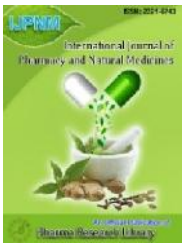
**International Journal of Pharmacy and Natural Medicines**

Journal Home Page: www.pharmaresearchlibrary.com/ijpnm



**Research Article** **Open Access**

# Formulation and Evaluation of Taste Masked Rapid Dissolving Tablets of Rizatriptan benzoate

**T. Ramchandar[1*], J. Bhaskar[2], V.L. Narasaiah[3]**

[1]*Dept. of Pharmaceutics, Mother Teresa college of Pharmacy, Ghatkesar, Hyderabad, Telangana, India.*
[2]*Dept. of Pharmaceutics, Avanthi Institute of Pharmaceutical Sciences, Gunthapally, Near Ramoji Film city, Hyderabad, Telangana, India.*
[3]*Dept. of Pharmaceutics, Dr Samuel George Institute of Pharmaceutical Sciences, Markapur, Prakasam, A.P, India.*

**A B S T R A C T**

Aim of this research work was to develop mouth dissolving tablet that disintegrates rapidly in mouth by using tasteless complex of Rizatriptan benzoate and Eudragit E 100. Effect of different parameters such as swelling time, drug-Eudragit E ratio as well as stirring time was optimized by taste and percentage drug loading. Formulated DEC (Drug-Eudragit E Complex) was characterized by infrared spectroscopy, thermal analysis. Tablets were formulated by direct compression with Spray dried mannitol SDM as diluent, Indion 234, Sodium Starch Glycolate (SSG) as super disintegrants. In these batches optimum hardness was achieved but disintegration time was found to be very high as ≥ 60 second, so further trials were planned by using different superdisintegrants such as Croscarmellose sodium, Sodium Starch Glycolate (SSG) as well as Indion 234 by direct compression method. Tablets formulated with 4% Indion 234 showed comparatively low disintegration time (26 sec), wetting time (20 sec) and friability (0.56 %) than the other batches. In present study we optimized the conditions required for maximum drug loading of Rizatriptan benzoate with Eudragit E 100. Among different superdisintergants, Indion 234 was found suitable with drug- Eudragit complex to get the low disintegration time, wetting time and friability of tablets. Selected tablets were found stable and followed diffusion controlled first order kinetics. The results revealed that Rizatriptan benzoate was successfully taste masked and formulated into a RDT as an alternative method to conventional tablets.

**Keywords:** Indion, Rapid-disintegrating tablets, Rizatriptan benzoate, Eudragit, Superdisintegrants.

**A R T I C L E I N F O**

**CONTENTS**



**Article History: Received** 27 April 2017, **Accepted** 28 May 2017, **Available Online** 15 June 2017

***Corresponding Author**
T. Ramchandar
Mother Teresa college of Pharmacy,
Ghatkesar, Hyderabad, Telangana India
Manuscript ID: IJPNM 2730

**PAPER-QR CODE**

**Citation:** T. Ramchandar, *et al*. Formulation and Evaluation of Taste Masked Rapid Dissolving Tablets of Rizatriptan benzoate. *Int. J. Pharm. Natural Med*., 2017, 5(1): 01-08.

## 1. Introduction

Oral route is most important and preferable route of administration for solid dosage forms. Tablets are the most common solid dosage form, administered orally, but many patients specially children, mentally ill patients and geriatrics have problem in swallowing the tablets. Mouth dissolving tablets (MDT) have advantage of ease of administration and rapid onset of action. Further there is advantage of rapid disintegration without use of water in oral cavity. When MDT is kept in oral cavity then saliva quickly penetrates into tablet pores and causes rapid disintegration [1]. The new generation anti-migraine drug, Rizatriptan benzoate is a potent and selective 5- hydroxy tryptamine 1B/1D receptor agonist and is considered more effective than the traditional triptans for the treatment of acute migraine attack. Chemically it is 3-[2-(dimethylamino) ethyl]-5-(1H- 1, 2,4-triazol-1-ylmethyl) indole onobenzoate. A 10mg dose of Rizatriptan benzoate is equipotent to a 100 mg of Sumatriptan, the traditional antimigraine drug. The bioavailability of Rizatriptan benzoate is about 45% which is superior to a poor 14-17% of Sumatriptan [2, 3]. Orally disintegrating tablets (ODTs) have received increasing attention during the last decade, and the field has become a rapidly growing area in the pharmaceutical industry. Upon introduction into the mouth, these tablets dissolve or disintegrate in the absence of additional water allowing the easy administration of active pharmaceutical ingredients. Such dosage forms are useful and convenient for children, older persons, and others who are unable to swallow conventional tablets and capsules. Masking the unpleasant taste of therapeutic agents is an important consideration in the formulation of ODTs and it can be achieved by minimizing direct contact between the active species and the taste receptors in the buccal cavity of the patient. The unpleasant taste of the active drug can also be overcome by adding flavoring ingredients and sweeteners to improve taste and palatability [4]. However, where the active drug possesses a particularly strong or bitter taste, such as is the case with many antibiotics, the mere addition of such flavoring ingredients and sweeteners is insufficient to improve taste and palatability. Accordingly, various taste-masked coating compositions have been used in the formulation of liquid suspensions and fast disintegrating tablet dosage forms The major advantage of the ODT formulation is that it combines the advantages of both liquid and conventional tablet formulations. It provides the convenience of a tablet formulation, and also allowing the ease of swallowing provided by the liquid formulation. The various technologies used to prepare ODT's include direct compression[5] sublimation, tablet moulding, spray drying, freeze drying and mass extrusion

