ISSN: 0975-8585

Research Journal of Pharmaceutical, Biological and Chemical Sciences

Formulation Development Studies of Rizatriptan Benzoate Fast Disintegrating Tablet

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ABSTRACT

The present study, attempts at highlighting the need of proper formulation study leading to good formulation development in order to achieve fast disintegration of Rizatriptan Benzoate. Rizatriptan benzoate is an antimigraine agent used in treatment of migraine. It is 5-Hydroxy Tryptophan $_{(1B/1D)}$ [5HT $_{(1B/1D)}$] receptor agonist. Migraine is a sudden attack lasting for 4-48 hrs and causes intense pain, hence there is a need to develop rizatriptan benzoate fast disintegrating tablets. Taste masking of rizatriptan benzoate was done by preparing the solid dispersions of drug with β Cyclodextrin by kneading method.1: 8 ratio of rizatriptan benzoate: β cyclodextrin solid dispersion was optimized for taste masking by time intensity method of taste evaluation. Tablets were prepared using various superdisintegrants like Ac-Di-Sol, Primojel, Polyplasdone and Tulsion 339 and were formulated by direct compression method and were evaluated for thickness, weight variation, drug content, hardness, friability, disintegration time, water absorption ratio and dissolution. The hardness was found to be 3 kg, with disintegration time of 15 seconds, and showed 100% release within 1.5 minutes for tablets containing the superdisintegrant Polyplasdone and hence considered superior as compared to other superdisintegrants.

Keywords: Rapidly disintegrating tablets; Rizatriptan benzoate; β Cyclodextrin; Taste masking; Direct compression.

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ISSN: 0975-8585

INTRODUCTION

Drug delivery using fast disintegrating tablets (FDTs) [1] is rapidly gaining importance since tablets either disintegrate or dissolve in the mouth rapidly, without requiring water to aid in swallowing. This novel dosage form is suitable for all age groups, particularly children, elderly and patient who are ill and have difficulty in swallowing conventional tablets and capsules. Current approaches of making fast disintegrating tablets are maximizing the porous structure of the tablet matrix by incorporating appropriate disintegrating agents and or highly water-soluble excipients in tablet formulation. Direct compression is the easiest way of manufacturing tablets. Disintegration and solubilization of the directly compressed tablets are based on action of disintegrants, water-soluble excipients and effervescent agents. In many cases, the disintegrants play a major role in disintegration and dissolution process of FDTs made by direct compression.

In today's era many people are suffering from migraine. Migraine [2] is a one sided throbbing headache followed by neurological and visual disturbances. Attack may prolong for long period. Rizatriptan benzoate is an antimigraine agent. It is $5HT_{1B/1D}$ receptor agonist used in treatment of migraine. It is the first online drug, which is most effective as compared to other triptans. Quick onset of action is necessary in order to protect the patient from migraine attack. The present study is aimed to design such a dosage form for rizatriptan benzoate, which is able to deliver drug as rapidly as possible so that onset of action is quick and patient does not require water for swallowing.

Research in formulation development of pharmaceuticals is focused on design of new drug delivery system to improve patient compliance. Hence it is necessary to individualize the drug therapy to optimize the drug concentrations and manufacturing technology for patient oriented drug delivery system.

Super disintegrants [3] like Croscarmellose sodium, sodium starch glycollate, crospovidone, and tulsion 339 have been selected due to their fast disintegration property.

β cyclodextrin [4] was used as the taste-masking agent to mask the taste of Rizatriptan benzoate and also it is used as stabilizing and solubilizing agent thus improving the dissolution rate.

MATERIALS AND METHODS

Materials

Rizatriptan Benzoate was procured from Cipla Ltd. (Mumbai) India, β Cyclodextrin, Ac-Di-sol, Crospovidone, Primojel, Avicel pH 102 was procured from Emcure labs Ltd. (Pune) India and Tulsion 339 from Thermax India Ltd. All the other ingredients are of A.R. grade.

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Methods

Taste masking using β cyclodextrin

The taste masking of rizatriptan benzoate was done by using β cyclodextrin as a taste-masking agent. The physical mixture of drug and β cyclodextrin was prepared and small quantity of water was added to prepare a paste [5], which was then allowed to dry at 50° C in hot air oven. The drug: β cyclodextrin in various ratios (1:1 to 1:10) were prepared by kneading method and the drug: β cyclodextrin ratio was optimized by taste evaluation.

