of new products with suitable therapeutic activity and substantial benefits for patients 1,2. Rizatriptan Benzoate has newly developed (5-HT) 1B & 5-HT 1D receptor blocker. It commonly used for relief of headaches in treatment of migraine.

This system remains buoyant 3-4hrs for an elongated duration of time in abdomen without impacting the

gastric deflated rate. Oral administration is greatest suitable manner of delivery drug and is related with superior patient compliance as contrast to different manner of drug intake. Oral administration has only short use for impact drugs, from different pharmacological class and bad oral bioavailability due to damaged absorption and dissoluteness in the GIT. Some drugs are property by a narrow absorption window at the upper part of the GIT. Execration high-level absorption properties of the duodenum & ileum. The area of absorption at these sites is narrow because the passage through this region is quick. Improving the gastric residence time Gastro-retentive time of a NAW the drug may major improve the net extent of its absorption.TheGastric emptying of dosage forms is greatly flexible and control emptying time. Several controlled release systems for higher absorption and increase bioavailability.[6-8]

Rizatriptan Benzoate is potent Anti-migraine drug having agonist activity at the 5-hydroxytryptamine (5-HT) 1B and 5-HT 1D receptor. It commonly used for relief of headaches in treatment of migraine. Conventional tablets of RZT are not capable of rapid action, which is required for immediate relief from migraine pain.In today's era many people are suffering from migraine. Migraine[3] is a one-sided throbbing headache followed by neurological and visual disturbances. Attack may prolong for long period. Rizatriptan benzoate is an antimigraine agent. It is 5HT1B/1D receptor agonist used in treatment of migraine. It is the first online drug, which is most effective as compared to other triptans. Quick onset of action is necessary in order to protect the patient from migraine attack. The present study is aimed to design such a dosage form for rizatriptan benzoate, which is able to deliver drug as rapidly as possible so that onset of action is quick and patient does not require water for swallowing. In sublimation method, the rapid disintegration of the tablets is achieved by creation of pores in the tablets up on sublimation of volatile components added in the tablets. The saliva will enter these pores and cause the rapiddisintegration of the tablets in the oral cavity. The porous structure is responsible for the faster water uptake, Hence it facilitates wicking action in bringing about faster disintegration.[9-12]

RZT are indicated for the acute treatment of migraine with or without aura in adults & in paediatric patients 6 to 17 years old.

MATERIALS AND METHODS

Rizatriptan benzoate was obtained as a gift sample from Jubilant Life SciencesRoorkeeIndia. Different polymers and excipients like HPMC (Nova Polychem Karol Bagh, New Delhi), HPMC K15M (S.D Fine chemicals Ltd, Mumbai, India), Ethyl cellulose (Bio-Sols*Pvt. Ltd.*, MumbaiIndia). All other ingredients used were of laboratory grade.

Fourier Transforms Infrared Spectroscopy

FTIR study was performed to verify pure drug and polymer interaction. The study of pure drug RZT Benzoateand HPMC, HPMC K 15 M and Ethyl Cellulose. It was performed by KBr pellet method. The pure drug powder with KBr and pellet was prepared by high pressure to 100kg/cm for 2min. The obtained tablet was analysed in (FTIR 8400S, Shimadzu, Japan). KBr was obtained initially before analysis of test samples. The procedure was repeated for the analysis of drug and excipients.[13]

Bulk Density and Tapped Density

Both bulk and tapped density were calculated a quantity of powder from each formula, previously light shaken for break any amount formed, was introduced into the 10ml of measuring cylinder. After initial volume was observed, the cylinder was allowed to fall down its own weight from the hard surface from a height of 2.5cm at 2sec Intervals. The tapping was continued until no further change in the volume was noted LBD and TBD were calculated using the following formulas.[14]

LBD = Wt of Powder/Vol of Powder ……. (1)

TBD = Powder wt/Tapped vol Powder …….. (2)

Carr's Index[15]

The floability of powder can be determined by differentiate the (LBD) and (TBD) of powder and the value at which it crowded depressed.