A number of superdisintegrants such as croscarmellose sodium, Indion 234 and sodium starch glycolate are used for rapid disintegration of tablet. In present study an attempt was made to mask the taste of Rizatriptan benzoate e with formulation of mouth dissolving tablet having desired good characteristics of MDT by direct compression, so as to give pleasant taste and good bioavailability.

## 2. Materials and method

Rizatriptan benzoate was generously gifted by Aurobindo Pharmaceuticals Ltd; Hyderabad, Eudragit E100 was obtained from Evonik Degussa Pvt Ltd; Mumbai. Spray dried and mannitol were procured from Indchem International; Mumbai. Indion 234 was procured from Ion exchange Ltd; Mumbai. Crosscarmellose sodium and SSG were obtained from S.Zaveri Pharmaken Ltd; Mumbai. All other chemicals used were of analytical grade.

**Method Of Preparation**

**Preparation of taste-masked granules of Rizatriptan benzoate using Eudragit E100 by mass extrution method [6, 7]:**

Fixed amount of the bitter drug was mixed with different amount of powdered Eudragit E 100 in the ratio of 1:1, 1:2, 1:3, 1:4 and 1:5 (Table: 1). Then 10% v/v of ethanol was added to each mixture in a glass beaker and a gel was prepared which was converted into the taste-masked granules by extrusion method. The prepared gel was manually extruded (pressed out) using a syringe. After extrusion of the gel, ethanol was removed by overnight evaporation at room temperature and subsequently the solidified gel was crushed into granules using a mortar. The drug: polymer ratio which produced taste masked granules was used for further studies.

**Determination of Drug content**

About 100 mg complex was weighed and taken in a 100-ml volumetric flask, and volume was made with 0.1 N HCl [8]. The solution in the volumetric flask was then sonicated for 20 min and stirred further for 2 h on magnetic stirrer and then filtered using 0.2-µ membrane filter. From filtrate, 10 ml of solution was pipetted out and diluted up to 100 ml with the 0.1 N HCl, and absorbance was measured at 280 nm using UV double beam spectrophotometer. Drug content was estimated in triplicate.

**FTIR Studies**

Compatbility of the drug with excipients was determined by FT-IR spectral analysis, this study was carried out to detect any changes on chemical constitution of the drug after combined it with the excipients [9]. The samples were taken for FT-IR study.

**DSC studies**

The optimized complexes were subjected to differential scanning calorimeter equipped with an intracooler (Mettler-Toledo, Switzerland). Indium/Zinc standards were used to calibrate the DSC temperature and enthalpy scale. The samples (pure Rizatriptan benzoate and drug-polymer complex) were sealed in aluminum pans and heated at a constant rate of 200C/ min over a temperature range of 20-2500 C. Inert atmosphere was maintained by purging nitrogen gas at a flow rate of 50 ml/min.

Preparation of RDT using Rizatriptan benzoate – Eudragit granules A schematic representation of the preparation

procedure of the taste-masked granules is illustrated in Fig. 1. The composition of each tablet is listed in table 2.

First of all formulation of MDTs was done by direct compression technique for all batches by taking DEC equivalent to 10 mg of Rizatriptan benzoate. SDM was used as diluent, croscarmellose sodium, Indion 234 and sodium starch glycolate are different superdisintegrants having different concentrations, Aspartame as sweetening agent, aerosil & talc are antiadherent, glidant and magnesium stearate as a lubricant [10, 11]. All the ingredients were accurately weighed and passed through 40 # sieve and mixed with complex. The above powder blend was compressed using rotary tablet machine using 8 mm concave punches.

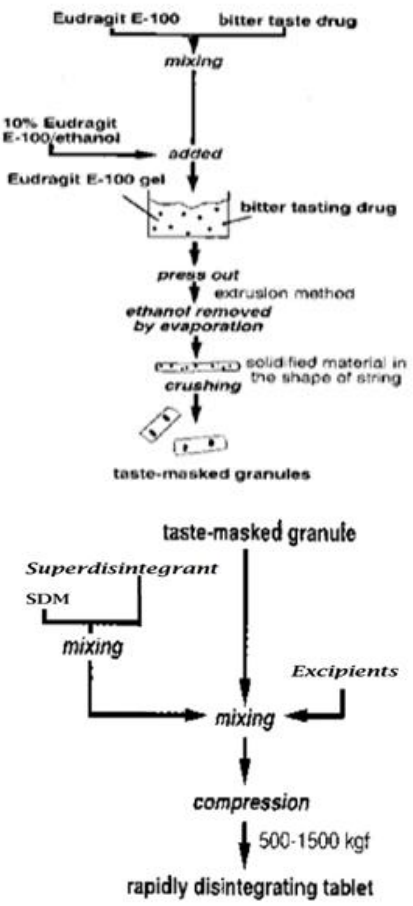



**Fig 1:** Preparation of RDT using drug: Eudragit granules

**Pre-compressional parameters [12]**

**Angle of repose (θ):** Angle of repose is defined as the maximum angle possible between the surface of a pile of the Powder and horizontal plane. The frictional force in a loose powder or granules can be measured by angle of repose.