Taste evaluation

The healthy human volunteers of age group 20- 25 years were used for taste evaluation; informed consent was obtained from all of them. Taste evaluation was done by a panel of 10 members using time intensity [6] method. Sample equivalent to normal dose was held in mouth for 10 sec., bitterness levels were recorded instantly and then after 10sec, 1, 2, 5, and 15 minutes and is mentioned in table. Volunteer's opinion for bitterness values were rated by giving different score values. That is, 0: no bitterness, 1: acceptable bitterness, 2: slight bitterness, 3: moderately bitterness, 4: strong bitterness.

Descriptive statistics mean and standard deviation were calculated for all variables. Paired t test was applied using INSTAT software. Value $P< 0.05$ has been considered as statistical significant level.

Evaluation of taste masked drug: polymer (1:8) solid dispersion

The drug and the prepared taste masked solid dispersion was evaluated for drug content, bulk density, Carr's index, and angle of repose.

Characterization of solid dispersion

Infrared spectroscopy

The drug, β cyclodextrin and drug: β Cyclodextrin solid dispersion was subjected to Infra Red (IR) spectroscopy studies to check drug polymer interaction using (Fourier Transform Infra Red) FTIR (SHIMADZU 8400 S). The Potassium Bromide (KBr) disk method was used for preparation of sample.

Differential Scanning Colorimetry Studies

The drug, β cyclodextrin and drug: β cyclodextrin solid dispersion was subjected to Differential scanning Colorimetry (DSC) study. DSC was performed on a METTLER DSC 30. First 10-30 mg of sample was weighed into aluminum crucible. Rizatriptan benzoate**,** β Cyclodextrin

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and Rizatriptan Benzoate with β Cyclodextrin solid dispersion were analyzed by heating at scanning rate of 20^0C / minute over a temperature range 40 to 300^0C.

X-ray diffraction analysis

Rizatriptan benzoate, β cyclodextrin and rizatriptan benzoate with β cyclodextrin were subjected to powder X-ray diffraction (XRD) using P.W. 1729, X-Ray Generator, Philips, Netherland. To study XRD pattern, the sample was placed into aluminum holder and the instrument was operated between initial and final 2θ angle of 5-50^0 respectively in an increment of $0.4^0$2θ.

Preparation of FDT's using rizatriptan benzoate

Table 1. *Formulation design of FDT's.*

Name Of Ingredient	Formulations (mg)			
Rizatriptan Benzoate	7.27	7.27	7.27	7.27
β Cyclodextrin	58.16	58.16	58.16	58.16
Superdisintegrants	*	**	***	****
MCC (PH 102)	60.95	59.2	57.45	55.7
Saccharin sodium	1	1	1	1
Mannitol	41	41	41	41
Strawberry flavor	1	1	1	1
Magnesium stearate	0.875	0.875	0.875	0.875
Aerosil	0.875	0.875	0.875	0.875
Colour	0.37	0.37	0.37	0.37
Total	175	175	175	175

* A1, A2, A3, A4 contains 3.5, 5.25, 7.0, 8.75 mg of Ac-Di-Sol respectively.

** B1, B2, B3, B4 contains 3.5, 5.25, 7.0, 8.75 mg of Polyplasdone- XL respectively.

*** C1, C2, C3, C4 contains 3.5, 5.25, 7.0, 8.75 mg of Primojel respectively.

**** D1, D2, D3, D4 contains 3.5, 5.25, 7.0, 8.75 mg of Tulsion 339 respectively

FDT's of Rizatriptan benzoate were prepared by using Ac-Di-sol (Croscarmellose Sodium), Polyplasdone XL (Crospovidone), Primojel (Sodium Starch Glycollate) and Tulsion 339(Polacrillin Potassium) as the superdisintegrants in the concentration of 2%, 3%, 4% and 5%

of the weight of the tablets. Tablets were prepared by direct compression method using Sixteen-station tablet machine (Cadmach, India). Table 1 indicates the formulation design of FDT's.

Evaluation of FDT's

The formulated FDT's were evaluated for different parameters like thickness, uniformity of weight, hardness, water absorption ratio, in vitro and in vivo disintegration time.