Carr's index is calculated by formula: -

$$\text{Carr's index (\%)} = \frac{\text{TBD}-\text{LBD}}{\text{TBD}} \times 100 \ldots\ldots. (3)$$

Hausner's Ratio[16]

The Hausner's can be determined by the following equation.

$$\text{Hausner's ratio} = \frac{\text{TBD}}{\text{LBD}} \ldots\ldots. \quad (4)$$

Where,

TBD= Tapped bulk density

LBD= Loose bulk density

Angle of Repose[17]

Angle of repose was determined by using funnel method of following formula.

$$\text{Tan}\theta = \frac{h}{r} \ldots\ldots. \quad (5)$$

Where,

θ = angle of repose

h = height of the pile

r = radius of the pile base

Evaluation Parameters of Compressed Tablet[18]

Tablet Hardness[19]

The RZT Benzoate floating tablets hardness was determined by using Monsanto hardness tester. From each batch the crushing strength of ten floating tablets with known weight was note in kg/cm2 and hardness of tablets was determined.

Tablet Thickness[20]
The thickness of floating tablets was determined, five tablets were used and average value was calculated by using Vernier Caliper.

2.2.3 Friability[21]
Friability of tablet was stand determined by using Roche Friability tester. Firstly, twenty tablets taken and weight accurately and transfer into Friability tester. The tester was operated at 25 rpm for 4 min or run up to 100 revolutions. The tablets were loss weighed; % friability was calculated by following formula.
F = Initial wt - Final wt/Initial wt × 100 ……. (6)

2.2.4 Weight Variation[22]
This method is performed as weight variation of tablets. Twenty tablets were individually weighed in (gm) on electronic balance. After that calculated the average weight of tablet and checked for weight variation of tablets.

Calculation of percentage weight deviation
% Variation = Individual wt-Average wt/Average wt × 100 ……. (7)

Content Uniformity[23]
This test is performed by taking 20 tablets weighed and powder. A quantity of powdered tablet equal to 100mg of RZT Benzoate tablet was dissolved in 0.1N HCl solution. It was diluted and absorbance was measured 234nm by using RZT Benzoate pacify was uniform by using UV Spectroscopy (Lab India UV 3000) at 234nm 0.1N HCl solution and % drug content was estimated.

Floating lag/time Study[24]
The tablets were transferred in a 100ml, beaker containing 0.1N HCL. The time required for the tablet to increase to the surface and float was performed as floating lag time and total duration of time by which dosage form remain buoyant is called total floating time (Rao *et.al*,. 2013).

In-Vitro Drug Release Studies
In-vitrodrug release study for the prepared matrix tablets were manage for a amount of 12hrs by using USP equipment II (Paddle type) at temperature 37±0.5ºC. The studies were performed with 100rpm using 900ml of 0.1N HCl. 10ml of samples were withdrawn at one hrs interval and replace equal volume of buffer. The RZT Benzoate release was measured at 234nm by using an ultraviolet visible spectrophotometer (Lab India UV 3000).[25]

Stability Studies
The stability studies were carried out according to ICH guideline. The correct formulation was subjected to stability at 40±2°C/75±5% RH for 30 days. After then duration the product was evaluated for colour, Hardness, Drug content & In-vitro drug release.[26]

Methods of Preparation of Matrix Tablets of Rizatriptan Benzoate
Floating matrix tablet containing Rizatriptan Benzoate were prepared by wet granulation method byusing various concentrations of different grades of polymers with NaHCO3. Rizatriptan Benzoate and polymers were mixed completely using mortar and pestle. Alcohol was utilized as granulating medium. Granules were ready by passing the wet coherent mass through # 18sieves. The granules were dried in hot air oven at a temp of 60°C for 1 hour. Dried granuleswere sifted along #20sieves & lubricated, Mg stearate and talc simply 4-5min beforecompression.[27]

Table 1: Composition Table All Ingredients.

S. No.	Ingredients (mg)	No. of Formulation					
1.	RZT Benzoate	F1	F2	F3	F4	F5	F6
		10	10	10	10	10	10
2.	HPMC	50	45	40	40	35	30
3.	HPMC K 15 M	15	20	25	15	20	25
4.	Ethyl cellulose	15	15	15	15	15	15
5	Sodium Bicarbonate	10	10	10	20	20	20
6	Magnesium Stearate	3	3	3	3	3	3
7	Talc	2	2	2	2	2	2
T. W		100	100	100	100	100	100

