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# Formulation And Evaluation Of Rizatriptan Benzoate Mouth Dissolving Tablets Using Natural Superdisintegrants

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## ABSTRACT

**Introduction:** Rizatriptan benzoate is a new generation anti-migraine drug, potent and selective 5-hydroxy tryptamine 1B/1D receptor agonist used for the treatment of acute migraine attack. The bioavailability of Rizatriptan benzoate is about 45%. The half-life is 2 to 3 hours. The aim of the study was to formulate Rizatriptan benzoate mouth dissolving tablets (MDT) to enhance the dissolution rate to facilitate quick onset of action.

**Methods:** Total nine formulations were developed by direct compression method using three natural super-disintegrants. DSC was conducted to study the drug-excipient interaction. All the formulations were subjected for *in vitro* evaluation tests. Stability study was performed on optimized formulation for 6 months period of time.

**Results:** All the developed formulations were lies within the pharmacopeia limits. Based on the disintegration time and drug release studies, F3 formulation was selected as optimized formulation. Further, it was subjected for stability studies and was stable for a period of 6 months.

**Conclusion:** Rizatriptan benzoate mouth dissolving tablets were successfully prepared by the direct compression method using karaya gum, xanthan gum and *plantago ovata* as superdisintegrants. The optimized formulation (i.e., F3) showed fast disintegration, highest dissolution and was stable for 6 months.

***Keywords:*** *Mouth dissolving tablets, natural super disintegrants, in-vitro release, plantago ovate.*

## 1. INTRODUCTION

Oral route of drug administration have wide acceptance up to 50-60% of total dosage forms. The convenience of administration, precise dosage, self-medication, pain avoidance, and—above all—patient compliance make solid dosage forms appealing. The most widely used solid dosage forms are tablets and capsules; nevertheless, some patients may find these forms difficult to swallow. When it comes to ingesting oral dose forms, drinking water is crucial (Battu *et al.*, 2017; Bi *et al.,* 1996).

Swallowing difficulties are widespread in elderly patients because of hand tremors, dysphasia, and choking fear; in young people, they are caused by underdeveloped neurological and muscular systems; and in patients with schizophrenia, they result in poor patient compliance. Swallowing issues affect about one-third of the population, primarily children and elderly people.

This leads to poor adherence to oral tablet medication therapy, which lowers the overall efficacy of therapy (Biradar *et al*., 2006; Choudhary *et al.,* 2013; Kumar and Babu, 2014; Wiedey *et al.,* 2021). Because of this, there has been a lot of interest in pills that dissolve or disintegrate quickly in the mouth

For both juvenile and geriatric patients, fast-dissolving medication delivery systems were created as an alternative to traditional dosage forms. These pills are made to break down or dissolve quickly in saliva—typically in less than 60 seconds. To fulfil these medical needs, pharmaceutical technologists have developed a novel oral dosage forms called as orally disintegrating/oro-dispersible tablets (ODTs) or fast disintegrating/ fast dissolving tablets (FDTs) or mouth dissolving tablets

(MDTs) which disintegrate rapidly in saliva, usually in a matter of seconds, without the need to take water (Banker and Rhodes, 1996; Kannuri *et al.,* 2011).

Rizatriptan benzoate is a new generation anti-migraine drug, potent and selective 5-hydroxy tryptamine 1B/1D receptor agonist used for the treatment of acute migraine attack (Krymchantowski and Bigal, 2004). The bioavailability of Rizatriptan benzoate is about 45%. The half-life is 2 to 3 hours. Based on the above characters, Rizatriptan benzoate was selected as a model drug in this study (Tiwari *et al.,* 2011; Prasanth *et al.,* 2013; Shahtalebi *et al.,* 2015;).

## 2. MATERIALS AND METHODS

### Materials

The pure drug, Rizatriptan benzoate was received as a gift sample from Aurobindo Pharmaceuticals Ltd., Hyderabad. Gum karaya, xanthan gum, *plantago ovata* husk and all other ingredients were purchased from S.D Fine chemicals, Mumbai, India.

### Methods

#### Drug-excipient compatibility study by DSC

The drug-excipient compatibility study was conducted by using differential scanning calorimeter. Pure drug, 1:1 ratio of drug and polymer, and physical mixture of optimized formulations were subjected to the analysis. About 5-15 mg of sample to be analyzed was taken in the pierced DSC aluminium pan and scanned in the temperature range of 50-300 °C. The heating rate was 10°C/min; nitrogen was served as purged gas and the system was cooled down by liquid nitrogen. The differential scanning colorimeter (DSC 4000, Perkin Elmer) was used for this purpose (Avula *et al.,* 2023; Chettupalli *et al.,* 2025; Chettupalli *et al.,* 2025.a; Chettupalli *et al.,* 2025.b).

