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Formulation & Evaluation of Anti Migrane Mouth Dissolving Tablet

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ABSTRACT

The objective of this study is to improve the safety, efficacy, and rate of action of the existing molecule by utilising novel techniques to the administration of medication. This will be accomplished by the application of novel approaches. Orally disintegrating pills containing rizatriptan benzoate were made by the direct compression technique in order to provide migraine sufferers with a more expedient manner of gaining relief from their condition. For the purpose of this inquiry, a 32-factororial design method was utilised, and eight different formulations were examined for each of the super disintegrants that were explored. There were a number of tests that were performed on the batches of tablets that were manufactured. These tests included weight variation, hardness, friability, wetting time, invitro dispersion time, drug content, and invitro dissolution. A UV spectrophotometric approach that is easy, sensitive, rapid, accurate, cost-effective, and repeatable was created in order to identify the dose form of Rizatriptan Benzoate tablets. This method was designed in order to determine the dose form. It has been determined that rizatriptan benzoate has the maximum absorbance at a wavelength of 225 nm, and its molar absorption is measured to be 1.619 Ao. According to Beer's law, the application of the law was observed between 1 and 10 µg/ml. In order to validate the conclusions of the investigation, statistical analysis and recovery studies were carried out. In order to validate the method, a number of various criteria were utilised. These criteria included linearity, accuracy, limit of detection (LOD), limit of quantification (LOQ), Sandell's sensitivity, and specificity were among the criteria that were utilised. The practice of determining the regular dosage of Rizatriptan Benzoate in both tablet and bulk forms was found to be one that is accurate and precise via the utilisation of the preferred method. This was identified through the utilisation of the recommended method. A time period ranging from fifteen to thirty seconds was required for the optimised formulation to be distributed throughout the body. Furthermore, it demonstrated a greater water absorption ratio and released 99.60% of the medication over a period of two minutes and fifteen seconds. This was in addition to everything else that it shown.

Keywords: Rizatriptan, ODDS, Hardness test, LOD, LOQ, Tablet formulation.

I. INTRODUCTION

Oral administration is by far the most common and preferred method of drug delivery. This is true regardless of whether the medication is taken in liquid or solid form. The use of solid dosage forms, on the other hand, is widespread due to the multiple advantages that they provide. These advantages include patient compliance, the avoidance of discomfort, the convenience of administration, and exact dosing for self-medication (1). Tablets and capsules are the most prevalent types of solid dosage forms that are currently available to healthcare providers. To put this into perspective, research has shown that a sizeable percentage of individuals have trouble swallowing tablets or capsules that are composed of firm gelatin (2). It has been observed that this issue is present in all patient demographics; however, it is more prevalent in the populations of children and the elderly of the community. Because of this, normal dose forms lead to a high incidence of noncompliance and poor swallowing therapy, particularly in cases involving children, the elderly, or those who have

