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FORMULATION AND CHARACTERIZATION OF RIZATRIPTAN BENZOATE MOUTH DISSOLVING TABLETS

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ABSTRACT

Many patients express difficulty in swallowing tablets and hard gelatin capsules, which results in high incidence of non-compliance and ineffective therapy. Recent advances in Novel Drug Delivery Systems (NDDS) aim to enhance safety and efficacy of drug molecule by formulating a convenient dosage form for administration and to achieve better patient compliance. One such approach is fast disintegrating/ dispersing tablet formulation. In the present work, fast disintegrating tablets of Rizatriptan benzoate were designed and optimized with a view to enhance patient compliance by direct compression method. In the direct compression method, crospovidone (2-10% w/w) was used as super-disintegrant along with microcrystalline cellulose (5-20%w/w) as disintegrant and directly compressible mannitol to enhance mouth feel. Estimation of rizatriptan benzoate in the prepared tablet formulations was carried out by extracting the drug with water and measuring the absorbance at 234nm. The prepared formulations were further evaluated for hardness, friability, drug content uniformity, wetting time, water absorption ratio and *in vitro* dispersion time. Based on *in vitro* dispersion time (approximately 8-14 s), one promising formulations was tested for *in vitro* drug release pattern (in pH 6.8 phosphate buffer) and drug excipient interaction (IR spectroscopy). Among all the formulations, promising formulation, the formulation prepared by direct compression method (containing 2% w/w crospovidone and 15% w/w Microcrystalline cellulose) emerged as the overall best formulation.

KEYWORDS: Rizatriptan benzoate; Directly compressible mannitol; Fast disintegrating tablets; Crospovidone.

INTRODUCTION

Among the different routes of administration, the oral route of administration continues to be most preferred route due to various advantages including ease of administration, avoidance of pain, versatility and most importantly patient compliance. Tablets and capsules are the most widely used dosage forms because of its convenience in terms of self-administration, compactness and ease in manufacturing.

Many patients find it difficult to swallow tablets and hard gelatin capsules and thus do not comply with prescription, which results in high incidence of non-compliance and ineffective therapy.[1] Recent advances in novel drug delivery systems (NDDS) aim to enhance the safety and efficacy of drug molecule by formulating a convenient dosage form for administration and to achieve better patient compliance.[1-4]

Nearly 35-50% of the general population, especially the elderly and children suffer from dysphasia or difficulty in swallowing, which results in high incidence of non-compliance and ineffective therapy. Swallowing problems also are very common in young individuals because of their poorly developed muscular and nervous systems. Other groups who may experience problems in swallowing conventional oral dosage forms are the patients. To overcome this problem, scientists have developed innovative drug delivery system known as “fast disintegrating tablets”, are the novel solid oral dosage form which disintegrates and dissolves rapidly in saliva without need for drinking water. This tablet disintegrates instantaneously or disperses in saliva.[5] These tablets usually dissolve within 15 s to 2 min. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach and produce rapid onset of action. In such cases bioavailability of drug is significantly greater than those observed from conventional tablet dosage forms.[1,6]

Direct compression is the easiest method to manufacture fast disintegrating tablets (FDTs) and fast melting tablets (FMTs). The great advantage of direct compression is its low manufacturing cost.

In many cases the disintegrates used have a major role in the disintegration and dissolution process of fast disintegrating tablets made by direct compression method.

In direct compression method[7], previously only crystalline compounds or materials were considered to be directly compressed, but now a days the scenario is changing and this technique is being applied for many non-crystalline materials too. The approach mainly employs importation or modification of certain physical properties of the material under consideration, such as cohesiveness, compactness and flow properties. Formulations constituted by ≤25% w/w of drug material are easy to be directly compressed by simply using such diluents, which are easy to be compressed and which act as a carrier for the drug.

MATERIALS AND METHODS

Table No. 01: Materials Used.