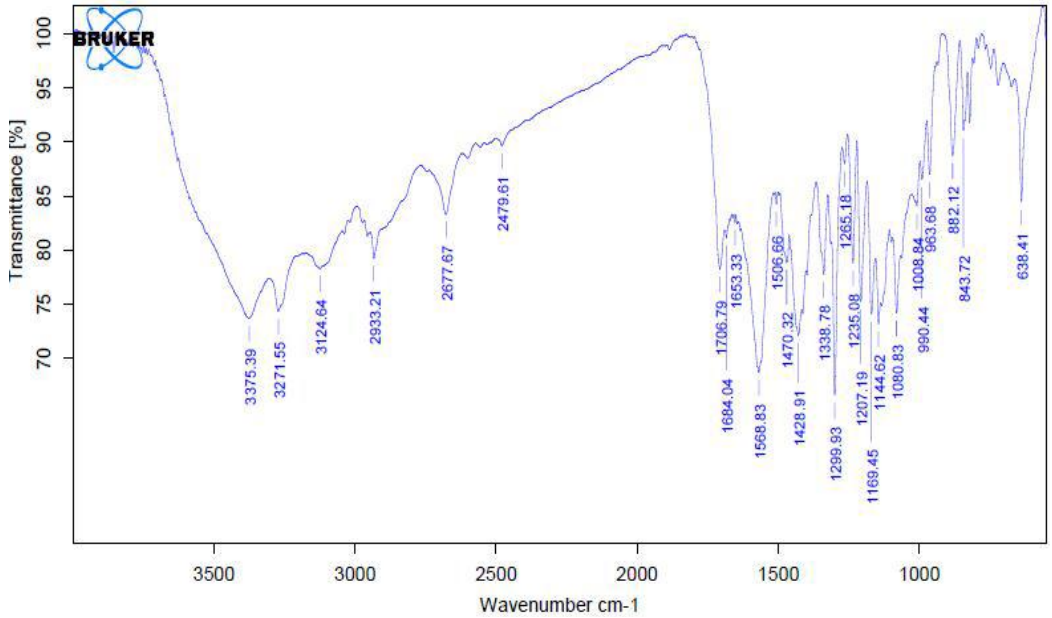

Figure 1: FTIR spectrum of Rizatriptan Benzoate +Ethyl Cellulose+HPMC K15M.

Floating matrix tablet containing RZT Benzoatewere prepared by wet granulation method by using various concentrations of different grades of polymers with NaHCO3. RZT Benzoate and polymers were mixed completely using mortar and pestle. Alcohol was utilized as granulating medium. Granules were ready by passing the wet coherent mass through # 18 sieves. The granules were dried in hot air oven at a temp of 60°C for 1 hour. Dried granules were sifted along # 20 sieves & lubricated, Mg stearate and talc simply 4-5min before compression (Patil*et.al.*2015).[28]

Table 2: All the formulation Composition of floating tablet RZT Benzoate.

S. No.	Ingredients (mg)	No. of Formulation					
1.	RZT Benzoate	F1	F2	F3	F4	F5	F6
		10	10	10	10	10	10
2.	HPMC	50	45	40	40	35	30
3.	HPMC K 15 M	15	20	25	15	20	25
4.	Ethyl cellulose	15	15	15	15	15	15
5	Sodium Bicarbonate	10	10	10	20	20	20
6	Magnesium Stearate	3	3	3	3	3	3
7	Talc	2	2	2	2	2	2
T. W		100	100	100	100	100	100

Table 3: Evaluation of Powders for matrix tablets of Rizatriptan Benzoate 10mg.

Formulation Code	Angle of Repose	Bulk density (gm/ml)	Carr's index (%)	Tapped density (gm/cc)	Hausner's ratio
F1	18.20±0.10	0.215±0.02	24.15±0.9	0.212±0.04	1.10±0.14
F2	20.34±0.06	0.289±0.12	26.38±0.6	0.270±0.06	1.32±0.18
F3	21.86±0.02	0.260±0.05	26.50±1.2	0.410±0.06	1.25±0.23
F4	24.28±0.10	0.235±0.08	32.64±0.8	0.316±0.05	1.38±0.20
F5	24.54±0.12	0.220±0.09	27.09±0.7	0.475±0.02	1.22±0.18
F6	22.70±0.04	0.295±0.10	33.52±0.8	0.339±0.09	1.30±0.13

Values are expressed as mean ±standard deviation SD (n=3)

The physical mixtures for matrix tablet were evaluated with respect to Angle of repose was found between 18.20±0.10 to 24.54±0.12 and Carr's index values were found between 24.15±0.9 to 33.52±0.8% the powder of all batches indicating excellent to poor flow ability and compressibility. Hausner ratio was found to be range 1.10±0.14 to 1.38±0.20. Bulk density ratio was found to be range 0.215±0.02 to 0.295±0.12 and tapped density ratio 0.212±0.04 to 0.475±0.02 for all the batches indicating that possible and poor flow properties.