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developed mental retardation (3). This is especially true in situations when the patient is unable to swallow the medication. Some of the numerous benefits that it offers are its stability, the fact that it can be administered without the need of water, its precise dosing, the convenience with which it can be manufactured, the fact that it is packaged in a little amount, and the fact that it can be handled (4). This particular dose type is extremely frequent, particularly among populations that are either mentally challenged, elderly, or children. This is primarily because to the simplicity with which it can be delivered. The use of superdisintegrants makes it possible for the drug to dissolve quickly, which in turn makes it possible for the medication to be absorbed quickly and, eventually, for the effects of the medication to start occurring more quickly (5). Oral administration of rizatriptan results in a bioavailability of 45%, which is a very high percentage. Both the normal tablet and the oral dosing tablet (ODT) have half-lives that range from two to three hours and Tmaxes that are one and a half hours, with the ODT needing a much longer amount of time to reach its maximum concentration. For the purpose of administering a conventional anti-migraine drug, one hundred milligrammes of sumatriptan is equivalent to ten milligrammes of rizatriptan benzoate. The drug that prevents migraines When compared to earlier generations of triptans, rizatriptan benzoate, which is a more current generation of triptans, is superior in terms of its ability to cure acute migraine attacks [1]. To be more specific, it is a 5-hydroxytryptamine1B/1D receptor agonist that is not only potent but also selective. The substance in question is represented by the chemical formula 3-[2-(dimethylamino) ethyl]monobenzoate of 5-(1H-1,2,4-triazol-1-ylmethyl)indole. Rizatriptan benzoate, which is an alternative to the more typical treatment for migraines known as sumatriptan, is equivalent to one hundred milligrammes of sumatriptan [2]. Rizatriptan benzoate is a medication that is used to treat migraines. The bioavailability of rizatriptan benzoate is roughly 45%, which is much greater than the bioavailability of sumatriptan, which is just 14–17%. In comparison, the bioavailability of rizatriptan benzoate is approximately 45%. Within the first hour of taking the medication for migraines, it is probable that you may start to feel the effects of the medication, which will help to lessen the discomfort that you are experiencing [1]. Migraine sufferers would benefit from acute treatment that enables them to resume functional activities as early as possible because of the severe impairment in their functional skills that they experience as a result of migraines. The availability of certain effective alternatives to solid dosage forms has been made possible as a result of technological advancements [3, 4]. Patients who have difficulty swallowing or digesting solid dose forms, who are immobile, who feel sick, or who do not comply with their treatment can now take advantage of these alternatives. When it comes to pills that dissolve in the mouth or otherwise disintegrate, they are an ideal choice because of this. The introduction of superdisintegrants into the formulation results in an increase in the bioavailability of the drug [5]. This is accomplished by accelerating the release of the drug into the bloodstream. Because the tablet that contains the drug dissolves rapidly in saliva when it is taken orally, it is possible to drink the medicine orally as a liquid without the requirement for water [3, 6, 7]. This is because the tablet contains the drug. This dosage form is suitable for usage in situations when there is a lack of readily available running water, such as while one is travelling [3]. Due to the fact that it is portable, it is an excellent choice for use in situations such as these. This dosage form is a blend of the most advantageous characteristics of both the liquid and tablet forms, which is another advantage of this dosage type. As saliva travels through the mouth, throat, and pharynx, it eventually arrives to the stomach, which is the place where certain medications are absorbed throughout the digestive process. Under these circumstances, the bioavailability of the medication is substantially higher than what is observed when the medication is provided in the form of tablets that are commonly used. Since this mode of drug delivery makes it possible for patients of all ages, including children, the elderly, and members of the general community, to take their pills in a quiet way wherever and whenever they are required to do so, it significantly reduces the likelihood that patients will not comply with their prescribed medication regimens. Due to the fact that these tablets provide a number of benefits, including patient compliance, rapid commencement of action, better bioavailability, and high stability, they have become increasingly popular as a dosage form of choice in the current market [8,9].

The bioavailability of Rizatriptan benzoate is approximately 45%, which is significantly higher than the low bioavailability of Sumatriptan, which ranges between 14-17% (6,7). The freeze-dried dosage form of Rizatriptan is available on the market, which enables the drug to be broken down more quickly. One of the most significant drawbacks of this technology is that it is quite expensive, the procedure is not feasible, and the product is extremely vulnerable to moisture. Drying in the freezer is a challenging process that results in a product that is both fragile and hygroscopic (8). Superdisintegrants that are naturally occurring were utilised in this work. Because natural superdisintegrants are safer, more biodegradable, better compressible, quicker to prepare, and more affordable, the production of organic dispersive materials (ODTs) can be improved as a result of these and other benefits (9). For the purpose of this experiment, the tablets that dissolve quickly were produced by the process of direct compression, with a number of different pharmaceutical excipients being utilised each time. Avicel pH 102, crospovidone, Plantago ovata mucilage, mannitol, aspartame, aerosil, and magnesium stearate

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were the excipients that were employed in this formulation.

II. MATERIAL & METHODS

A complimentary sample of Rizatriptan Benzoate was made available by Cipla Ltd. in Kurkumbh, Pune. Indion 234 was the sample that was provided by Wyeth Ltd., which is located in Verna, Goa. The Indion 414 was given as a gift by Ion exchange (India) Ltd., which is located in Mumbai. Arihant Trading Co., which has its headquarters in Mumbai, was the supplier of the carboxymethylcellulose calcium. Aspartame, mannitol, magnesium stearate, crospovidone, and avicel PH-102 were all ingredients that were provided by Glenmark Pharmaceuticals Ltd., which is located in Colvale, Goa. Simply put, we only used chemicals of an analytical grade for everything else.