SL. NO.	MATERIALS	SOURCE
1.	Rizatryitan benzoate	Aurbindo.pharma limited.
2.	Mannitol (Pearlitol SD 200)	Aurbindo.pharma limited.
3.	MCC (PH 102)	Aurbindo.pharma limited.
4.	Crospovidone	Aurbindo.pharma limited.
5.	Sodium stearyl fumarate	Aurbindo.pharma limited.
6.	Talc	SD fine chemicals.
7.	Aspartame	Aurbindo.pharma limited.
8.	Pineapple flavor	Aurbindo.pharma limited.
9.	Potassium dihydrogen orthophosphate	SD fine chemicals.

Table No: 02- Equipment Used.

Sl. No.	Equipment	Model/ Source
1.	UV-spectrophotometer	T60 UV-Visible Spectrophotometer.
2.	Digital Balance	BL-220H, Shimadzu.
3.	Digital pH meter	Motex 152- R.
4.	Dissolution apparatus	Sisco Mumbai.
5.	IR spectroscopy	Perkin Elmer FTIR Series model-1615 Spectrometer.
6.	Hot air oven	Sisco,Mumbai.
7.	Hardness tester	Pfizer.
8.	Friability Test Apparatus	Sisco,Mumbai.
9.	Tablet punching machine	Cadmach,16 station.

METHODS

1. Design of formulations by direct compression method using crospovidone as super-disintegrant.
2. Evaluation of the formulation designed by the above two methods.

- Hardness and friability.
- Drug content uniformity
- *In vitro* dispersion time
- Wetting time and water absorption ratio

- *In vitro* dissolution rate from promising formulations using pH 6.8 phosphate buffer.

3. To study the drug-excipients compatibility.

FORMULATION OF FAST DISINTEGRATING TABLETS

Direct Compression[8]

Fast disintegrating tablets of Rizatriptan benzoate were prepared by direct compression according to the formulae given in table-3.

- All the ingredients were passed through 60 mesh sieve separately.
- The drug and MCC was mixed by small portion of both each time and blending it to get a uniform mixture and kept aside.
- Then the ingredients were weighed and mixed in geometrical order and tablets were compressed at 7 mm size to get a tablet of 120 mg weight using a Rotary Clit 10 station compression machine. The tablets were prepared according to the formulae shown in table-3.

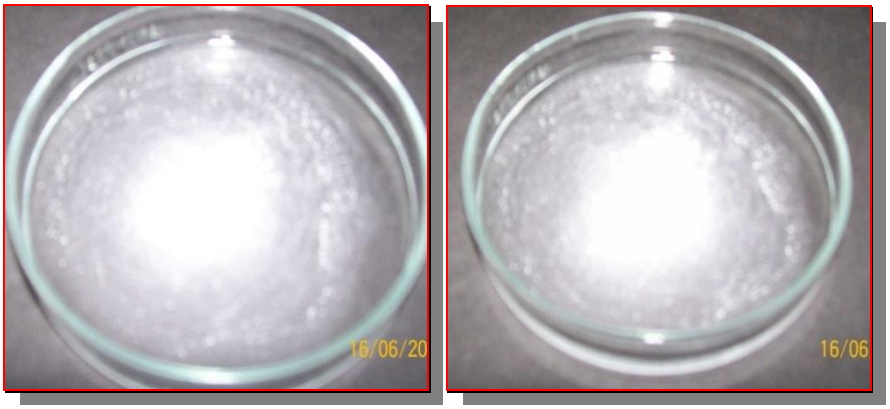

Figure 1 -: *In vitro* dispersion of Tablets prepared by Direct Compression Method.

Table-3: Formulations chart of Rizatryitan benzoate fast disintegrating tablets prepared by direct compression method.