$\tan \theta = h / r$

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

Where, θ is the angle of repose, 'h' is height of pile, 'r' is radius of the base of pile

**Bulk density:** Bulk density is defined as the mass of a powder divided by the bulk volume. The bulk density of a powder depends primarily on particle size distribution, particle shape, and the tendency of the particles to adhere to one another.

LBD=Weight of the powder --------- (a)
Volume of the packing

TBD=Weight of the powder ---------- (b)
Tapped volume of packing

**Carr's compressibility index:** The compressibility index of the granules was determined by Carr's compressibility index.

Carr's Index (%)=TBD – LBD/TBD x 100 ----- (c)

**Hausner's ratio:** It is determined by comparing tapped density to the bulk density by using following equation

Hausners ratio=TBD / LBD

The results of the powder flow properties determination are summarised in Table 3.

**Evaluation of rapidly disintegrating Tablets [13]**

**a) Thickness:** The thickness of the tablets was determined using a vernier calipers. Five tablets from each batch were used, and average values were calculated.

**b)Weight variation test:**

Weight variation test was carried out as per IP. Twenty tablets were randomly selected and individually weighed. The average weight and standard deviation was calculated.

**c) Hardness:**

The tablet hardness, which is the force required to break a tablet in a diametric compression force. The hardness tester used in the study was Monsanto hardness tester, which applies force to the tablet diametrically with the help of an inbuilt spring. It is expressed in Kg / cm2. Results are shown in Table: 4.

**d) Friability:**

Friability of the tablets was determined using Roche friability (Electrolab, Mumbai). This device subjects the tablets to the combined effect of abrasions and shock in a plastic chamber revolving at 25 rpm and dropping the tablets at a height of 6 inches in each revolution. Preweighed sample of tablets was placed in the friabilator and were subjected to 100 revolutions. Tablets were dedusted using a soft muslin cloth and reweighed. Results are shown in Table: 4.

The friability (f) is given by the formula.

$f = (1 - W0 / W) \times 100$

Where, W0 is weight of the tablets before the test and

W is the weight of the tablet after the test

**e) In vitro disintegration time:**

The disintegration time of the tablet was measured in water (37±2°C) according to disintegration test apparatus with disk [14]. The time in seconds taken for the complete disintegration of the tablet with no palpable mass in the apparatus was measured in seconds. Three tablets from each batch (formulation) were tested for the disintegration time calculations. Results are shown in Table: 5.

**f) In vitro dispersion time:**

In vitro dispersion time was measured by dropping a tablet in a beaker containing 50 ml of Sorenson's buffer pH of 6.8 at 37±0.5°C. Time required for complete dispersion of a tablet was measured [15]. Three tablets from each formulation were randomly selected and in vitro dispersion time was performed.

**g) Wetting time:** The wetting time of the tablets can be

measured using a simple procedure. Five circular tissue papers of 10 cm diameter are placed in a Petri dish with a 10 cm diameter. Ten millimeters of water containing Eosin, a water soluble dye, is added to Petri dish [16]. 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 a wetting time. Results are shown in Table 5.

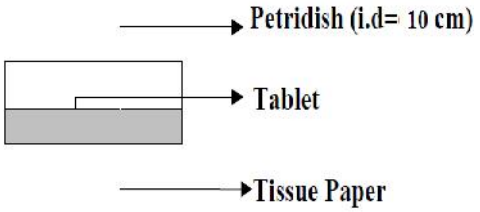



**Fig 2:** Determination of wetting time

**h) Water absorption ratio:**

A piece of tissue paper folded twice was placed in a small Petri dish containing 6 ml of water. A tablet was put on the paper and the time required for complete wetting was measured. The wetted tablet was then weighed. Results are shown in Table 5. Water absorption ratio (R) is calculated by using the equation.

$$R = \frac{10 \times Wa - Wb}{Wb}$$

Where,

Wa is the weight of the tablets before the test and

Wb is the weight of the tablet after water absorption.

**i) In vitro dissolution profile:**

In-vitro drug release study was performed at 37±0.5°C using eight station USP type-II apparatus with paddle rotating at 50 rpm. The drug release study was carried out in 0.1N HCl by taking about 900ml of the dissolution medium. The drug release study was performed in 0.1N HCl to demonstrate the availability of Rizatriptan benzoate in gastric pH. About 5 ml of sample was withdrawn at specified time intervals from the dissolution medium and replaced with equal volume of fresh medium. Samples were filtered through whattmann filter paper and analyzed using UV spectrophotometer (UV-1700, Shimadzu Corporation, Japan) at 280 nm [17]. Results are shown in Fig. 3-6.