Thickness

Thickness of the tablets was determined using a thickness gauge (Mitutoyo, New Delhi, India). Five tablets from each batch were used, and average values were calculated.

Weight variation test [7]

To study weight variation 20 tablets of each formulation were weighed using an electronic balance (Schimadzu), and the test was performed according to the official method.

Drug content

Five tablets were weighed individually and powdered. The powder equivalent to average weight of tablets were weighed and extracted in water and concentration of drug was determined by measuring absorbance at 227.5 nm by Ultra Violet (UV) spectrophotometer (Schimadzu 1601)

Hardness and Friability [7]

For each formulation the hardness and friability of 6 tablets were determined using the Monsanto hardness tester (Cadmach, Ahmedabad, India) and the Roche Friabilator (LabHosp Mumbai, India) respectively.

Disintegration time [8]

In vitro disintegration time of 6 tablets from each formulation was determined by using Digital Tablet Disintegration Apparatus (Veego Scientific, Mumbai, India). In vitro disintegration test was carried at 37 ± 2^0C in 900 ml distilled water.

In vivo disintegration time of tablet was checked in healthy human volunteers by putting a tablet on tongue and time required for complete disintegration was checked.

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Water absorption ratio [9]

A piece of tissue paper folded twice was placed in a small Petri dish containing 6 ml of water. A tablet was kept on the paper and the time required for complete wetting was measured. The wetted tablet was then weighed.

Water absorption ratio, R, was determined using following equation:

$R = 100 \times Wb - Wa / Wa$

Where, Wa = Weight of tablet before water absorption.

Wb = Weight of tablet after water absorption.

Dissolution studies [10]

The in vitro dissolution studies were carried out using United States Pharmacopoeia (USP) apparatus type II (VGA Scientific 6DA Apparatus) at 100 rpm. The dissolution medium used was distilled water (900 ml) maintained at $37 \pm 0.5\ ^0$ C. Aliquots of dissolution media were withdrawn at different intervals, concentration for Rizatriptan benzoate was determined by measuring absorbance at 227.5 nm by UV spectrophotometer. The dissolution experiments were conducted in triplicate.

Stability Studies

Stability study was conducted by storing the tablets at 40 ± 2^0C/75 ± 5% Relative Humidity (RH) for three months. The content and dissolution behavior from dissolving tablets were tested monthly for three months.

1. RESULT AND DISCUSSION

Table 2. Volunteers opinion test for rizatriptan benzoate before and after taste masking

Sr. No	Time (seconds)	Before taste masking Mean ± SD	After taste masking Mean ± SD
1	10	2.3 *** ± 0.58	0.5 * ± 0.84
2	60	3.3 *** ± 0.48	0.3 **± 0.69
3	120	3.4 ***± 0.51	0.2 ** ± 0.31
4	300	3.8 *** ± 0.42	0
5	600	3.8 *** ± 0.32	0
6	900	4 *** ± 0.0	0

P< 0.001*** P< 0.01** P< 0.05*

Each reading is a mean of ten determinations ± Standard Deviation (SD)

ISSN: 0975-8585

Table 3. Evaluation of solid dispersion rizatriptan benzoate: β cyclodextrin (1:8)

(n=3)

Parameters	Pure Drug	Solid Dispersion
Drug Content (%)	100	97.38 ± 0.5210
Bulk Density	0.5774 ± 0.2561	0.5728 ± 0.3126
Carr's Index	9.64 ± 0.5229	15.25 ± 0.1892
Angle of Repose	26.53 ± 0.2983	31.55 ± 0.2182

Rizatriptan benzoate: β cyclodextrin (1:1 to 1:10) solid dispersions were prepared by paste method to mask the bitter taste of the drug. Panel of 10 members using time intensity method were evaluated for the taste masking of drug. The ratio of drug: β cyclodextrin for taste masking was optimized to 1:8. The data in Table 2 indicates the taste evaluation of drug: β cyclodextrin (1:8) solid dispersion. The optimized drug: β cyclodextrin (1:8) solid dispersion was evaluated for drug content, bulk density, Carr's index and angle of repose as in table 3.

Drug content of drug: β cyclodextrin (1:8) was found to be 97.38 %. Drug and solid dispersion showed good flow properties.

The physical state of rizatriptan benzoate in the complex was analyzed by IR, DSC and XRD.

