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Original Research Article

DESIGN AND DEVELOPMENT OF FAST DISSOLVING TABLET OF RIZATRIPTAN BY USING NATURAL (BANANA POWDER) SUPERDISINTEGRANT

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Abstract

The demands for fast dissolving tablets have received ever increasing during the last 2-3 decade. In the present project study, the effect of natural Superdisintegrants was compared with synthetic Superdisintegrants and conventional Superdisintegrants in the formulation of fast dissolving tablet formulation of Rizatriptan. The new anti-migraine drug, rizatriptan benzoate is a potent and selectively 5-hydroxytryptamine$_{1B/1D}$ receptor agonist and is considered as more effective than the other traditional triptans for the treatment of acute migraine attack. In the proposed work 9 formulations of FDTs of Rizatriptan were prepared by using Superdisintegrants was evaluated and compiles with the official parameters with all the specifications. Various formulations were prepared using four different superdisintegrsnts namely natural super disintegrats Fenugreek Powder, sodium starch glycolate, Crospovidone with three concentrations (4%, 6%, 8%) by direct compression method. Formulation F2 showed the minimum disintegration time and in-vitro dissolution studies shows that formulation F2 showed 96.50% drug release at the end of 3 minutes.

Keywords: Natural Superdisintegrants, Migraine, Rizatriptan, Crospovidone, Fenugreek powder, hydroxytryptamine, dissolution time.

INTRODUCTION

The tablet is most widely used conventional solid dosage form because of its convenience in term of self-administration, compactness, dose accuracy and easy in manufacturing, but over this one drawback of these conventional tablets is difficulties in swallowing by pediatric and geriatric patients. The fast dissolving tablets that dissolving in few seconds in the mouth when they come with contact with saliva without requirement of any additional water. The advantage of FDTs (Fast dissolving tablet) is onset of action, higher patient acceptance, and increased bioavailability.[1-3]

The new generation anti-migraine drug, rizatriptan is a potent and selective 5-hydroxytryptamine1B/1D receptor agonist and is considered more effective than the other traditional triptans for the treatment of acute migraine attack. Chemically it is 3-[2-(dimethylamino) ethyl]-5-(1H1,2,4-triazol-1-ylmethyl)indole monobenzoate. The bioavailability of rizatriptan benzoate

is about 45% which is superior to a poor 14-17% of other triptan category. It shows a very fast onset of action within half an hour of intake, providing immediate relief from migraine.[4-7]

MATERIAL AND METHOD: -

MATERIAL: -

Rizatriptan was received as gift sample by Apotex labs, Bangalore, Fenugreek powder was gifted by Ayursatva, MP, Asparteme used was procured from Sweetener India, Delhi, and other reagents and chemicals used were of analytical grade from Central Drug House.

METHOD: -

Fast dissolving tablet of Rizatriptan were prepared by using required amount of drug and excipients were taken for every formulation suggested by (Table No. 1). Then weighed quantity of super disintegrates and aspartame taken for each formulation and properly mixed, finally magnesium stearate and talc powder were added and mixed well. The mixed blend of drug and excipients were compressed using 10 station tablet punching machine. Tablet preparation /punch the mixture blend of all designed formulations were subjected to compatibility studies (IR) and pre-compression parameters like- Angle of repose, Bulk density, Tapped density, compressibility index, Hauser's ratio[8]

Pre-formulation studies: -

Angle of Repose (θ):

The angle of repose is determined by the funnel method suggested by scientist Newman. Angle of repose is determined by the following formula

$\text{Tan } \theta = h/r$

$\theta = \text{Tan}^{-1} h/r$

Where θ = Angle of repose, r = Radius of the cone, h = height of the cone

Bulk Density:

Density defined as weight per unit volume. Bulk density can be defined as the mass of the powder is divided by the bulk volume of powder and is expressed as gm/ cm^3. There are two types of bulk density.[9]

Tapped Density (Dt):

It was the ratio index of total mass of the powder to tapped volume of the powder. Volume was reported by tapping the powder for 500 times and the tapped volume was recorded, if the difference between these two volumes was less than 2%. It was expressed in g/ml and was given as following,