Formulation Code						
Ingredients (mg/Tablet)	**DCR_1**	**DCR_2**	**DCR_3**	**DCR_4**	**DCR_5**	**DCR_6**
Rizatryitan benzoate	1.00	1.00	1.00	1.00	1.00	1.00
Crospovidone	2.40	2.40	2.40	6.00	6.00	6.00
Microcrystalline cellulose (PH 102)	6.00	12.00	18.00	6.00	12.00	18.00
Aspartame	1.20	1.20	1.20	1.20	1.20	1.20
Talc	2.40	2.40	2.40	2.40	2.40	2.40
Sodium stearyl fumarate	1.20	1.20	1.20	1.20	1.20	1.20
Flavour (pineapple)	1.20	1.20	1.20	1.20	1.20	1.20
Mannitol (SD 200)	104.60	98.60	92.60	101.00	95.00	89.00
Total	120.00	120.00	120.00	120.00	120.00	120.00

EVALUATION OF TABLETS

Weight Variation[9]

Twenty tablets were selected at random and average weight was determined. Then individual tablets were weighed and the individual weight was compared with an average weight. The results are shown in table-5.

Hardness and Friability[10]

Friability of the tablets was checked by using Roche Friabilator. This device subjects a number of tablets to the combined effect of abrasions and shock by utilizing a plastic chamber that revolves at 25 rpm dropping the tablets from a height of 6 inches with each revolution. Pre-weighed sample of tablets was placed in the friabilator, which was then operated for 100 revolutions. Tablets were dusted and reweighed. The results are shown in table-5.

Content Uniformity Test[11]

Ten tablets were weighed and powdered, a quantity of powder equivalent to 1 mg of Rizatriptan benzoate was transferred to a 50 ml volumetric flask and 40 ml water is added. The drug is extracted into the methanol by vigorously shaking the stoppered flask for 15 minutes. Then the volume is adjusted to 50 ml with water and the liquid is filtered. The Rizatriptan benzoate content was determined by measuring the absorbance at 234 nm after appropriate dilution with water. The drug content was calculated using the standard calibration curve. The mean percent drug content was calculated as an average of three determinations. The results are shown in table-5.

Wetting Time and Water Absorption Ratio[12]

A piece of tissue paper folded twice was placed in a small petridish containing 6 ml of water. A tablet was put on the paper and the time required for complete wetting is measured (figure-3). The wetted tablet was then weighed. The results were shown in table-5.

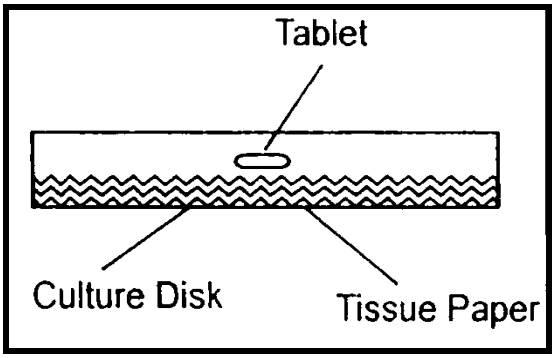

Figure-2: Schematic representation of wetting time/ water absorption ratio determination.

Water absorption ratio 'R' was determined using following equation.

$$R = 100 \times \left(\frac{W_a - W_b}{W_a} \right)$$

Where, W_a is weight of tablet after water absorption and

W_b is weight of tablet before water absorption.

Figure-3: Wetting time and water absorption ratio of Fast Disintegrating Tablets.

In Vitro Dispersion Time[13]

Tablet was added to 10 ml of phosphate buffer solution, pH 6.8 at 37±0.5ºC. Time required for complete dispersion of a tablet was measured. The results were shown in table-5 and figure-3.

Dissolution Study[14]

In vitro dissolution of a Rizatryitan benzoate fast disintegrating tablet was studied in USP type-II dissolution apparatus (Sisco) employing a paddle stirrer. 900 ml of phosphate buffer pH 6.8 was used as dissolution medium. The stirrer was adjusted to rotate at 50 rpm. The

temperature of dissolution media was previously warmed to 37±0.5ºC and was maintained throughout the experiment. One tablet was used in each test. 5 ml of sample of dissolution medium were withdrawn by means of syringe fitted with pre-filter at known intervals of time and analyzed for drug release by measuring the absorbance at 281nm. The volume withdrawn at each time interval was replaced with fresh quantity of dissolution medium. Percentage amount of Rizatriptan benzoate released was calculated and plotted against time.