Preparation of oral disintegration tablets

For the production of Rizatriptan pills that disintegrate when taken orally, the direct compression method was utilised. To separate each component, a sieve with a mesh size of sixty was utilised. All of the following components were mixed together with the help of a mortar and pestle: rizatriptan, crospovidone, psyllium mucilage, avicel PH 102, mannitol, and aspartame. For the purpose of lubricating the mixtures, one percent aerosol had been combined with one percent magnesium stearate. After being prepped for compression, the mixes were then turned into tablets so that they could be compressed. A tablet machine (ErwekaAR 4100, Germany) equipped with a flat round punch of 3 millimetres in diameter was utilised in order to crush the tablets. The experimental factorial design compositions were presented in Table 1.

Evaluation of mixed powder blend of drug and excipients

Every single formulation was put through a series of tests to determine its angle of repose, bulk density, tapped density, Hausner's ratio, and Carr's index, in addition to being evaluated for drug and excipient preparations.

Bulk and tapped density

Two densities were measured: the bulk density and the tapped bulk density. A 10-milliliter measuring cylinder was filled with an appropriate amount of powder from each recipe. This was done after gently stirring the powder to remove any clumps that may have developed. After the initial volume was measured, the cylinder was dropped from a height of 2.5 cm onto a hard surface at two second intervals. It was permitted that the cylinder should collapse due to its own weight. After the output volume stopped changing noticeably, tapping was stopped. Two density computations were performed: the bulk density and the tapped bulk density.

Table 1: Composition of Different Batches of Mouth Disintegrating Tablets of Rizatriptan Benzoate

Ingredients	F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8	F_9
Rizatriptan benzoate	10	10	10	10	10	10	10	10	10
Crospovidone	3	6	9	3	6	9	3	6	9
Psyllium mucilage	6	6	6	9	9	9	12	12	12
Aerosil	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
Aspartame	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Avicel PH 102 up to	150	150	150	150	150	150	150	150	150

Carr's index

Through the utilisation of Carr's index, the compressibility index of the powder blend was determined. The Db and Dt values of a powder, in addition to the packing down rate, can be simply evaluated with the help of this basic test. To calculate Carr's Index, the formula is as follows:

$$Carr\ index = \frac{D_t - D_b}{D_t} \times 100$$

Where Dt is tapped density of the powder and Db is bulk density of the powder.

Hausner ratio

The formula for Hausner's ratio was determined by comparing the bulk and tapped densities of the Rizatriptan blend powder:

$$Hausner's\ ratio = \frac{D_t}{D_t}$$

Where D_t is tapped density and D_b is bulk density.

Angle of repose

The fixed funnel method was used to determine the angle of repose (θ). The funnel's height was set such that its tip barely touched the top of the granules pile. Without restriction, the granules were let to pour out of the funnel and land on the ground. Using the following formula, we were able to determine the granular cone's diameter and angle of repose:

$$\tan\theta = \frac{h}{r}$$

Evaluation of disintegration tablets Weight variation

Code	Angle of repose (θ)	Bulk density (gr/cm³)	Tapped density (gr/cm³)	Carr's index (I)	Hausner's ratio
F_1	31.4±0.02	0.37±0.06	0.41±0.02	10.15±1.13	1.11
F_2	31±0.03	0.32±0.07	0.35±0.02	09.10±1.01	1.10
F_3	30.6±0.02	0.34±0.04	0.37±0.02	07.94±0.35	1.08
F_4	30.1±.003	0.36±0.02	0.39±0.02	06.63±1.27	1.07
F_5	30.3±0.01	0.33±0.03	0.36±0.02	09.53±1.05	1.10
F_6	29.4±0.05	0.35±0.04	0.39±0.01	09.53±1.11	1,10
F_7	29±0.02	0.36±0.07	0.39±0.01	07.08±1.36	1.07
F_8	29.4±0.01	0.37±0.05	0.43±0.01	14.75±1.55	1.17
F_9	28.9±0.03	0.34±0.07	0.37±0.02	07.94±0.35	1.08

F: formulation

Tablet thickness

The thickness was measured by placing tablet between two arms of the Vernier calipers. 5 tablets were taken and their thickness was measured.

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Tablet hardness

The force needed to break a tablet is proportional to the square of its diameter; this is the hardness of the tablet. The erweka Hardness Tester (16) was used to determine the tablets' hardness through diametral compression.