#### Preparation of Rizatriptan benzoate mouth dissolving tablets

MDTs of riztriptan benzoate were created by employing the direct compression method. In short, each excipient (component) was separately filtered through a 60-mesh sieve before being combined using a mortar and pestle. Small amounts of the medication and microcrystalline cellulose were added gradually to create a uniform blend each time. With the exception of magnesium stearate, which was added at the conclusion of the mixing procedure, all of the other ingredients were then weighed and combined geometrically. Finally, the tablets were compacted employing an 8 mm flat-faced punch to yield tablets weighing 100 mg each, using a 10-station rotary tablet compression machine (Sheshala *et al*., 2011; Komati *et al*., 2019).

#### Weight variation

20 tablets were selected randomly from a batch and were individually weighed and then the average weight was calculated (Pandala *et al*., 2019).

#### Thickness

Thickness was determined for 20 pre-weighed tablets of each batch using a digital vernier callipers and the average thickness was measured in mm (Sapavatu and Jadi, 2019).

#### Hardness test

The crushing load which is the force required to break the tablet was measured using a Monsanto hardness tester. The hardness of 10 tablets was noted and the average hardness was calculated (Sapavatu and Jadi, 2020).

#### Friability

In friability testing the tablets are subjected to abrasion and shock. It gives an indication of the tablets ability to resist chipping and abrasion during transportation and shipping. The tablets were rotated in the Roche Friabilator for 100 revolutions at 25 rpm. The tablets were dusted and reweighed and percentage weight loss (friability) was calculated (Togaru *et al*., 2017).

% Friability = (Loss in weight / Initial weight) × 100

#### Disintegration time

Disintegration time is the time taken by the tablet to breakup into smaller particles. Six tablets were placed in each of the tubes and the time required for complete passage of tablet fragments through the mesh (# 10) was considered as the disintegration time of the tablet.

#### Wetting time

Wetting time of the ODT is another important parameter, which needs to be assessed to give an insight into the disintegration properties of the tablet. Lower wetting time implies a quicker disintegration of the tablet. The wetting time of the tablets can be measured by using the simple procedure. Five circular tissue papers of 10 cm diameter are placed in a petri-dish. Ten ml

of water soluble dye solution is added to petri-dish. A tablet is carefully placed on the surface of the tissue paper. The time required for water to reach upper surface of the tablet is noted as the wetting time (Jadi *et al.,* 2016; Prasad *et al.,* 2018).

***In vitro* drug release studies**

*In vitro* drug release studies for all the developed formulations were performed according to USP type II apparatus, paddle method (Electro lab, Mumbai, India). Paddle speed was maintained at 50 rpm and 900 ml of buffer was used as the dissolution medium. Samples (5 ml) were collected at predetermined time intervals and replaced with equal volume of fresh medium, filtered through a Whatman filter paper, and analyzed with a UV–Visible spectrophotometer at 278 nm (Devprakash *et al*., 2012; Jadi *et al.,* 2016; Sharaff *et al.,* 2024).

**Assay**

Twenty tablets were weighed individually and powdered. Drug powder equivalent to 10 mg was weighed and transferred to 100 ml volumetric flask. Drug was dissolved by using methanol and volume was made up with methanol. The solution was further diluted to get final concentration of 10 µg/ml and assayed for the drug content utilizing a UV-Visible spectrophotometer at a wavelength of 278 nm (Devprakash *et al*., 2012; Sapavatu *et al.,* 2020).

**Stability studies**

The stability studies were performed on optimized formulation for a period of six months according to ICH (international conference on harmonization) guidelines. All the physical and *in vitro* tests were performed and observed for any significant changes (Sapavatu *et al.,* 2020).

