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DESIGN AND DEVELOPMENT OF A RIZATRIPTAN FAST-DISSOLVING TABLET USING NATURAL DISINTEGRANT (MUSA PARADISIACA POWDER)

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ABSTRACT

Over the last two to three decades, there has been a steady increase in the demand for tablets that dissolve quickly. In the current project research, the effects of conventional, synthetic, and natural superdisintegrants were compared with those of the former in the formulation of Rizatriptan's fast-dissolving tablets. The strong and selective 5-hydroxytryptamine1B/1D receptor agonist rizatriptan benzoate is a novel anti-migraine medication that is thought to be more effective than other conventional triptans in treating acute migraine attacks. Nine formulations of Rizatriptan FDTs were created utilizing superdisintegrants in the proposed study, which was then analyzed and compiled with all the specifications and official criteria. Four distinct superdisintegrants—natural superdisintegrants Fenugreek Powder, sodium starch glycolate, and crospovidone—were used to generate several formulations at three different concentrations (4%, 6%, and 8%) by the use of the direct compression technique. According to in-vitro dissolution investigations, formulation F2 had the shortest disintegration time and 96.50% drug release after three minutes.

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

INTRODUCTION:

Due to its ease of self-administration, compact size, precise dosage, and ease of production, the tablet is the most often used traditional solid dosage form. However, a disadvantage of these conventional tablets is that they might be difficult for elderly and pediatric patients to swallow. The quick-dissolving pills dissolve in the mouth in a matter of seconds when they come into touch with saliva and don't need any extra water. Fast dissolving tablets (FDTs) provide the advantages of quicker start of action, better patient acceptability, and improved bioavailability.1-3

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As a strong and selective 5-hydroxytryptamine1B/1D receptor agonist, rizatriptan is a new generation anti-migraine medication that is thought to be more successful than other conventional triptans in treating acute migraine attacks. It is 3-[2-(dimethylamino) ethyl] chemically.Monobenzoate of 5-(1H1,2,4-triazol-1-ylmethyl)indole. Risatriptan benzoate has a bioavailability of around 45%, which is higher than the subpar 14–17% of other triptan categories. Within 30 minutes of consumption, it has a very quick beginning of action, offering migraine sufferers instant relief. 4–7

MATERIAL AND METHOD:-

Apotex Labs, Bangalore, gave a gift sample of rizatriptan, Ayursatva, MP, gave fenugreek powder, Sweetener India, Delhi provided asparteme, and Central Drug House provided additional analytical-grade reagents and chemicals.
The necessary quantity of medication was used to create Rizatriptan fast-dissolving tablets, and excipients were taken for each formulation recommended by (Table No. 1). After aspartame and super disintegrates were weighed and well combined for each batch, talc powder and magnesium stearate were added and thoroughly mixed. A ten station tablet punching machine was used to crush the combined mixture of medication and excipients. All planned formulations were put through compatibility tests (IR) and pre-compression characteristics such as Hauser's ratio, bulk density, taped density, compressibility index, and angle of repose throughout the tablet manufacturing and mixture blend process.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

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

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

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 Rizatriptan pills were chosen at random from each formulation, and their weights were recorded using Digital Balance for each tablet.

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 USP (United States Pharmacopeia) dissolution test apparatus type 2, also known as the paddle dissolution apparatus, was used to conduct the in-vitro dissolution study. Phosphate buffer was used as the dissolution medium; 900 ml of PH 6.8 was placed in the vessel, and the temperature was kept at 37±0.50C in accordance with standard protocols.20–21

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

Ingredients(mg)	FD1	FD2	FD3	FD4	FD5	FD6	FD7	FD8	FD9
Rizatriptan	5	5	5	5	5	5	5	5	5
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	30	30	30	30	30	30	30	30	30

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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	0.514	1.32	24.60	20.21
FD_2	0.395	0.521	1.31	24.18	20.44
FD_3	0.396	0.511	1.29	22.50	21.11
FD_4	0.405	0.481	1.87	15.80	20.66
FD_5	0.414	0.492	1.18	15.85	23.09
FD_6	0.419	0.488	1.16	14.13	24.35
FD_7	0.389	0.495	1.27	21.41	21.81
FD_8	0.395	0.497	1.25	20.52	21.81
FD_9	0.394	0.498	1.26	20.88	21.77