Friability Testing

In order to determine the impact that shock and friction would have, we conducted this experiment. In the Erweka friabilator, ten tablets that had been weighed in the past were spun at a speed of twenty-five revolutions per minute for approximately four minutes. Following the dedusting process, the tablets were reweighed in order to ascertain the percentage of their friability. When it comes to compressed pills, a weight loss of less than one percent is considered acceptable (17).

$$Percentage\ friability = \frac{Initial\ weight - Final\ weight}{Initial\ weight} \times 100$$

Wetting time

For the purpose of determining how long it took for the pills to become wet, a straightforward procedure was utilised. Five tissue papers with a diameter of ten centimetres each were placed inside of a petridish that had a diameter of ten centimetres. In a volume of ten millilitres of water, a dye that is water-soluble and is known as eosin was added to the petridish. The surface of the tissue paper was covered with a tablet in a very delicate manner. The wetting time was considered to be a measurement of the amount of time it took for water to reach the top surface of the tablets. The lengths of time that the area was wet were recorded (18).

Water absorption ratio

The contents of a small petri dish with an interior diameter of 6.5 centimetres were filled with 6 millilitres of water, and a piece of tissue paper that had been folded twice was placed within the little dish. When a tablet was placed on the paper, the amount of time it took for the tablet to become totally saturated with water was then recorded. This equation was utilised in order to ascertain the water absorption ratio, which is denoted by the letter R.

$$R = \frac{W_a - W_b}{W_a} \times 100$$

Invitro disintegration test

The in vitro disintegration experiments were carried out with the assistance of a computerised tablet disintegration test device manufactured by Erweka ZT out of Germany. The basket assembly was constructed with six tubes, and each of those tubes was initially filled with one tablet. After that, a disc was placed inside of each tube. Next, the combination was maintained at a constant temperature of 37±2 degrees Celsius while it was suspended in a beaker that contained water and had a capacity of one litre. A pace of 28 to 32 cycles per minute was then used to lower and raise the basket by a distance of 5 to 6 centimetres each minute. The amount of time that was required for the tablet to completely dissolve was recorded as twenty.

Dissolution test

For the purpose of determining the rate at which Rizatriptan benzoate was released from orally dissolving tablets, we utilised the paddle method, which is described in the United States Pharmacopoeia (USP) XXIV dissolution testing equipment II. A dissolution test was conducted at 37±0.5 ºC and 50 rpm, with 900 ml of 0.1N HCl with a pH of 1.2. The temperature was maintained at 37±0.5 ºC. After one, two, three, four, five, ten, twenty, and thirty minutes, a five-milliliter sample of the solution was exhausted from the apparatus used for dissolving. For the purpose of filtering the samples, a 0.45 membrane filter was utilised. For the purpose of determining the absorbance of the solutions at 280 nm, a Shimadzu spectrophotometer was utilised. In order to generate an equation that was utilised to estimate the cumulative proportion of medicine release, a standard curve was utilised.

Content uniformity

Before being turned into powder, each batch's 10 pills were measured and then ground. After measuring out an exact quantity of 5 milligrammes (mg) of this Rizatriptan benzoate powder, it was combined with approximately 50 millilitres (ml) of 0.1 N hydrochloric acid and then shaken for a period of fifteen minutes. via the addition of 0.1 N hydrochloric acid and the subsequent filtration of the mixture via Whatmann No. 1 filter paper, a final volume of 100 ml was accomplished. Ten millilitres of this were used to create a solution that was one hundred millilitres in volume. The final volume was obtained by diluting 2 millilitres of the solution described above with 10 millilitres of 0.1 N hydrochloric acid. Through the utilisation of a UV/Vis spectrophotometer, the absorbance of the solution was determined at 280 nm in comparison to a blank for the reagent itself. On the other hand, the content was evaluated by means of a calibration curve that had been developed by employing standard Rizatriptan benzoate in the same medium (see to Table 3 for more information). The mean percent of drug content was calculated by taking the average of the three measurements and calculating the average.