**j) Stability studies:**

The tablet formulations were packed in aluminum foil and were exposed to 40°C ± 2°C / 75% ± 5% RH in humidity control oven as per ICH guidelines118 Q1C: "Stability testing of new dosage forms [18]." Sampling was done at predetermined time intervals of initial and 30 days. Results are shown in Table: 6.

## 3. Results and Discussion

The blends of different formulations were evaluated for angle of repose, LBD, TBD, compressibility index, and hausners ratio (Table 3). The results of angle of repose and compressibility index (%) ranged from 20.88 ± 1.77 to 23.94 ± 1.51, and 10.54 ±0.98 to 14.12 ±0.26, respectively. The results of LBD and TBD ranged from 0.53 ± 0.01 to 0.57 ± 0.04 and 0.59 ± 0.02 to 0.68 ± 0.18, respectively. The results of hausners ratio ranged from 1.09 ± 0.09 to 1.17 ± 0.64. The results of angle of repose (<30) indicate good flow properties of the blend. This was further supported by lower compressibility index values. Generally, compressibility index values up to 15% result in good to excellent flow properties and Hausner's ratio below 1.25 which indicated good compressibility and flow ability. Orally disintegrating tablets were prepared by direct compression method. A total of twelve formulations were prepared using different superdisintegrants described above. All the formulations passed weight variation test. The hardness of all the tablets containing superdisintegrants was found in the range of 2.8-3.6 kg/cm2. Friability was found to be below 1% which was an indication of good resistance of tablets. The results of these evaluations are shown in table 4.

**Wetting time:** Wetting time was determined for all the formulations were observed that all formulations showed less wetting time. It was also observed that the batch P4 (made with Indion 234) showed the wetting time of 20.03 ± 0.12 seconds which was less as compared to other batches. It was also observed that the batches containing CCS showed better wetting time as compared to tablets containing SSG. The results were shown in table 5.

**Water absorption ratio:** Water absorption ratio for the three different superdisintegrants used was in the order: Indion 234 P4 (81.91 ± 1.64) > Croscarmellose sodium P8 (77.83 ± 1.22) > SSG P12 (75.25 ± 1.29) as shown in Table 5. It was observed that with increase in water absorption ration the disintegration of tablets was faster as compared to the tablets with low water absorption ratio.

**In-vitro disintegration Test:**

Disintegration time is a significant parameter of importance in the formulation of RDTs. The disintegration time was found to be in the range of 26.34 ± 0.17 to 39.01 ± 0.43 sec for the tablets containing different superdisintegrants in the order Indion 234 < CCS < SSG. It was also observed that the tablets with the least wetting time also showed minimum disintegration time respectively shown in Table 5. It shows a strong correlation between wetting time and disintegration time.

**In vitro drug release Study:**

The in-vitro dissolution was studied in 0.1N HCl of pH 1.2. The In-Vitro drug release data for each of the formulation is shown below: In vitro dissolution study of formulations P1, P2, P3 and P4, P5, P6 batches showed drug release, 99.561, 98.884, 99.281 and 99.548, 86.774, 98.816 within 5 min, in this P4 batch show good dissolution property (Figure 2-5). Among these formulations, the release rate was increased in the following polymer order: Indion 234 > CCS > SSG. In vitro dissolution study of formulations P7 batch drug release with in 5 min 98.242, with in 5 min P8 batch drug release 98.516, with in 5 min P9 batch release the drug 72.245, with in 5 min P10 batch drug release is 83.019, with in 5 min P11 batch release the drug 97.435, with in 5 min P12 batch release the drug release 97.777. From above results comparison of different formulation from P1 to P12, from the above results the formulation P4 has shown good dissolution profile.

**FTIR studies:** FT-IR studies are carried out to investigate if there is any chemical interaction between polymer, added excipients and Rizatriptan benzoate in the formulated product, the FT-IR of pure drug of Rizatriptan benzoate, and Optimized formulation. The pure rizatriptan benzoate exhibited characteristic peaks at 3120 cm−1 (aromatic secondary amine N-H stretching), 2974 cm−1 (aromatic C-H stretching), 1608 cm−1 (C=O five member cyclic stretching) and 1270 cm−1 (C-N aliphatic amine stretching). It was observed however, that the entire characteristic peak observed for both pure drug and excipients remained unchanged, and no significant shift or reduction in the intensity of peak of rizatriptan benzoate. FT-IR spectroscopic studies indicate that drug is compatible with polymer. Results are shown in Figure: 7 and 8.

**DSC:** In order to check chemical interaction between drug and polymer, thermal analysis was carried out by using DSC. The melting point of drug was confirmed from the endothermic peak of Rizatriptan benzoate at 183°C in DSC analysis. DSC thermograms of Rizatriptan benzoate, Rizatriptan benzoate + excipients showed that there were no changes in the endotherms. The drug exhibited a small melting endotherm in the drug polymer mixture. These slight changes in the melting endotherm of the drug may be attributed to the mixing process, which lowers the purity of each component in the mixture, thus resulting in slightly broader and lower melting points, but not truly representing any incompatibility. Results are shown in Fig. 9 and 10.