Table 4: Evaluation of Compressed floating tablet of Rizatriptan Benzoate.

Formulation Code	Weight variation Average wt in (mg)	Floating Lag/Time (Sec)	Hardness (Kg/cm2)	Friability (%)	Thickness in (mm)	Drug Content Uniformity (%)
F1	207±3.4	36±2.0	4.80±0.4	0.50±0.02	3.16±0.1	96.45±0.9
F2	209±2.2	38±3.4	5.46±0.2	0.68±0.04	3.30±0.4	96.37±1.5
F3	2010±3.0	34±3.0	4.50±0.4	0.64±0.02	3.10±0.6	95.79±1.0
F4	201±2.5	26±1.7	4.16±0.2	0.70±0.06	3.20±0.2	98.00±1.6
F5	199±1.4	39±2.6	4.20±0.6	0.62±0.05	3.22±0.1	98.56±1.0
F6	203±3.0	26±2.5	4.36±0.3	0.76±0.04	3.26±0.7	96.55±2.5

Values are intimate as design ±SD (n = 3)

The prepared tablets were evaluated for physical parameters hardness; friability, weight variation, thickness and drug content result are given in (table 5.3). Hardness of tablets were found to be in range of 4.16±0.2 to 5.46±0.2kg/cm2. The friability of all prepared tablets was found to be range 0.50±0.02 to 0.76±0.04%. The Thickness of prepared tablets were found range 3.10±0.6 to 3.30±0.4mm. The weight variations of all tablets were established to be 199±1.4 - 2010±3.0mg. The Floating time 26±2.5 to 39±2.6and highest % drug content 98.56±1.6.

Table 5: In vitro drug release studies F1-F6.

Time	% Release drug					
Formulation	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**
1	26.46±0.07	37.88±0.05	48.90±0.15	23.72±0.05	28.13±0.10	26.45±0.02
2	36.76±0.04	45.87±0.13	58.32±0.17	28.34±0.07	36.44±0.012	36.46±0.36
3	48.80±0.061	58.90±0.32	75.67±0.24	37.15±0.06	56.56±0.125	47.18±0.023
4	68.70±0.064	70.34±0.07	88.92±0.06	51.32±0.009	70.33±0.065	66.25±0.08
5	78.40±0.035	76.45±0.14	91.34±0.022	64.74±0.034	78.70±0.017	70.44±0.058
6	88.54±0.026	90.54±0.021	96.77±0.014	84.64±0.022	95.50±0.06	84.15±0.020
7	94.43±0.014	96.78±0.012	97.54±0.027	95.27±0.012	98.75±0.02	94.19±0.032

Point are communicate as mean ±standard deviation (n = 3)

The percentage of drug released from the formulation F1, F2 and F3 was found to be 94.43±0.014%, 96.78±0.012% and 97.54±0.027% respectively. The percentage of drug released from the formulations F4, F5 and F6 was found to be 95.27±0.012%, 98.75±0.02% and 94.19±0.032%. The best % drug released of formulation F5. It was also observed that the amount of polymer increases in the formulation then it was decrease in drug release rate, may be due to drug entrapped in hydro gel by forming hydrophilic polymer. The minimum combination of HPMC, HPMC K 15 M and Ethyl Cellulose of various ratios in the different formulation.

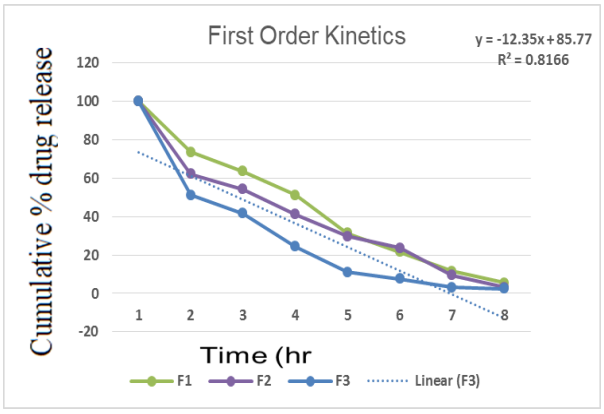

Figure 3: First-order release kinetics.