Table: 3 Evaluation of the prepared orodispersible tablets of Rizatriptan

Tests	F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8	F_9
Weight variation (Mean±SD)	151±3.45	149±2.24	149±3.12	150±3.71	152±3.32	148±1.58	147±3.28	151±3.45	149±2.24
Hardness (kg/cm²)	3.81±0.25	3±0.27	3.8±0.22	3.8±.023	3.7±0.27	3.1±0.19	3.7±0.22	3±0.23	3.2±0.21
Friability	0.57±0.16	0.68±0.14	0.81±0.15	0.93±0.147	0.96±0.157	0.72±0.155	0.44±0.138	0.80±0.149	0.66±0.153
Thickness (mm)	3.2	2.9	3.00	3.1	3.1	3.2	2.9	3.3	3.4
Wetting time (s)	62	59	51	49	44	41	40	30	33
Water absorption ratio	78.12	80.25	82.34	85.74	86.64	88.57	90.47	93	91
In-vitro disintegration time (s)	56	54	48	45	41	37	32	27	30
Assay	98.3	97.2	98.7	96.7	98.2	95.8	99.4	97.2	97.3

F: formulation

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III. RESULT & DISCUSSION

A. Pre formulation Study

Characterization of Rizatriptan Benzoate

Organoleptic properties:

Melting point:

The melting point of Rizatriptan benzoate was foundto be in the range of 179° to 181°C.

Determination of saturation solubility:

`Rizatriptan benzoate's solubility in various solutions is shown in Table 5. These solutions include deaerated water, buffer pH 6.8, and 0.1 N hydrochloric acid. When comparing deaerated water, 0.1 N HCl, and buffer pH 6.8, the drug's solubility is higher in the former.

Table 4: Solubility Data of Rizatriptan Benzoate

Solvent	Solubility (mg/mL)
0.1 N HCl	43.42
Diaurated water	219.98
Buffer pH 6.8	50.12

UV spectroscopy (Determination of λ max):

Wavelength of maximum absorbance (λ max) of Rizatriptan benzoate was found to be 225 nm in deaerated water (Figure 1).

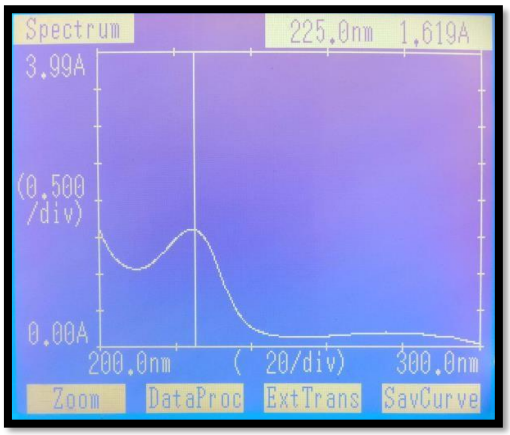

Figure (1): UV Spectra of Rizatriptan Benzoate(λ max.).

Calibration Curve for Rizatriptan Benzoate:-

Figure 2 and Table 4 present the calibration curve for rizatriptan benzoate when it is used in deionized water.Within the concentration range of 1-10 µg/ml, rizatriptan benzoate demonstrated a linear connection between absorbance and concentration at 225 nm. this relationship was seen. A value of 0.999 for the R2 of the calibration curve indicates that it adheres to the Beers Lambert law, at least within the concentration range that is being considered.

Table 5 Calibration curve of RizatriptanBenzoate

Sr. no.	Concentration (µg/ml)	Absorbance at 225nm
1	0	0
2	1	0.2763
3	2	0.4676
4	3	0.7083
5	4	0.9149
6	5	1.1441
7	6	1.3439
8	7	1.5565
9	8	1.8086
10	9	2.0412
11	10	2.2827

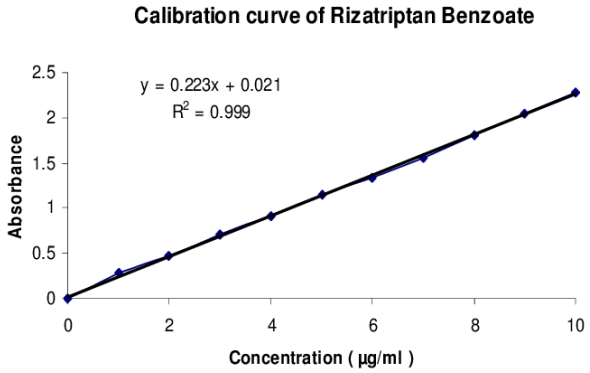

Fig: 2 Calibration curve of Rizatriptan Benzoate.

FTIR Spectroscopy:-

Figure 3 shows the FTIR spectrum of pure Rizatriptan benzoate, and Table 6 provides the interpretation of these spectra. All of the peaks in the Fourier transform infrared (FTIR) spectrum of Rizatriptan benzoate were assigned to the functional groups that are present in its structure.