**Stability Study:**

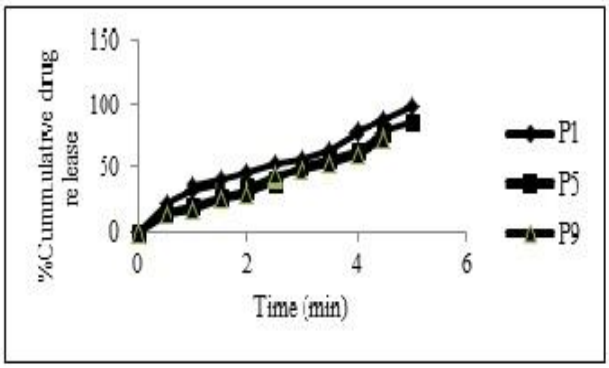



**Fig 3:** In-vitro release of Rizatriptan benzoate from RDT containing 1% Indion 234 (P1) CCS (P5) and SSG (P9)

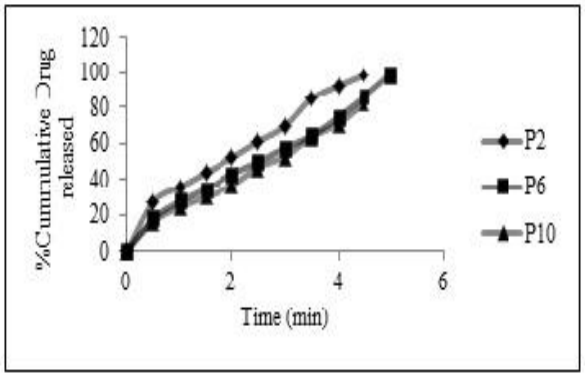



**Fig 4:** In-vitro release of Rizatriptan benzoate from RDT containing 2% Indion 234 (P2) CCS (P6) and SSG (P10)

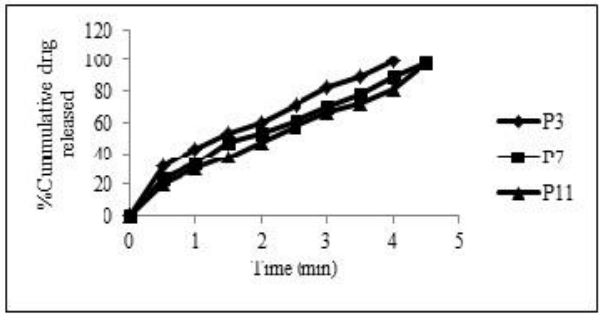



**Fig 5:** In-vitro release of Rizatriptan benzoate from RDT containing 3% Indion 234 (P3) CCS (P7) and SSG (P11)

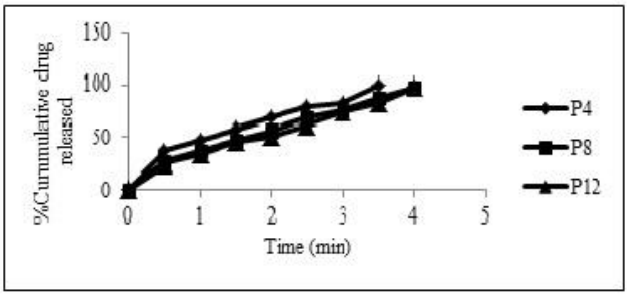



**Fig 6:**In-vitro release of Rizatriptan benzoate from RDT containing 4% Indion 234 (P4) CCS (P8) and SSG (P12)

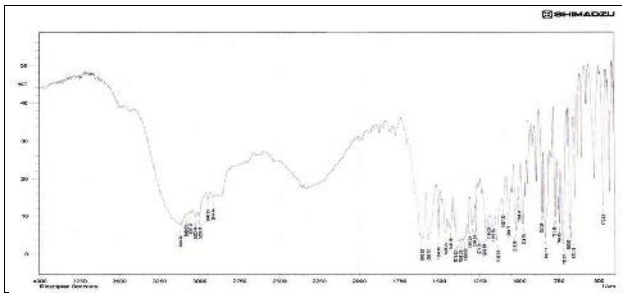


**Fig 7:** IR spectra of Rizatriptan benzoate pure drug

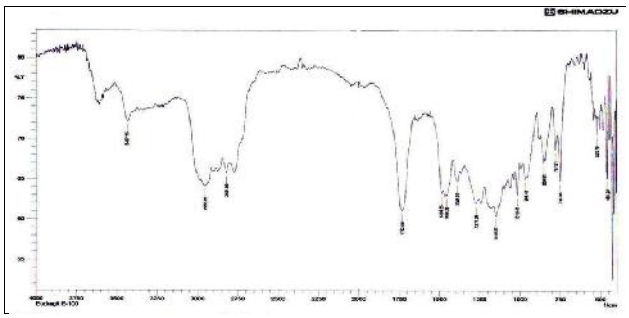


**Fig 8:**IR spectra of Physical mixture containing Drug: Eudragit E-100 complex

The best formulation of each batch was subjected for one month stability study by exposing the tablets to 40±2°C temperature and relative humidity 75±5% in programmable environmental test chamber. The stability studies revealed that there is not much considerable change in appearance, physical attributes, drug content, and in vitro drug release. The Rizatriptan benzoate rapid disintegrating tablets were found to be stable with respect to stability studies. Results are shown in Table 6.