The interaction between the drug and the carrier often lead to identifiable changes in IR profile of the solid dispersion. The drug and the solid dispersion were subjected to IR analysis in order to evaluate possible solid-solid interaction between the drug and β cyclodextrin. The data was compared with the standard spectrum of drug and the characteristics peaks associated with specific structural characteristics of the molecule and their presence/absence in β cyclodextrin as well as the solid dispersion were noted.

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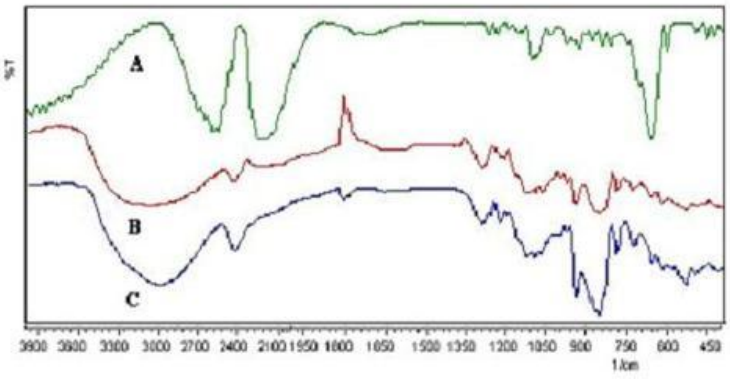

Fig. 1 Infrared Spectrum for A) rizatriptan benzoate B) β cyclodextrin

C) Rizatriptan benzoate: β cyclodextrin

The IR spectra of the solid dispersion (Fig 1.) showed that there was no significant evidence for interaction between drug and β cyclodextrin. Peaks of both drug as well as β cyclodextrin were observed and interpreted.

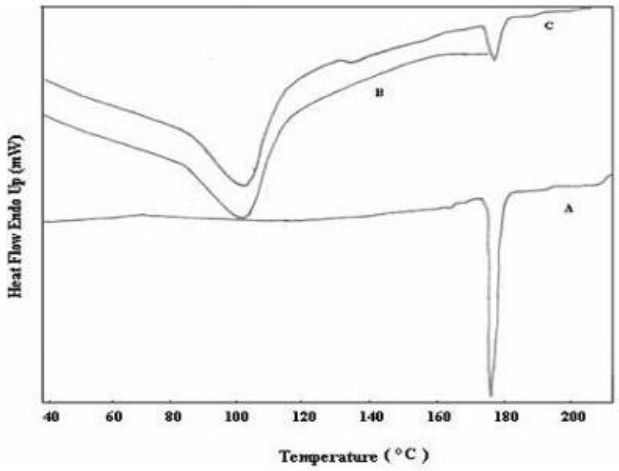

Fig.2 Differential scanning calorimetry for A) rizatriptan benzoate B) β cyclodextrin

C) rizatriptan benzoate: β cyclodextrin

The DSC of drug: β cyclodextrin (1:8) did not show any interaction of drug and β cyclodextrin. Pure drug and pure β cyclodextrin shows melting point at 180°C and 256°C respectively. Rizatriptan benzoate and β cyclodextrin (1:8) in their solid dispersion showed melting point at 179^0C and 254^0C respectively. (Fig 2)

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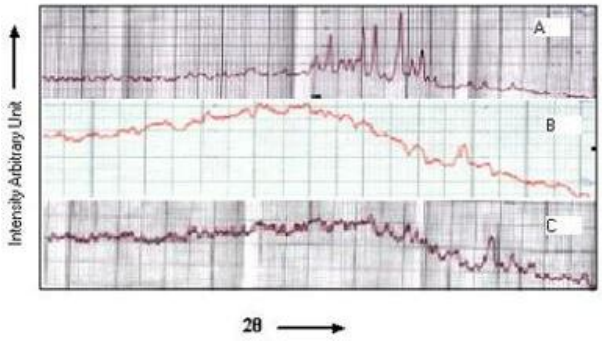

Fig.3 Powder X- ray diffraction pattern for A) rizatriptan benzoate B) β cyclodextrin C) rizatriptan benzoate: β cyclodextrin

The XRD pattern of drug: β cyclodextrin (1:8) showed no defined peak; this implies the absence of apparent crystallinity in the solid dispersion. However the pure drug powder showed typical peak of rizatriptan benzoate, conforming the satisfactory sensitivity of the method (Fig.3).