Table 6:- Interpretation of FTIR Spectrum of Rizatriptan Benzoate

Peak observed (cm^{-1})	Interpretation
3446	-NH stretching
2947	-CH3 stretching
2893	-CH2 stretching
1608	-C=C stretching
1506	-C=N stretching

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1570	-NH bending
1458	-CH2 bending
1375	-CH3 bending
1296	-C-N stretching
1140	
1016	

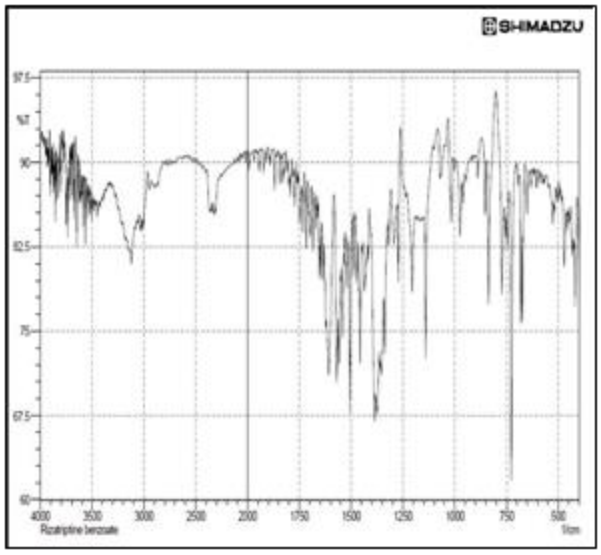

Figure (3): FTIR Spectra of RizatriptanBenzoate.

IV. EVALUATION OF TABLETS

Tablets were prepared by **direct compression** technique.

Table 7: Data of Pre-formulation Study:

Formulation	Bulk density (gm/cm^3)	Tapped density (gm/cm^3)	Hausner's ratio	Carr's index (%)	Angle of repose
F1	0.40	0.41	1.10	10.05	31.54
F2	0.35	0.38	1.07	07.94	27.71
F3	0.36	0.35	1.06	09.11	25.60
F4	0.40	0.33	1.11	14.75	26.47
F5	0.33	0.40	1.08	09.53	28.90
F6	0.37	0.34	1.08	09.53	28.92
F7	0.36	0.32	1.07	10.54	26.43
F8	0.38	0.34	1.10	09.34	26.72

Because the material was free-flowing and die-filled uniformly, all of the formulations' tablets were able to meet the norms for weight uniformity that were required by the pharmacopoeia. The tablet hardness of the compositions is kept within the range of three to four kilograms per square centimeter. It was determined that tablets had a good mechanical resistance when the formulation had friability values that were lower than one percent. The amount of substance that was tested was within the permissible range, which was between 95% and 105%.

Table 8 Evaluation of directly compressible orally disintegrating tablets

Formulation	Wt. variation (%)	Hardness (kg/cm^2)	Friability (%)	Thickness (mm)	Wetting time (s)	Water absorption ratio (%)	Disintegrant time (s)	*in-vitro* dispersion time (s)	Assay(%)
F1	4.50	4.2	0.82	3.20	32	79.90	58±1.2	52±1.0	97.70
F2	4.00	3.6	0.85	3.14	22	82.25	56±1.2	48±1.2	98.22
F3	4.20	3.9	0.74	3.23	19	83.34	46±1.4	42±1.0	96.40
F4	3.56	3.2	0.45	3.15	18	85.76	43±1.3	40±1.3	98.42
F5	3.76	3.4	0.35	3.20	16	88.57	40±1.2	32±1.1	97.50
F6	3.56	3.2	0.36	3.22	16	92.72	36±1.6	31±1.2	97.40
F7	3.96	3.8	0.42	3.14	14	93.20	32±1.2	28±1.2	98.33
F8	3.00	3.2	0.42	3.10	13	99.00	20±1.4	15±1.2	99.40

Dissolution profile:-

Table 9 Cumulative drug release (%) [CDR] of all formulation

Sr.no.	Time (minute)	F1	F2	F3	F4	F5	F6	F7	F8
1	0	0	0	0	0	0	0	0	0
2	1	86.85	86.65	85.86	87.30	90.46	94.89	90.87	97.85
3	2	88.49	88.20	89.49	89.40	93.89	97.93	94.60	99.60
4	3	95.71	94.71	95.24	93.60	96.98	99.78	97.86	--
5	4	97.52	97.04	96.52	96.46	99.87	--	99.43	--
6	5	98.52	98.85	98.40	98.97	--	--	--	--
7	10	99.98	--	--	--	--	--	--	--
8	20	--	--	--	--	--	--	--	--
9	30	--	--	--	--	--	--	--	--