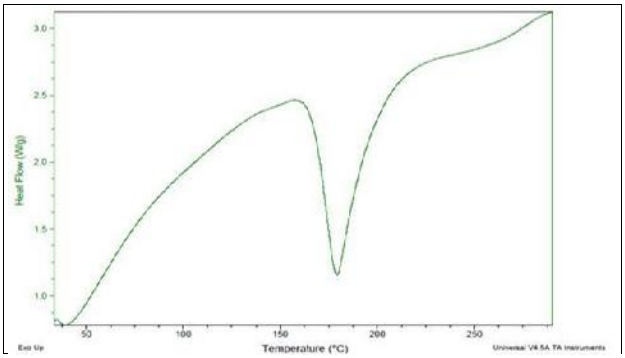



**Fig 9:** DSC thermograms of Rizatriptan benzoate pure drug

## 4. Conclusion

In present study we optimized the conditions required for maximum drug loading of Rizatriptan benzoate with Eudragit E100. All the optimized tablet (MDT) formulations of Rizatriptan benzoate (B10 to B21) showed all parameters within limit as well as good physicochemical properties. Drug release rate of formulated MDTs was also found to higher as compared to conventional tablet. Indion 234 of 4% Batch P4 having hardness (3.1 kg/cm2), friability (0.56%), wetting time (20 sec) and assay 99.5%, hence tablets formulated with Indion 234 not only increases rate of dispersion but also increases rate of drug release.

**Table 1:** Effect of concentrations of drug-Eudragit E 100 complexes on drug content

| S. No | Drug-Polymer ratio | Yield (%) | Drug content*(%) |
|---|---|---|---|
| 1 | 1 : 1 | 90.34 ± 0.12 | 94.40 ± 0.32 |
| 2 | 1 : 2 | 96.43 ± 0.21 | 96.12 ± 0.11 |
| 3 | 1 : 3 | 98.54 ± 0.13 | 98.82 ± 0.25 |
| 4 | 1 : 4 | 98.92 ± 0.41 | 98.23 ± 0.24 |
| 5 | 1 : 5 | 98.98 ± 0.11 | 98.49 ± 0.04 |

**Table 2:**Composition of Rizatriptan benzoate – Eudragit E100 complex (1:3) rapidly disintegratingtablets

| Ingredients (mg/tablet) | Formulation code | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **P1** | **P2** | **P3** | **P4** | **P5** | **P6** | **P7** | **P8** | **P9** | **P10** | **P11** | **P12** |
| Rizatriptan benzoate – Eudragit E100 Complex* | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 40 | 40 |
| SDM | 150 | 148 | 146 | 144 | 150 | 148 | 146 | 144 | 150 | 148 | 146 | 144 |
| Indion 234 | 2 | 4 | 6 | 8 | - | - | - | - | - | - | - | - |
| CCS | - | - | - | - | 2 | 4 | 6 | 8 | - | - | - | - |
| SSG | - | - | - | - | - | - | - | - | 2 | 4 | 6 | 8 |
| Magnesium stearate | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Talc | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Aerosil | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Aspartame | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| **Total weight** | **200** | **200** | **200** | **200** | **200** | **200** | **200** | **200** | **200** | **200** | **200** | **200** |