## *3.* RESULTS AND DISCUSSION

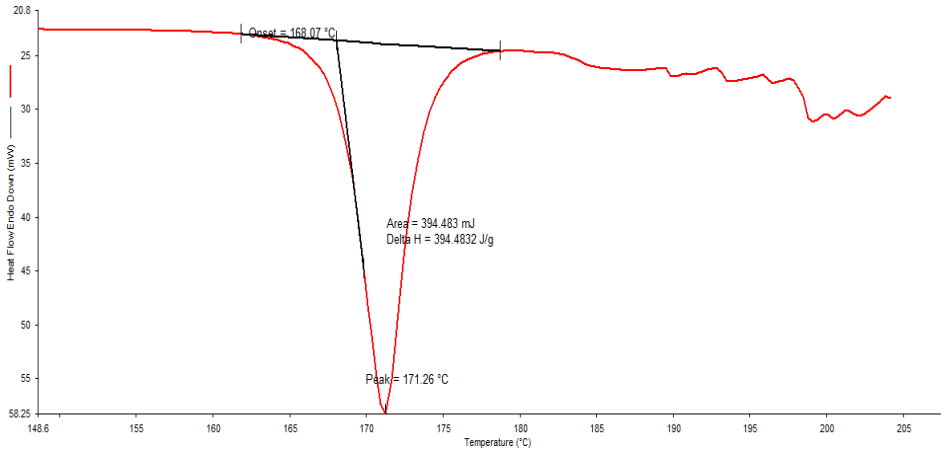


**Fig 1: DSC thermogram for pure drug**

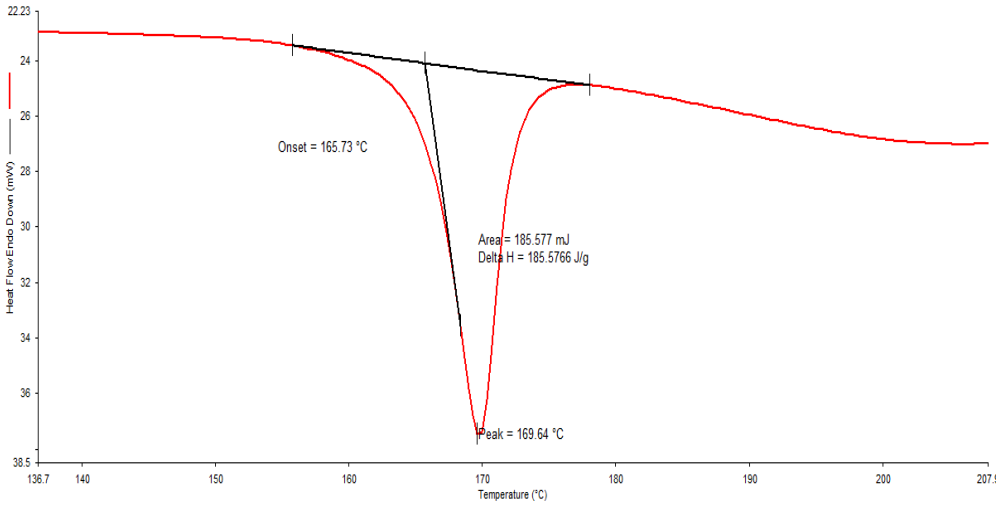


**Fig 2: DSC thermogram for drug and physical mixture**

**Table 1: Composition of Rizatriptan benzoate mouth dissolving tablets**

| Ingredients | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
|---|---|---|---|---|---|---|---|---|---|
| **Rizatriptan benzoate** | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| **MCC** | 45 | 40 | 35 | 45 | 40 | 35 | 45 | 40 | 35 |
| **Gum Karaya** | 5 | 10 | 15 | -- | -- | -- | -- | -- | -- |
| **Xanthan gum** | -- | -- | -- | 5 | 10 | 15 | -- | -- | -- |
| **Plantago ovata husk** | -- | -- | -- | -- | -- | -- | 5 | 10 | 15 |
| **Mannitol** | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 |
| **Aspartame** | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| **Magnesium stearate** | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| **Talc** | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **Total weight** | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 |

**Table 2: *In vitro* characterization of Rizatriptan benzoate mouth dissolving tablets**

| Formulation | Weight Variation (mg) | Hardness ($kg/cm^2$) | Thickness (mm) | Friability (%) | Wetting Time (sec) | DT (sec) | Assay (%) |
|---|---|---|---|---|---|---|---|
| **F1** | 99.1±2.11 | 3.43±0.3 | 4.3±1.11 | 0.21 | 59.12 | 42.5 | 95.8 |
| **F2** | 101.3±0.12 | 3.11±0.2 | 4.7±1.32 | 0.15 | 51.23 | 34.1 | 97.5 |
| **F3** | 100.1±1.21 | 3.71±1.4 | 4.5±1.01 | 0.13 | 42.14 | 22.3 | 100.3 |
| **F4** | 100.2±1.02 | 3.54±1.2 | 4.1±2.02 | 0.18 | 65.21 | 49.6 | 99.1 |
| **F5** | 102.1±0.12 | 3.61±1.3 | 5.2±1.12 | 0.23 | 56.31 | 37.2 | 98.7 |
| **F6** | 101.5±2.11 | 3.48±0.4 | 4.9±1.02 | 0.26 | 53.12 | 31.1 | 97.4 |
| **F7** | 100.4±1.04 | 3.53±1.1 | 5.1±1.21 | 0.16 | 69.23 | 52.1 | 98.5 |
| **F8** | 99.2±0.12 | 3.39±0.7 | 5.3±1.25 | 0.12 | 56.01 | 47.3 | 97.1 |
| **F9** | 100.1±1.21 | 3.43±0.5 | 5.2±1.61 | 0.23 | 50.32 | 35.6 | 96.3 |