Drug-Carrier Interaction Studies[15]

While developing a new formulation, it is necessary to check the drug compatibility with the carrier or excipient used and that the drug has not undergone any degradation when it passes through the various processes. Suitable evidential experiments are conducted to justify and prove the intactness of the drug in the formulations. Various methods available for characterizing the products are: TLC, IR spectra, X-ray diffraction, scanning electron microscopy, diffuse reflectance spectroscopy and differential scanning calorimetry.

Infrared Spectroscopy[16]

Infrared spectroscopy is one of most powerful analytical technique when it comes to the determination of presence of various functional groups involved in making up the molecule. It provides very well accountable spectral data regarding any change in the functional group characteristics of a drug molecule occurring while in the processing of a formulation. IR spectra of lorazepam and its formulations were obtained by KBr pellet method using Perkin Elmer FTIR series model-1615 spectrometer in order to rule out drug-carrier interaction occurring during the formulation process.

RESULTS

Table 4: Precompression parameters of formulations prepared by Direct Compression Method.

Parameters	Formulation code					
	DCR_1	DCR_2	DCR_3	DCR_4	DCR_5	DCR_6
Angle of repose (º)	30.96	27.63	29.20	25.56	27.85	26.55
Bulk density (gm/cc)	0.440	0.440	0.473	0.455	0.475	0.455
Tapped density (gm/cc)	0.528	0.528	0.550	0.528	0.596	0.535
Carr's Index (%)	16.39	15.49	15.70	14.78	19.10	17.16
Hausner's ratio	0.80	0.82	0.80	0.84	0.83	0.83

Table-5: Post compression parameters of formulations prepared by direct compression method.

Parameters	Formulation code					
	DCR_1	**DCR_2**	**DCR_3**	**DCR_4**	**DCR_5**	**DCR_6**
Hardness* (kg/cm^2)±SD	2.73±0.16	2.70±0.11	2.83±0.12	2.76±0.15	2.96±0.20	3.03±0.21
Thickness (mm)	3.10	3.30	3.15	3.20	3.10	3.30
Friability (%)	0.43	0.39	0.45	0.46	0.43	0.48
In vitro dispersion time* (sec)±SD	16.85±0.58	12.4±0.20	8.10±0.18	9.89±0.10	8.17±0.16	7.49±0.23
Wetting time* (sec)±SD	14.22±0.43	13.23±0.39	7..83±0.35	9.49±0.54	7.29±0.06	6.99±0.10
Water absorption ratio* (%)±SD	53.29±0.42	56.29±0.34	68.86±0.36	66.79±0.42	74.26±0.39	74.26±0.38
Drug content* (%)±SD	102.71±0.390	104.39±0.811	102.14±1.53	101.15±1.09	101.75±0.93	104.5±2.84
Weight variation	119-126 mg within the IP limits of±7.5%.					

* Average of three determinations.

Table-6: In vitro dissolution data of tablet formulations of Rizatriptan benzoate and Formulation in pH 6.8 Phosphate Buffer.