Powder Properties of Control Formulation by Direct Compression

It was found that powdered blend of controlled formulation for direct compression was low in angle of repose, compressibility and found excellent in flowability. It has also showed less porosity than powders containing superdisintegrants. The porosity gets altered by the number of contact points and by the shape and diameter of constituent particles. As tablet porosity and average pore size decreases with increase in compression forces due to high compressibility of Microcrystalline Cellulose (MCC), it was observed that there is decrease in porosity with increase in MCC contents [11].

Powder Properties of Formulation Containing Ac-Di-Sol

Powder properties of formulation containing 2, 3, 4 and 5% of Ac-Di-Sol as superdisintegrant, for direct compression had angle of repose in range of 4.6 – 9.8^0 while percentage compressibility values were ranged in 12.0-15.4 %. Porosity, which was ranged between 13.1-15.9 %, was found to increase with increase in concentration of superdisintegrant. Also all formulation had shown good flowability [12].

Powder Properties of Formulation Containing Polyplasdone-XL

It was observed that formulations containing Polyplasdone-XL as superdisintegrant have angle of repose between ranges of 7.6- 12.9^0, which was higher than control formulation. Also it was observed that there was increase in percentage compressibility with increase in concentration of superdisintegrants while porosity was more than powder blend of control formulation and it was increased with increase in concentration of Polyplasdone-XL, which is

because of highly spongy and porous nature of Polyplasdone-XL. Powdered blend of all formulation had shown good flowability.

Powder Properties of Formulation Containing Primojel

It was observed that powder blend containing Primojel as superdisintegrant had shown angle of repose between 13.3- 19.1^0 and percentage compressibility between 12.2-15.5 %, which indicated that all powders had good flowability. Porosity of the powder blend is directly proportional to concentration of Primojel.

Powder Properties of Formulation Containing Tulsion 339

It was found that powder containing Tulsion 339 as superdisintegrant had shown angle of repose between 12.6- 23.5^0 while percentage compressibility 15.8- 16.3 %. It was found that porosity of powder blend increase with increase in concentration of Tulsion 339 upto 4% concentration of Tulsion 339 while beyond this it get decreased. Also powder had shown good flowability.

Tabletting Properties of Control Formulation

By comparing tablet properties of control tablet with other tablet prepared by using various concentration of superdisintegrant, it was found that control tablet had greater hardness while showing less water absorption ratio.

MCC has more free hydroxyl group and thus the interaction forces in a contact point may be stronger because of stronger hydrogen bond of hydroxyl groups, which can cause increase in hardness.

During manufacture of MCC accessible amorphous region of cellulose molecules are hydrolyzed so that MCC shows relatively high crystallinity. So it can absorb only small amount of water and reaches equilibrium rapidly. Also, MCC particles are concave convex shape and their pores are fairly collapsed by compression due to which tortuosity of a pore in MCC tablet is increased which ultimately hampers the water absorption ratio. Control tablet had also shown least friability and it had passed for both weight variation and uniformity of content test. It was found that, in vitro disintegration time of control tablet was 29 seconds while that of in vivo was 34 seconds.

Tabletting Properties of Formulation containing Ac-Di-Sol

Hardness of all tablets found between 3.2- 3.4 kg while friability and weight variation test result were found within acceptable limits. Also all tablets were passed for uniformity of content test. Ac-Di-Sol is made by cross -linking (etherification) reaction of Sodium Carboxy Methyl Cellulose (Sodium CMC). This cross linking greatly reduced water solubility of Sodium CMC while permitting material to swell and absorbs water many times it's weight without

ISSN: 0975-8585

loosing fiber integrity [13] Due to this it was found that as concentration of Ac-Di-Sol increased water absorption ratio was also increased and it was ranged between 91.6-110.1, which was highest than formulation prepared with other disintegrant. As shown in table 4. Tablet prepared by using Ac-Di-Sol as superdisintegrant were found to have more water absorption ratio and hence both invitro and in vivo disintegration time for all formulations was very less when compared with other superdisintegrants.