$Dt = M/Vt$

Where, M is the mass of powder, Vt is the tapped volume of the powder.[10]

Carr's index (or) % compressibility:

Carr's index results powder flow properties. It is expressed by percentage and is given by:

$I = Dt - Db/Dt \times 100$

Where, Dt denotes the tapped density of the powder and Db is the bulk density of the powder.[11]

Hausner ratio:

Hausner ratio is an indirect index of ease of powder flow properties. It is calculated by the following formula:

Hausner ratio=Dt/Db Where, Dt show the tapped density, Db is the bulk density. Lower hausner ratio (<1.25) indicates better flow properties than higher ones (>1.25)[12]

EVALUATATION OF TABLET: -

All prepared tablets of Rizatriptan were evaluated for the following parameters as per IP guideline; all the calculations are represented in the table No.3

WEIGHT VARIATION: -

Twenty tablets of Rizatriptan formulation were selected randomly from each of the formulation and weighted individually using Digital Balance for their weight data. The average weight of the tablets calculated was found in standard range.[13-14]

HARDNESS: -

Hardness of the Rizatriptan tablet was measured with the tablet hardness testing apparatus known as Monsanto tablet harness tester.[15]

THICKNESS: -

The thickness of the tablet was measured in mm by the Vernier Calipers for all the designed formulation batches.[16]

FRIABILITY: -

The friability of the Rizatriptan tablet, a sample of twenty tablets was measured using USP type Roche fraibilator. The tablets reweighed and percentage weight-loss was calculated, was found in standard range.[17-18]

%Friability= Initial Weight−Final Weight * 100/ Initial Weight

DISINTEGRATION STUDY: -

Disintegration time study was carried out by selecting 6 tablets of Rizatriptan and performed disintegration test using 900 ml distilled water at temperature ($37^0C \pm 2^0C$) [19]

DISSOLUTION STUDY: -

The In-vitro for the dissolution study was carried out in the USP (United state pharmacopeia) dissolution test apparatus type 2 known as Paddle dissolution apparatus, used phosphate buffer as dissolution medium as 900 ml containing PH 6.8 was taken in vessel and the temperature maintained at 37 ± 0.5^0C as per standard guidelines.[20-21]

Table No. 1: Formulation of fast dissolving tablet of Rizatriptan:

Ingredients(mg)	**FD1**	**FD2**	**FD3**	**FD4**	**FD5**	**FD6**	**FD7**	**FD8**	**FD9**
Rizatriptan	10	10	10	10	10	10	10	10	10
Fenugreek Powder	4	6	8	-	-	-	-	-	-
Sodium Starch Glycolate	-	-	-	4	6	8	-	-	-
Crospovidone	-	-	-	-	-	-	4	6	8
Aspartame	1	1	1	1	1	1	1	1	1
Flavour	1	1	1	1	1	1	1	1	1
Talc	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Magnesium Stearate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Mannitol	25	25	25	25	25	25	25	25	25
Sorbitol	30	30	30	30	30	30	30	30	30
Lactose	26	24	22	26	24	22	26	24	22
TOTAL	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**

RESULT AND DISCUSSION: -

Table No. 2: Pre-compression parameters of Rizatriptan FDTs

Parameters / Formulation	Bulk Density (mg/ml)	Tapped Density (mg/ml)	Hausners Ratio	Compressibility Index (%)	Angle of Repose
FD_1	0.388± 0.01	0.514±0.02	1.32±0.02	24.60± 0.02	20.21± 0.01
FD_2	0.395± 0.03	0.521±0.03	1.31±0.03	24.18± 0.01	20.44± 0.02
FD_3	0.396± 0.02	0.511±0.01	1.29±0.01	22.50± 0.02	21.11± 0.01
FD_4	0.405 ± 0.01	0.481±0.01	1.87±0.01	15.80± 0.01	20.66± 0.02
FD_5	0.414 ± 0.10	0.492±0.02	1.18±0.02	15.85± 0.03	23.09± 0.03
FD_6	0.419 ± 0.04	0.488± 0.01	1.16±0.03	14.13± 0.02	24.35± 0.02
FD_7	0.389 ± 0.03	0.495± 0.03	1.27±0.01	21.41± 0.01	21.81± 0.01
FD_8	0.395 ± 0.02	0.497± 0.03	1.25±0.02	20.52± 0.02	21.81± 0.02
FD_9	0.394 ± 0.03	0.498± 0.02	1.26±0.01	20.88± 0.01	21.77± 0.01