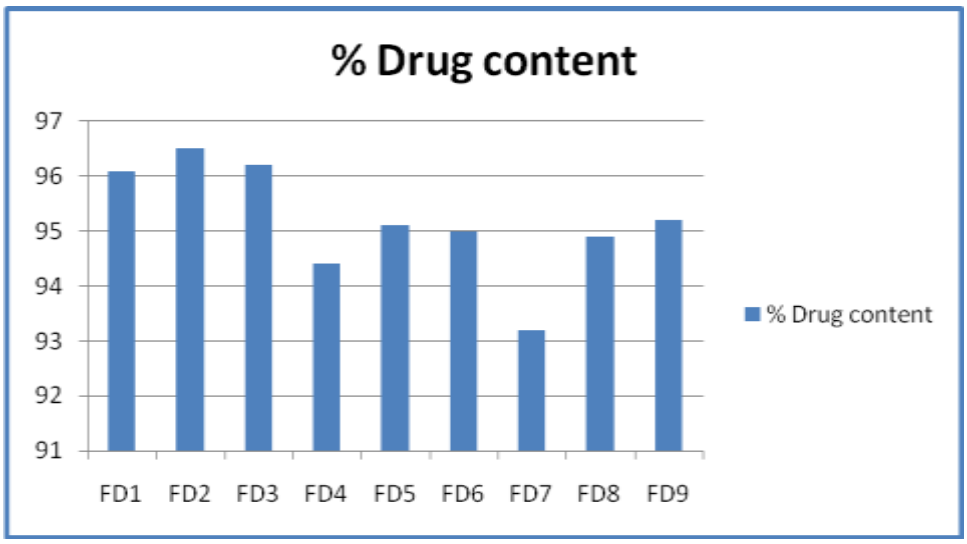
Table No. 3:- Post-Compression parameters of Rizatriptan FDTs:

Parameters **Formulation**	**Thickness (mm)**	**Weight (mg)**	**Hardness (Kg/cm^2)**	**Friability (%)**	**Disintegration Time (Sec)**	**Swelling Time (Sec)**
FD_1	4	98.05±0.55	3.15±0.15	0.48±0.84	45±0.01	16±1
FD_2	4	100.07±0.78	3.02±0.01	0.52±0.25	30±0.02	12±2
FD_3	4	99.01±0.11	3.10±0.09	0.59±0.17	42±0.01	15±1
FD_4	4	99.02±0.25	3.22±0.12	0.61±0.16	46±0.02	22±1
FD_5	4	100.01±0.11	3.23±0.01	0.64±0.12	42±0.03	20±2
FD_6	4	99.05±0.15	3.20±0.10	0.63±0.32	43±0.01	21±2
FD_7	4	100.01±0.15	3.35±0.05	0.65±0.13	45±0.02	21±2
FD_8	4	101.50±0.04	3.30±0.09	0.66±0.23	42±0.03	19±2
FD_9	4	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



RESULTS AND DISCUSSION:

It was discovered that the mix of all formulas had an angle of repose between 20.21 and 24.35°. The range of the compressibility index was determined to be 14.13% to 24.60%. Every formulation exhibited acceptable flow characteristics. The range of 1.16 to 1.87 for Hausner's ratio suggested that all formulations had satisfactory flow characteristics. Weight fluctuation, thickness, and disintegration time (sec) are all within the acceptable range for all metrics. Based on the aforementioned findings, it was determined that formulation F2, which contains 6% fenugreek powder, had a superior formulation in terms of quick dissolving. However, formulation F2, which also contains 6% fenugreek powder, had a maximum percentage drug release of 96.50%.

CONCLUSION:

The whole investigation leads to the conclusion that Rizatriptan pills dissolve quickly. Oral medication distribution may make use of natural superdisintegrants as pharmaceutical excipients. It was determined that the greatest percentage of drug release for formulation F2, including fenugreek powder, was 96.50%.

The study's findings indicated that natural superdisintegrants, such as fenugreek powder, outperformed synthetic superdisintegrants, such as sodium starch glycolate (SSG) and crospovidone (CP). As a result, fenugreek powder can be used at higher concentrations because of its non-

toxic, inexpensive, biodegradable, and side-effect-free qualities.

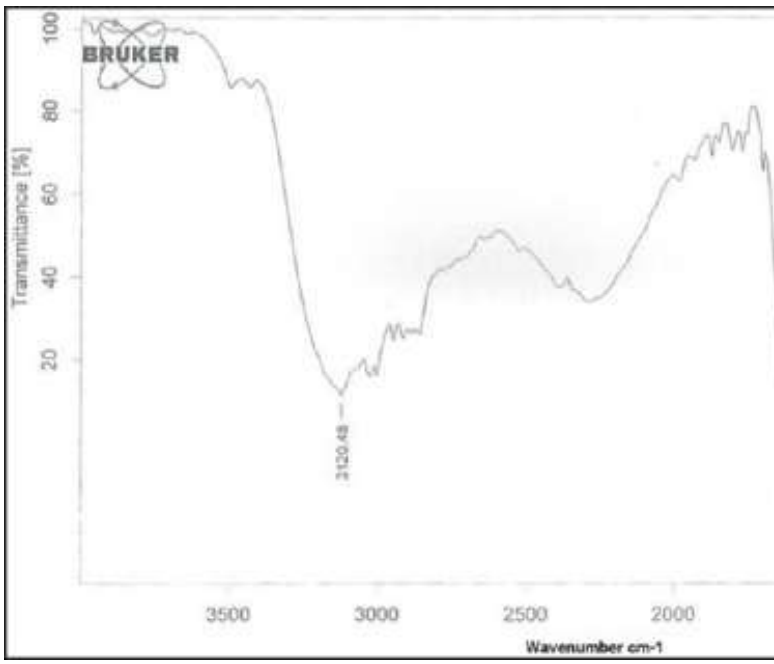


Figure: 2-IR spectra of Rizatriptan

Conflict of Interest

No conflict of interest to all authors.

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