Tabletting Properties of formulation containing Polyplasdone-XL

Table 4: *Evaluation of mouth dissolving tablets. (n =3)*

Parameters	A1	A2	A3	A4	B1	B2	B3	B4	M 1
Uniformity of Weight	Passes	Passes	Passes	Passes	Passes	Passes	Passes	Passes	Passes
Uniformity of Content (%)	99.22 ± 1.2613	100.08 ± 1.4319	99.86 ± 2.1945	99.12 ± 0.6981	100.5 ± 2.5692	100.42 ± 1.3592	99.88 ± 1.2468	99.27 ± 1.4658	99.23 ± 0.9835
In Vitro Disintegration time(sec.)	23 ± 0.1236	17 ± 0.2569	18 ± 0.1564	25 ± 0.3658	26 ± 0.6598	15 ± 0.1358	17 ± 0.3267	19 ± 0.1567	23 ± 0.3126
In Vivo Disintegration Time (sec.)	27 ± 0.3564	21 ± 0.1564	22 ± 0.3165	27 ± 0.2366	33 ± 0.6154	18 ± 0.1326	21 ± 0.1665	24 ± 0.3265	28 ± 0.4615
Hardness (kg/cm^2)	3.2± 0.3165	3.25± 0.6532	3.2± 0.6432	3.4± 0.6431	3.3± 0.5426	3.4± 0.1568	3.2± 1.0159	3.45± 0.7139	3.5± 0.4583
Friability (%)	0.74± 0.3165	0.75± 0.1258	0.68± 0.2498	0.64± 0.5481	0.71± 1.06	0.69± 0.9613	0.65± 0.8167	0.61± 0.2465	0.72± 0.6843
% Water absorption	58.56 ±0.32	70.23 ±0.62	80.8 ±0.54	92.3 ±0.38	91.64 ±0.31	95.64 ±0.19	99.8 ±0.135	103.75 ±0.203	64.5 ±0.203

Tabletting properties of tablet containing 2%, 3%, 4% and 5% of Polyplasdone-XL as superdisintegrant have shown in table 4.

Hardness of all tablets was found in the range of 3.2- 3.4 kg while friability was observed below 1% which is an indication of good mechanical resistance of tablet. Also rise in water absorption ratio was found with increase in concentration of crospovidone.

Due to highly porous structure of crospovidone, it draw large amount of water by water wicking mechanism into porous network of tablet and thus crospovidone swells very little, yet rapidly absorbs water into its network. Due to this with increase in concentration of Polyplasdone-XL improved water uptake and reduction in disintegration time was observed with all four formulation containing Polyplasdone-XL as compared to control tablet.

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It was found that invitro disintegration time was ranged between 12-22 seconds while in vivo disintegration time was ranged between 17-27 seconds, which was quite less than control tablet.

Tabletting Properties of formulation containing Primojel

Table 5. Evaluation of mouth dissolving tablets. (n=3)

Parameters	C1	C2	C3	C4	D1	D2	D3	D4	M1
Uniformity of Weight	Passes	Passes	Passes	Passes	Passes	Passes	Passes	Passes	Passes
Uniformity of Content (%)	99.65 ± 1.2613	100.08 ± 1.4319	99.86 ± 2.1945	99.5 ± 0.6981	100.5 ± 2.5692	100.42 ± 1.3592	99.88 ± 1.2468	99.7 ± 1.4658	99.23 ± 0.9835
In Vitro Disintegration time (sec.)	23 ± 0.1236	15 ± 0.2569	18 ± 0.1564	15 ± 0.3658	26 ± 0.6598	15 ± 0.1358	17 ± 0.3267	20 ± 0.1567	23 ± 0.3126
In Vivo Disintegration Time (sec.)	27 ± 0.3564	17 ± 0.1564	22 ± 0.3165	17 ± 0.2366	33 ± 0.6154	18 ± 0.1326	21 ± 0.1665	24 ± 0.3265	28 ± 0.4615
Hardness (kg/cm^2)	3.2± 0.3165	3.25± 0.6532	3.2± 0.6432	3.4± 0.6431	3.3± 0.5426	3.4± 0.1568	3.2± 1.0159	3.45± 0.7139	3.5± 0.4583
Friability (%)	0.7± 0.3165	0.75± 0.1258	0.68± 0.2498	0.64± 0.5481	0.71± 1.06	0.69± 0.9613	0.65± 0.8167	0.61± 0.2465	0.72± 0.6843
% Water absorption	60.2 ±0.32	65.69 ±0.62	80.8 ±0.54	92.3 ±0.38	91.64 ±0.31	95.64 ±0.19	99.8 ±0.135	110.1 ±0.203	64.5 ±0.203