**SDM:** Spray Dried Mannitol, **CCS:** Crosscarmellose Sodium, **SSG:** Sodium Starch Glycolate

**Table 3:** Micrometric properties of prepared blend

| Formulation Code | Bulk density g/cm$^3$ | Tapped density g/cm$^3$ | Angle of repose (Θ) | Carr's index % | Hausner's ratio |
|---|---|---|---|---|---|
| **P1** | 0.57 ± 0.04 | 0.64 ± 0.14 | 22.11 ± 0.44 | 11.49 ±0.63 | 1.13 ± 0.82 |
| **P2** | 0.56 ± 0.24 | 0.62 ± 0.08 | 21.70 ± 1.63 | 13.96 ±2.08 | 1.10 ± 0.71 |
| **P3** | 0.55 ± 0.01 | 0.60 ± 0.06 | 22.88 ± 1.77 | 12.93 ±0.77 | 1.09 ± 0.09 |
| **P4** | 0.55 ± 0.04 | 0.64 ± 0.12 | 20.76 ± 0.78 | 10.54 ±0.98 | 1.16 ± 0.36 |
| **P5** | 0.56 ± 0.02 | 0.67 ± 0.04 | 22.94 ± 1.51 | 11.93± 0.98 | 1.17 ± 0.64 |
| **P6** | 0.56 ± 0.01 | 0.68 ± 0.18 | 24.56 ± 0.70 | 13.86 ±1.42 | 1.13 ± 0.42 |
| **P7** | 0.56 ± 0.24 | 0.65 ± 0.14 | 23.11 ± 0.44 | 12.20 ±0.42 | 1.16 ± 0.07 |
| **P8** | 0.53 ± 0.01 | 0.59 ± 0.02 | 22.70 ± 1.63 | 13.60 ±0.14 | 1.11 ± 0.32 |
| **P9** | 0.55 ± 0.04 | 0.63 ± 0.06 | 20.88 ± 1.77 | 14.12 ±0.26 | 1.14 ± 0.54 |
| **P10** | 0.56 ± 0.02 | 0.66 ± 0.11 | 23.13 ± 0.78 | 12.69 ±0.21 | 1.14 ± 0.02 |
| **P11** | 0.56 ± 0.01 | 0.62 ± 0.14 | 23.94 ± 1.51 | 13.47 ±0.16 | 1.10 ± 0.72 |
| **P12** | 0.55 ± 0.02 | 0.63 ± 0.09 | 22.25 ± 0.81 | 12.88 ±1.98 | 1.14 ± 0.54 |

**Table 4:** Physico-chemical evaluation of rapidly disintegrating tablets

| Formulation Code | Hardness[+] ($kg/cm^2$) | Friability[†] (%) | Weight variation* (%) | Thickness*** (mm) | Drug Content (%)* |
|---|---|---|---|---|---|
| **P1** | 3.1 ± 0.30 | 0.60 ± 0.03 | 1.10 ± 0.48 | 7.14 ± 0.05 | 99.34 ± 0.40 |
| **P2** | 2.9 ± 0.28 | 0.53 ± 0.06 | 1.28 ± 0.65 | 7.18 ± 0.06 | 99.69 ± 0.06 |
| **P3** | 3.3 ± 0.35 | 0.61 ± 0.01 | 0.94 ± 0.16 | 7.24 ± 0.06 | 99.52 ± 0.33 |
| **P4** | 3.1 ± 0.40 | 0.56 ± 0.04 | 1.15 ± 0.75 | 7.21 ± 0.02 | 99.50 ± 0.16 |
| **P5** | 2.9 ± 0.46 | 0.52 ± 0.02 | 1.26 ± 0.35 | 7.12 ± 0.06 | 99.64 ± 0.37 |
| **P6** | 2.8 ± 0.24 | 0.66 ± 0.03 | 0.98 ± 0.29 | 7.22 ± 0.05 | 99.86 ± 0.02 |
| **P7** | 2.9 ± 0.40 | 0.58 ± 0.06 | 1.22 ± 0.75 | 7.14 ± 0.04 | 99.93 ± 0.01 |
| **P8** | 2.9 ± 0.96 | 0.48 ± 0.01 | 0.94 ± 0.35 | 7.15 ± 0.01 | 99.74 ± 0.07 |
| **P9** | 3.3 ± 0.24 | 0.67 ± 0.04 | 0.94 ± 0.29 | 7.19 ± 0.03 | 99.77 ± 0.16 |
| **P10** | 3.6 ± 0.83 | 0.58 ± 0.02 | 0.99 ± 0.34 | 7.13 ± 0.04 | 99.66 ± 0.22 |
| **P11** | 2.8 ± 0.55 | 0.42 ± 0.03 | 1.10 ± 0.19 | 7.18 ± 0.07 | 99.48 ± 0.23 |
| **P12** | 3.1 ± 0.24 | 0.61 ± 0.08 | 1.07 ± 0.37 | 7.19 ± 0.04 | 99.51 ± 0.16 |

**Table 5:**Physico-chemical evaluation of rapidly disintegrating tablets

| Formulation Code | Wetting time (sec)* | Water absorption ratio (%)* | Disintegration time (sec)* |
|---|---|---|---|
| **P1** | 28.63 ± 0.72 | 75.54 ± 1.58 | 34.19 ± 0.83 |
| **P2** | 25.39 ± 0.14 | 77.25 ± 1.29 | 31.96 ± 0.27 |
| **P3** | 22.47 ± 0.38 | 79.43 ± 1.67 | 28.32 ± 0.39 |
| **P4** | 20.03 ± 0.12 | 81.91 ± 1.64 | 26.34 ± 0.17 |
| **P5** | 32.14 ± 0.27 | 71.13 ± 1.91 | 36.01 ± 0.13 |
| **P6** | 29.93 ± 0.18 | 73.81 ± 1.86 | 33.55 ± 0.21 |
| **P7** | 25.78 ± 0.31 | 75.76 ± 1.34 | 30.16 ± 0.25 |
| **P8** | 23.82 ± 0.26 | 77.83 ± 1.22 | 28.28 ± 0.12 |
| **P9** | 37.33 ± 0.17 | 68.16 ± 1.16 | 39.01 ± 0.43 |
| **P10** | 35.64 ± 0.45 | 70.81 ± 1.43 | 35.78 ± 0.68 |
| **P11** | 32.63 ± 0.72 | 72.54 ± 1.58 | 30.19 ± 0.83 |
| **P12** | 29.39 ± 0.14 | 75.25 ± 1.29 | 27.96 ± 0.27 |