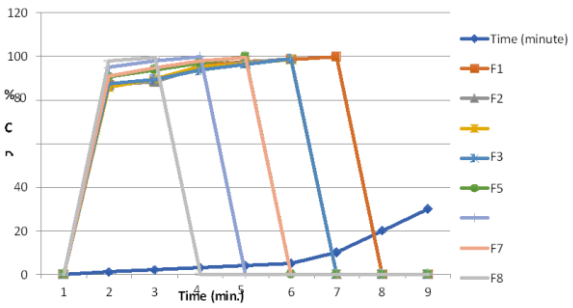

Fig. (4): Cumulative drug release(%[CDR] of all formulation.

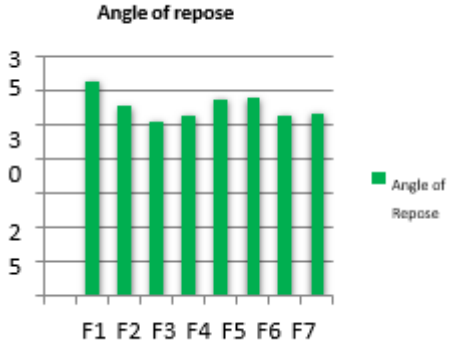

Fig. (5): Comparison of Angle of repose

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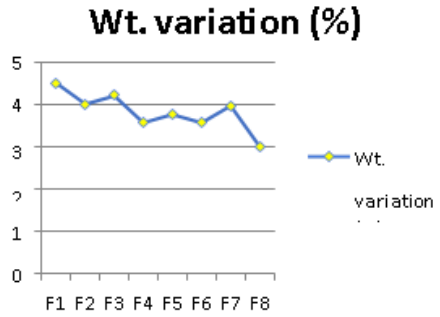

Fig. (6): Comparison of wt. variation

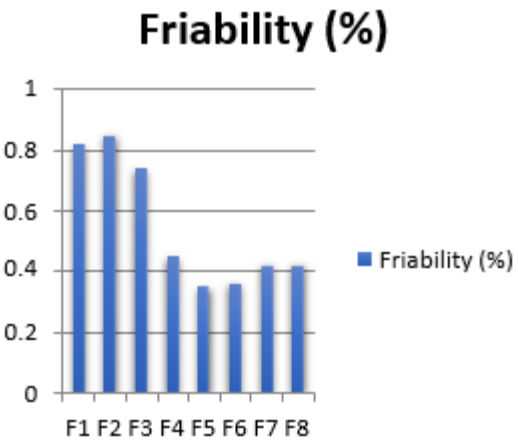

Fig:7 Comparison of Friability (%)

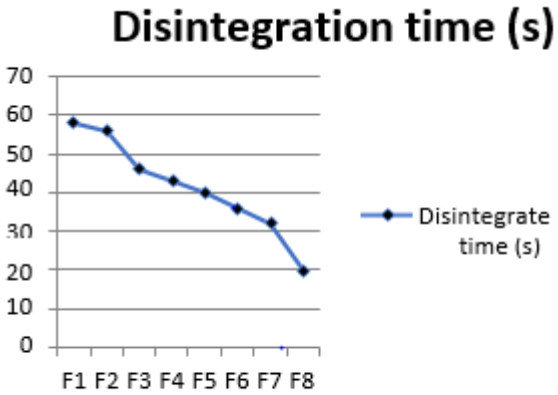

Fig.: (8) Comparison of wetting time(s)

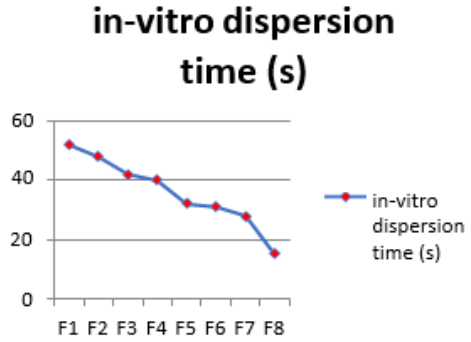

Fig.:9 Comparison of in-vitro dispersion time

***Validation Parameters*:-**

Accuracy (Recovery Test): In order to establish the applicability and reproducibility of the procedure, recovery studies were carried out. These investigations consisted of augmenting the tablet with known amounts of standard Rizatriptan benzoate (concentrations of 80%, 100%, and 120%), and then evaluating the mixtures using the method that was provided. A total of three samples were taken at each stage of the recovery process. According to the data presented in Table 11, the percentage recovery of Rizatriptan benzoate was 99.7169 ± 0.7532%. This indicates that the method is not influenced by the excipients or any other factors.