As per table 5, it was found that hardness of all formulations containing Primojel was found in the range of 3.2- 3.4 kg while both friability and weight variation was observed in acceptable limit. Tablet also passes for uniformity of content test. It was also observed that water absorption ratio of tablet was directly proportional to concentration of Primojel. But both in vivo and in vitro disintegration time was increased with increase in concentration of Primojel. Superdisintegrant action of Primojel, which is governed by it's extensive swelling which increase with increase in concentration of Primojel. Also formations of viscous plugs were observed with increasing concentration of superdisintegrant.

Due to these viscous plugs, though tablets breaks, their plugs were not passed through mesh of disintegration test apparatus and ultimately disintegration time was found to be increased with increasing concentration of Primojel.

Tablet Properties of Formulation containing Tulsion 339

As shown in Table 5, it was observed that all formulation containing 2, 3, 4 and 5% Tulsion 339 as superdisintegrant have hardness 3.2- 3.4 kg. All tablets have friability and weight variation within acceptable limit and also all tablet passes for uniformity of content test. It was found that increase in water absorption ratio and decrease in both in vitro and in vivo disintegration time of tablet was observed with increase in concentration of Tulsion 339 upto 4% concentration of Tulsion 339 while beyond this all values were vice versa.

Effect of concentration of superdisintegrant on the dissolution release rate

Formulation containing Polyplasdone XL showed faster release rate than other formulations. Fig 4, Fig 5, Fig 6, and Fig 7 shows the dissolution profiles using superdisintegrants Ac-Di-Sol, Primojel, Polyplasdone XL and Tulsion 339 respectively. All the above-mentioned formulation showed faster release than conventional marketed preparations.

Formulation containing Ac-Di-Sol showed 100% drug release within 2 mins. Whereas formulation containing Polyplasdone-XL (B1 to B4) showed 100% drug release within 1.5 to 2 min.

Formulation C1 to C4 (containing primojel as the superdisintegrant) showed slow rate of release as compared to Ac-Di-Sol and Polyplasdone-XL that is 100% release within 2 to 2.5 min. It was found that the formulation D1 to D4 containing Tulsion 339 showed 100 % release within 2 to 2.5 mins.

All the formulations showed improvement in dissolution rate with increasing the amount of superdisintegrant. Slow release of the formulation containing Primojel is attributed to the formation of viscous gel with increasing the amount of primojel.

ISSN: 0975-8585

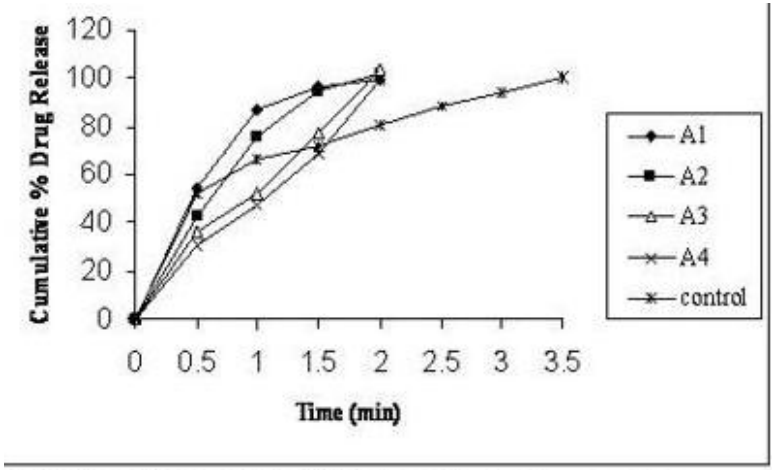

Fig.4 Dissolution profile for tablet prepared by direct compression technology using ac-di-sol