Kinetics Parameter of all Formulation

Figure 2: Zero-order release kinetics.

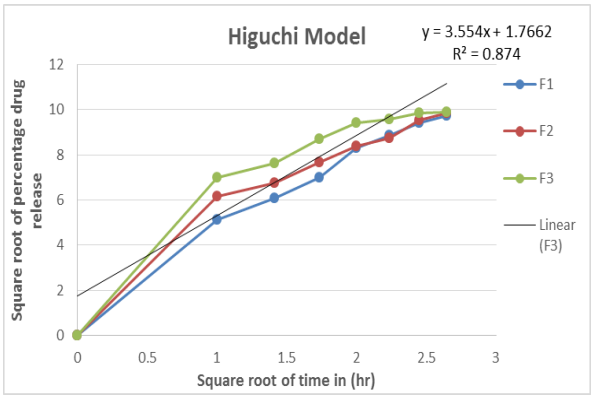

Figure 4: Higuchi model release kinetics.

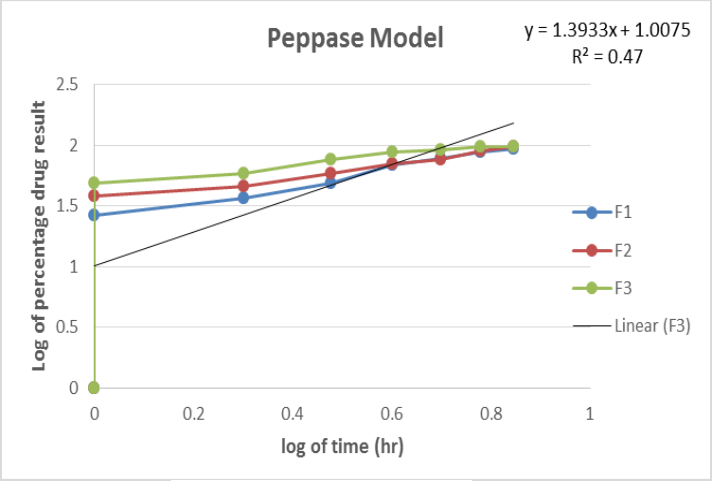

Figure 5: Korsmeyer-Peppas model release kinetics.

Table 6: Release kinetics for all floating tablets of Rizatriptan Benzoate.

Formulation code	Zero order	1st-order	Higuchi	Peppa's
	r^2	r^2	r^2	r^2
F1	0.9726	0.9728	0.9763	0.6061
F2	0.9331	0.9331	0.9327	0.5226
F3	0.8164	0.8166	0.874	0.47

According to this data the release kinetics were studied by fitting the data into various models. The r^2 values for each kinetic model as Zero order, 1st-order, Higuchi and KorsmeyerPeppas in show (table 3.6). The release kinetics of some formulation like F1& 2 followed Higuchi model, formulation F3 followed the 1st order.

Stability Studies

Table 7: stability study for best formulation F5.

S.No.	Parameters	Initial	1 Month
1	Colour	No Change	No Change
2	Hardness	4.20±0.4	4.19±0.2
3	Drug Content	98.56±1.0	98.48±0.4
4	In-Vitro Drug Release	98.75±0.02	97.68±0.013

The duration of stability studies of the Formulation 5, there is no change in colour, but the variation of a Hardness, Drug Content and In vitro Drug Release.

CONCLUSION

Rizatriptan Benzoate prepared by wet Granulation methods using effervescent agents like sodium bicarbonate & citric acid, which increased rate of dissolution may leads to increase in oral bio availability. Various studies such as, Pre-formulation studies, UV spectroscopy, Physical drug excipients compatibility studies, FTIR Spectroscopy, Evaluation of powders for matrix tablet, Formulation Development, Evaluation Parameter, Kinetic Release Parameters and Stability studies were performed. The formulations were prepared by wet granulation method using distinct drug as Viscosity grades of Hydroxy Propyl Methyl Cellulose. The correct formulation was subjected to stability at 40±2°C/75±5% RH for 30 days. Rizatriptan Benzoate is potent anti-migraine drug having agonist activity at the 5-hydroxytryptamine (5-HT) 1B and 5-HT 1D receptor. It commonly used for relief of headaches in treatment of migraine. Conventional tablets of Rizatriptan are not capable of rapid action, which is required for immediate relief from migraine pain.

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