All the Rizatriptan benzoate MDT formulations were within the range of 99.1–102.1 mg as shown in Table 2. The observed weight variation was within the acceptable limits specified in pharmacopeias. It is noteworthy that all formulations of Rizatriptan benzoate tablets successfully passed the weight variation test, demonstrating uniform weights with low SD value. The thickness of all the prepared Rizatriptan benzoate tablets varied from 4.1 to 5.3 mm which shows uniformity of the tablets (Table 2). Ten tablets of each formula were assessed for the thickness test and all the formulations were within the acceptable limits. The hardness of tablets provides significant indications regarding tablet withstanding handling storage and shipping processes, and to be acceptable, it should be between 2 and 8 $kg/cm^2$. According to the results, the hardness values listed range from 3.11 to 3.71 as all the values for the ODT formulations are acceptable. The friability test for all the formulations being less than 1%, as listed in the USP. The recorded loss in total weight due to friability ranged from 0.13% to 0.26% and shown in Table 2. Markedly, none of the formulations exceeded a friability value of more than 1%. These

results indicated that the Rizatriptan benzoate tablets exhibited mechanical stability, demonstrating their resistance to the stresses of transportation and handling. The assay was conducted for all the formulations with 95.8% -100.3% and all these values were in the acceptable range. Wetting time, a crucial indicator of the tablet's disintegration ease, reflects the time taken for a tablet to fragment when placed on the tongue without movement. The wetting time was recorded for all the formulations ranged between 42.14 to 69.23 sec. Formulation F3 showed less wetting time compared to all other formulations. This formulation (F3) disintegrated quickly within 22.3 sec, whereas formulation F7 showed highest wetting time and disintegration time compared to other formulations. As the concentration of superdisintegrant increased, the wetting time and disintegration time decreased (Kalyankar *et al*., 2015).

***In vitro* drug release**

*In vitro* release studies of Rizatriptan benzoate formulations were performed at 37°C by the USP Dissolution Test Apparatus II (paddle). The release of drug from the various formulations was judged by determining the amount of drug released as a percentage.

Total nine formulations were developed with three natural superdisintegrants. F1-F3 formulations were developed with gum karaya, F4-F6 formulations were developed with xanthan gum. F7-F9 formulations were developed with *plantago ovata*. The results had shown that the drug release was in the range of 81.12 to 99.01 % for all 9 formulations in 15 min. From the *in vitro* dissolution data, F3 formulation showed highest drug release which containing high amount of gum karaya disintegrated fastly and showed highest drug release 99.01% within 15 min, when it comes in contact with aqueous fluids (Kalyankar *et al*., 2015) So, it can be concluded that gum karaya is the strongest superdisintegrant, which resulted in the fastest disintegration and dissolution compared to other superdisintegrants such as xanthan gum and *plantago ovata* (Fig. 3-5). Fast release of the active agent was markedly noted in the preparations containing gum karaya than the formulations developed with the other super-disintegrants.

The determination of the optimal kinetic order for the *in vitro* release profile of Rizatriptan benzoate formulations is generally inferred from the greatest values of the calculated correlation coefficients. The results indicated that all prepared formulations of Rizatriptan benzoate ODT follow Higuchi's diffusion model. This is mainly due to quick diffusion through the porous structure of the tablets. The highest value of correlation coefficients of the prepared Rizatriptan benzoate tablet formulas was 0.9678.

**Accelerated stability studies**

For accelerated stability studies, F3 formulation was stored at various temperature conditions, at 40°C and 60°C. Moreover, the humidity was controlled to 75% by utilizing a saturated solution of sodium chloride. Sample was withdrawn at specific periods of 0, 1, 3 and 6 months. The samples were examined for color change, hardness, *in vitro* drug release and drug content.

**Table 3: Physical stability studies of optimized formulation (F3 formulation)**

| Time (Months) | Color change | Hardness ($Kg/cm^2$) | Drug content (%) | Drug release (%) |
|---|---|---|---|---|
| **0** | No | 3.71±1.4 | 100.3 | 99.01 |
| **1** | No | 3.71±1.2 | 99.7 | 99.02 |
| **3** | No | 3.70±0.1 | 99.5 | 98.90 |
| **6** | No | 3.71±1.3 | 99.4 | 99.03 |

## 4. CONCLUSION

Rizatriptan benzoate mouth dissolving tablets were prepared successfully by direct compression method using three natural super-disintegrants such as gum karaya, xanthan gum and *plantago ovata* husk. The best formulation was made based on the evaluation parameters such as dissolution study, disintegration time and wetting time. The F3 formulation was selected as optimized formulation among all the formulations and was stable for six months.

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## CONFLICT OF INTEREST

There is no conflict of interest.

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