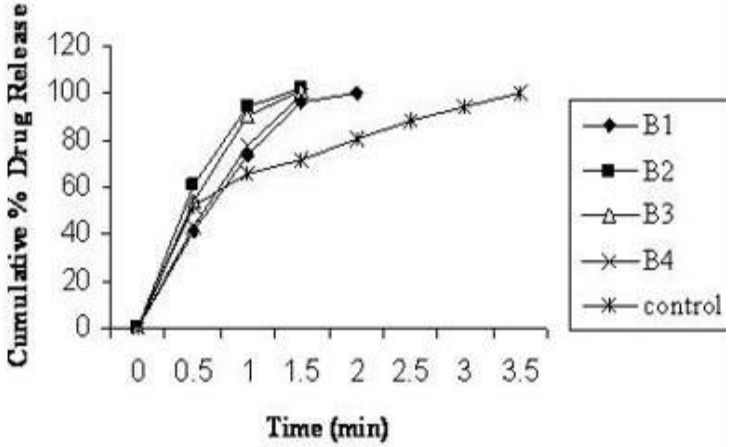

Fig. 5 Dissolution profile for tablet prepared by direct compression technology using primojel

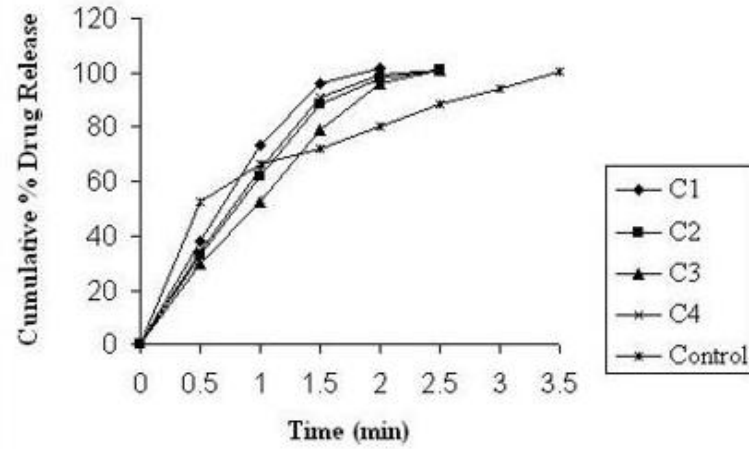

Fig. 6 Dissolution profile for tablet prepared by direct compression technology using polyplasdone XL

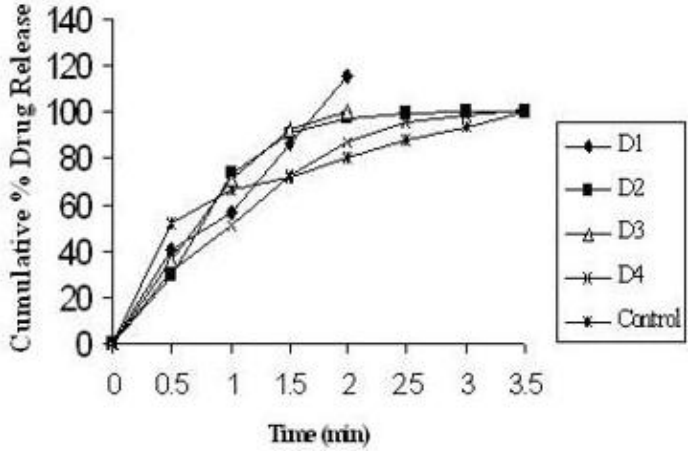

Fig.7: Dissolution profile for tablet prepared by direct compression technology using tulsion 339

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Stability Studies

During storing the tablets at 40 ± 2^0C/75 ± 5% RH for three months, the tablets were tested for their contents and dissolution behavior monthly. It was observed that the content from the tablets remained same. While the dissolution release rate of tablets is decreased with time. This is due to slight increase in hardness of tablets followed by decrease in disintegration time.

CONCLUSION

Solid dispersion prepared by using β cyclodextrin effectively masked the taste of Rizatriptan benzoate. Solid dispersion gave good flowability and there was no interaction between drug and β cyclodextrin. Tablets prepared showed fast disintegration and dissolution, which is the major aim.

ACKNOWLEDGMENT

We are very grateful to Ranbaxy Labs.Ltd for providing Rizatriptan Benzoate, Emcure Research Center (Pune) for providing Ac-Di-Sol, Polyplasdone, Primojel and Thermax India Ltd. For providing us Tulsion 339 as gift sample. Authors wish to thank the faculty of physics University of Pune. Grant was provided by AICTE.

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