Table 10 Calibration curve of Rizatriptan Benzoate

Sr. no.	ncentration (µg/ml)	Absorbance	standard deviation
1	0	0	0
2	1	0.2763	± 0.01695
3	2	0.4676	± 0.01364
4	3	0.7083	± 0.00825
5	4	0.9149	± 0.01014
6	5	1.1441	± 0.00699
7	6	1.3439	± 0.00416
8	7	1.5565	± 0.00654
9	8	1.8086	± 0.01402
10	9	2.0412	± 0.00121
11	10	2.2827	± 0.00195

Precision: Six test samples of Rizatriptan benzoate were analysed in order to determine the intra-day precision of the medication. By analysing the samples of Rizatriptan benzoate on various days and by two different analyzers working in the same laboratory, the intermediate precision, also known as the inter-day precision, of the procedure was found. On the other hand, the values for the relative standard deviation (RSD) and the assay are respectively 99.668% and 0.8554 and 98.563% and 1.0603 (Table 13).

Linearity: The greatest absorption of rizatriptan benzoate is observed at 225 nm, and it complies with Beer's law whenever the concentration is between 1 and 10 µg/ml. The equation y = 0.223x + 0.021 for absorbance versus concentration was obtained by linear

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regression, and the correlation coefficient was found to be 0.999.

Limit of Detection & Limit of Quantification:

The limits of detection (LOD) and limits of quantification (LOQ) of Rizatriptan benzoate were established by employing the slope technique and the standard deviation of the response, as outlined in the recommendations established by the International Conference on Harmonisation (ICH).7 The limits of detection (LOD) and limits of quantification (LOQ) were determined to be 0.31 µg/ml and 0.94 µg/ml, respectively. Rizatriptan benzoate was determined using the suggested method, which demonstrated a molar absorptivity of 1.619Ao and Sandell's sensitivity of 8 0.004305 µg/cm2 /0.001 absorbance units.

Table 11 Validation parameters

Sr. no.	Parameter	Result
1	Absorption maxima (nm)	225
2	Linearity Range (µg/ml)	1-10
3	Standard Regression Equation	y = 0.223x + 0.021
4	Correlation Coefficient (r2)	r2 = 0. 999
5	Molar absorptivity	1.619 A°
6	A (1% 1cm)	233.13
7	Accuracy (% recovery ±SD)	99.7169 ± 0.7532%
8	Precision (%)	99.668, 98.563
9	Specificity	A 5ug/ml solution of drug in 0.1N HCl at UV detection lambda of 225 nm shows an absorbance value of 1.1441± 0.00699
10	s Sensitivity8 (ug/cm2/0.001 absorbance unit)	0.004305
11	LOD µg/ml)	0.31
12	LOQ (µg/ml)	0.94

Table 12 Determination of Accuracy by percentage recovery method

Ingredients	Tablet amount (µg/ml)	Level of addition (%)	Amount added (µg/ml)	Amount recovered (µg/ml)	% recovery	Average recovery %
Rizatriptan benzoate.	5	80	4	8.8967	98.8531	99.7169 + 0.7532%
	5	100	5	10.0236	100.2368	
	5	120	6	11.0067	100.0609	

Table: 13Determination of Precision

Sample number	Assay of rizatriptan benzoate as % of amount	
	yst-I (Intra-dayprecision)	st-II (Inter-dayprecision)
1	99.842	97.360
2	98.190	97.124
3	100.323	99.493
4	100.559	99.431
5	99.860	98.732
6	99.239	99.239
Mean	99.668	98.563
Std. deviation	0.8554	1.0603

V. CONCLUSION

The findings indicate that the optimised orally disintegrating tablets of Rizatriptan, which contained 9.4 mg of C.P. and 8.32 mg of P.M. and were administered as a super disntegrant by the direct compression method, exhibited reactions that were in accordance with our expectations.

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