**Table 6:**Physico-chemical data of selected RDT before and after stability study

| Formulation code | Hardness test ($kg/cm^2$) | | Friability (%) | | Weight variation (%) | | Thickness(mm) | | Drug content (%) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **Before** | **After** | **Before** | **After** | **Before** | **After** | **Before** | **After** | **Before** | **After** |
| **P4** | 3.1± 0.40 | 3.1± 0.91 | 0.56± 0.04 | 0.51± 0.04 | 1.15± 0.75 | 1.13± 0.54 | 5.34± 0.03 | 5.54± 0.3 | 99.50 ± 0.16 | 99.20± 0.26 |
| **P8** | 2.9± 0.96 | 2.9± 0.64 | 0.48± 0.01 | 0.42± 0.01 | 0.94± 0.35 | 1.24± 0.23 | 5.83± 0.05 | 5.93± 0.25 | 99.74 ± 0.07 | 99.54 ±0.17 |
| **P12** | 3.1± 0.24 | 3.0± 0.37 | 0.61± 0.08 | 0.60± 0.08 | 1.07± 0.37 | 1.60± 0.11 | 5.13± 0.03 | 5.33± 0.63 | 99.51 ± 0.16 | 99.41 ±0.16 |

## 5. References


[1] Sinko PJ, Martin AN. Physical Pharmacy. 4th ed. Philadelphia: Lippincott Williams and Wilkins; 2001. 512–555.

[2] Banker GS, Anderson NR. Tablets. In: Lachman L, Liberman HA, Kanig JL, editors. The Theory and Practice of Industrial Pharmacy. 3rd ed. Philadelphia: Lee and Febiger; 1986. pp. 293–345.

[3] Gohel MC, Jogani PD. A review of coprocessed directly compressible excipients. J. Pharm. Sci. 2005;8:52–64.

[4] Birader SS, bhagwati S, Kuppasad IJ. Fast dissolving drug delivery system; a brief overview. Int. J. Pharmacol. 2006;4:516–519.

[5] Chatap VK, Sharma DK, Gupta VB. Taste masking properties of IER: a review. Pharm. Times. 2008;40

[6] Sohi H, Sultana Y, Khar R. Taste masking technologies in oral pharmaceuticals: recent developments and approaches. Drug Dev. Ind. Pharm. 2004;30:429–448.

[7] Vijay KSG, Mishra DN. Rapidly disintegrating oral tablets of meloxicam. Indian Drugs. 2006; 43:117–121.
[8] Chandrashekar NS, Kulkarni PK, Parimala P. Formulation and evaluation of fast dissolving tablets of rofecoxib. Int. J. Pharm. Excip. 2006; 1:14–17.
[9] Shishu A, Bhatti T, Singh, Preparation of tablets rapidly disintegrating in saliva containing bitter taste-masked granules by sublimation method, Ind. J. Pharm. Sci, 4(9), 2007, 80-84.
[10] Marshall KI, Lachman L, Liberman HA, Kanig JL. The Theory andPractice of Industrial Pharmacy, (3rdedn), Varghese publishing house India, 1987,66-99.
[11] Kakade SM, Mannur VS, Ramani KB, Dahada AA, Naval CV.Formulation and evaluation of mouth dissolving tablets of losartan potassiumby direct compression techniques. Int J Res Pharm Sci 1: 2010, 290-295.
[12] A. Wade, P. J. Weller, Polymethacrylates in Handbook of Pharmaceutical Excipients, (The Pharmaceutical Press, London, 1994, 362-366.
[13] Kamalpreet, Varun RK, Development of taste-masked fast disintegrating tablets of tinidazole, Asian Journal of Pharmaceutical Sciences, 1(4), 39-45.
[14] Vineet B, Mayank B, Sharma PK, Formulation and Evaluation of Fast Dissolving Tablets of Amlodipine Besylate Using Different Super Disintegrants and Camphor as Sublimating Agent, American-Eurasian Journal of Scientific Research, 2(5), 2010, 264-269.
[15] Friability of uncoated tablets. European Pharmacopoeia. (5thedn), Council of Europe, Strasbourg, 2004, 3103.
[16] Uniformity of drug content. Indian Pharmacopoeia vol 2 ($4^{th}$ edn), Controller of publication. Government of India, New Delhi. 1996: 734-736.
[17] Yunxia B, Yorinobu Y, Kazumi D, Akinobu O. Preparation and evaluation of oral tablet rapidly dissolving in oral cavity. Chem Pharm Bull 44: 1996, 2121-2127.
[18] Gohel MC, Bansal G, Bhatt N. Formulation and Evaluation of Orodispersible Taste Masked Tablets of Famotidine. Pharma Bio World 3: 2005, 75-80.