Table No. 3: - Post-Compression parameters of Rizatriptan FDTs:

Parameters / Formulation	Thickness (mm)	Weight (mg)	Hardness (Kg/cm^2)	Friability (%)	Disintegration Time (Sec)	Swelling Time (Sec)
FD_1	3	98.05±0.55	3.15±0.15	0.48±0.84	45±0.01	16±1
FD_2	3	100.07±0.78	3.02±0.01	0.52±0.25	30±0.02	12±2
FD_3	3	99.01±0.11	3.10±0.09	0.59±0.17	42±0.01	15±1
FD_4	3	99.02±0.25	3.22±0.12	0.61±0.16	46±0.02	22±1
FD_5	3	100.01±0.11	3.23±0.01	0.64±0.12	42±0.03	20±2
FD_6	3	99.05±0.15	3.20±0.10	0.63±0.32	43±0.01	21±2
FD_7	3	100.01±0.15	3.35±0.05	0.65±0.13	45±0.02	21±2
FD_8	3	101.50±0.04	3.30±0.09	0.66±0.23	42±0.03	19±2
FD_9	3	99.02±0.22	3.25±0.18	0.61±0.19	44±.0.4	20±1

Table No. 4: - Drug Content in the Fast Dissolving Tablet of Rizatriptan

Parameters / Formulation	Drug Content (mg per Tablet)	% Drug Content
FD_1	96.10±0.015	96.10
FD_2	96.50±0.031	96.50
FD_3	96.20±0.015	96.20
FD_4	94.40±0.010	94.40
FD_5	95.10±0.025	95.10
FD_6	95.00±0.021	95.00
FD_7	93.20±0.018	93.20
FD_8	94.90±0.015	94.90
FD_9	95.20±0.012	95.20

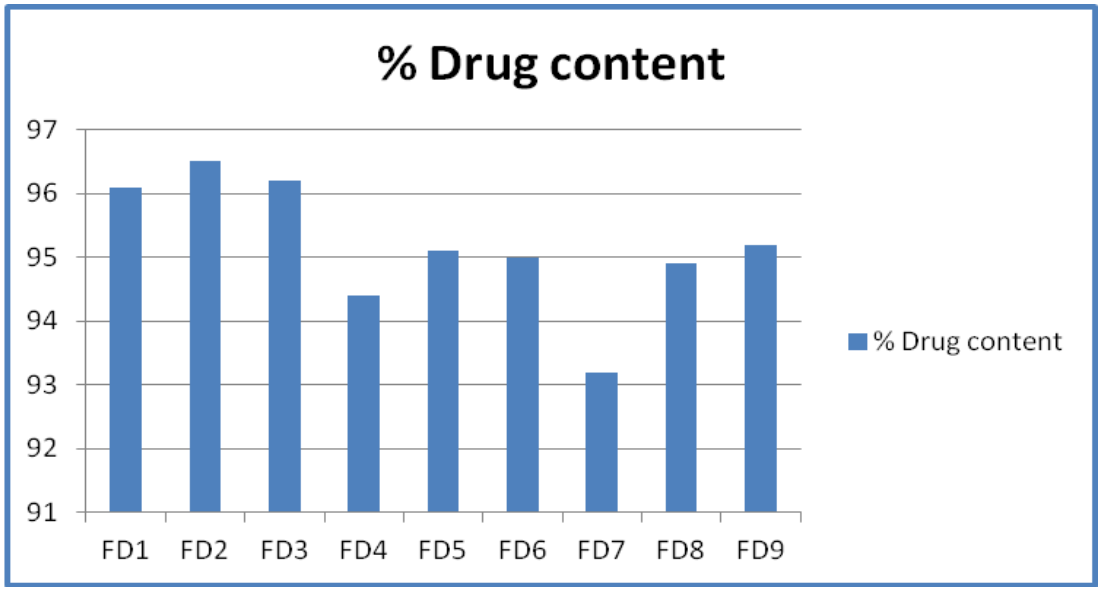

Figure:1- Drug Content in the Fast-Dissolving Tablet of Rizatriptan

RESULTS AND DISCUSSION:

The angle of repose for the entire formulations blend was found to be in the range 20.21 to 24.35°. Compressibility index was found to be in the range 14.13 % to 24.60 %. All formulations showed good flow properties. Hausner's ratio was found to be in the range 1.16 to 1.87 and that indicated that all formulation has good flow properties. All parameters show weight variation, thickness, Disintegration time (sec) within standard limit. From all the above observations it was concluded that the formulation F2contain Fenugreek powder 6% found to be better formulation

in terms of rapid dissolution and but maximum percentage drug release was found 96.50% of formulation F2, with Fenugreek Powder (6%).

CONCLUSION:

It can be concluded from the whole study that fast dissolving tablets of Rizatriptan drug. Natural Superdisintegrants can be used as pharmaceutical excipients for oral drug delivery. It was concluded formulation F2 maximum percentage drug release was found 96.50%, with Fenugreek Powder.

From the study, it was concluded that Natural Superdisintegrants like Fenugreek Powder showed better disintegrating property over the synthetic super disintegrate like, SSG (Sodium starch glycolate) and CP (Crospovidone)

Hence the Fenugreek Powder can be used at higher concentration at it has advantage of being non-toxic, low cost, biodegradable and biocompatible with no side effect.

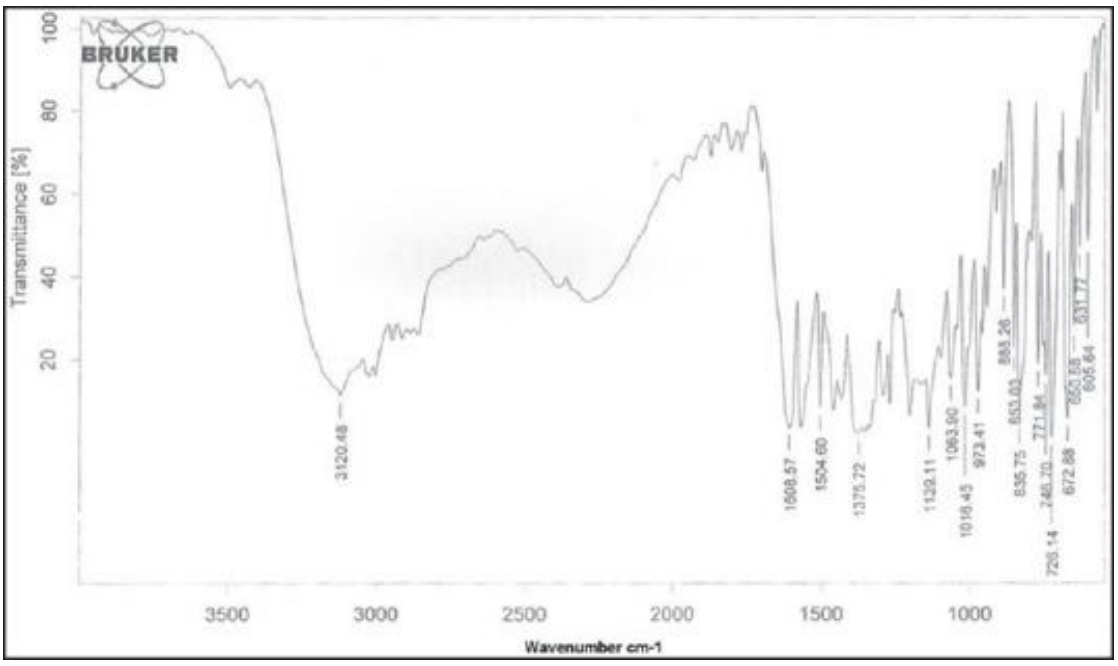

Figure: 2-IR spectra of Rizatriptan

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