Time (min)	Cumulative Percent Drug Released					
	DCR_1	**DCR_2**	**DCR_3**	**DCR_4**	**DCR_5**	**DCR_6**
2	2.17±0.72	4.20±0.92	58.04±1.20	6.20±0.71	62.03±0.91	54.20±0.79
4	2.90±0.72	6.29±1.20	74.38±1.81	9.16±1.20	74.31±1.21	62.69±1.11
6	5.57±1.10	9.12±0.82	84.38±1.11	13.20±0.78	82.31±1.14	79.20±1.23
8	8.72±0.73	14.09±1.18	92.67±2.85	18.39±1.29	92.91±2.01	85.16±2.12
10	13.56±1.51	18.06±0.69	99.75±1.44	24.31±0.64	97.20±1.0	98.23±2.70
15	16.71±0.72	21.24±1.89	--	28.21±0.98	--	--
30	23.01±1.11	--	--	--	--	--

Preparation of Standard Calibration Curve of Rizatryitan benzoate in water and phosphate buffer solution(6.8pH)

Procedure: 25mg of Rizatriptan benzoate was accurately weighed and dissolved in 25ml of water and phosphate buffer into a volumetric flask (1000 mcg/ml) respectively. 1 ml of this solution was taken and made up to 100 ml with water and phosphate buffer solution, which gives 10 mcg/ml concentration (stock solution).

From this stock solution, concentration of 10, 20,30,40,50 mcg/ml in water and phosphate buffer solution were prepared. The absorbances of the diluted solution were measured at 234 and 281 nm respectively and a standard plot was drawn using the data obtained.

The correlation coefficient was calculated by linear regression analysis. The absorbance of the above concentration is shown in table-7 and 8.

Table-7: Standard graph of Rizatriptan benzoate in water (λ_{max} 234nm).

Sl. No.	Concentration (mcg/ ml)	Absorbance			Mean±SD
		I	II	III	
1.	0.00	0.00	0.00	0.00	0.000±0.000
2.	1.00	0.17	0.17	0.18	0.173±0.080
3.	2.00	0.33	0.33	0.32	0.339±0.030
4.	3.00	0.48	0.48	0.48	0.487±0.000
5.	4.00	0.62	0.62	0.63	0.627±0.030
6.	5.00	0.77	0.77	0.76	0.775±0.070

a=0.005; b=0.0.141; r=0.0.999

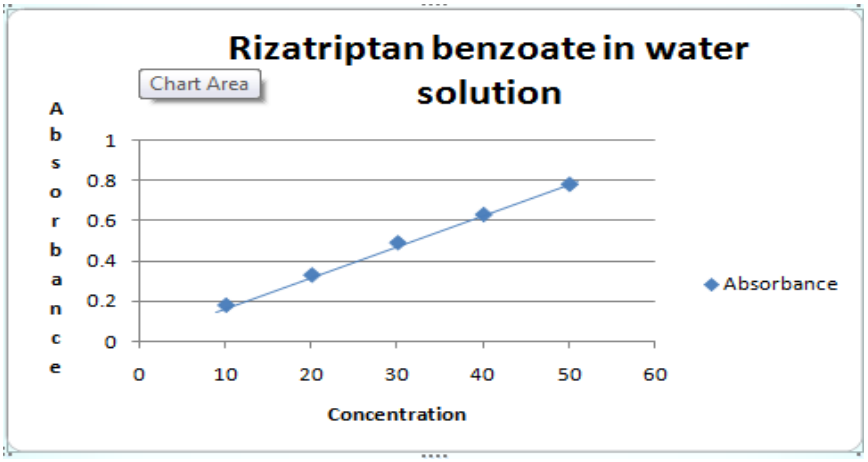

Figure-4: Standard Graph of Rizatriptan benzoate in water(λ_{max} 234 nm).

Table-8: Standard graph of Rizatriptan benzoate in pH 6.8 Phosphate Buffer (λ_{max} 281 nm).

Sl. No.	Concentration (mcg/ ml)	Absorbance			Mean±SD
		I	II	III	
1	00	0.000	0.000	0.000	0.000±0.000
2	01	0.214	0.216	0.212	0.214±0.002
3	02	0.459	0.456	0.453	0.459±0.003
4	03	0.667	0.665	0.667	0.667±0.003
5	04	0.875	0.870	0.875	0.875±0.016
6	05	1.123	0.126	0.126	1.123±0.005

a=–0.0012; b=0.120; r=0.999

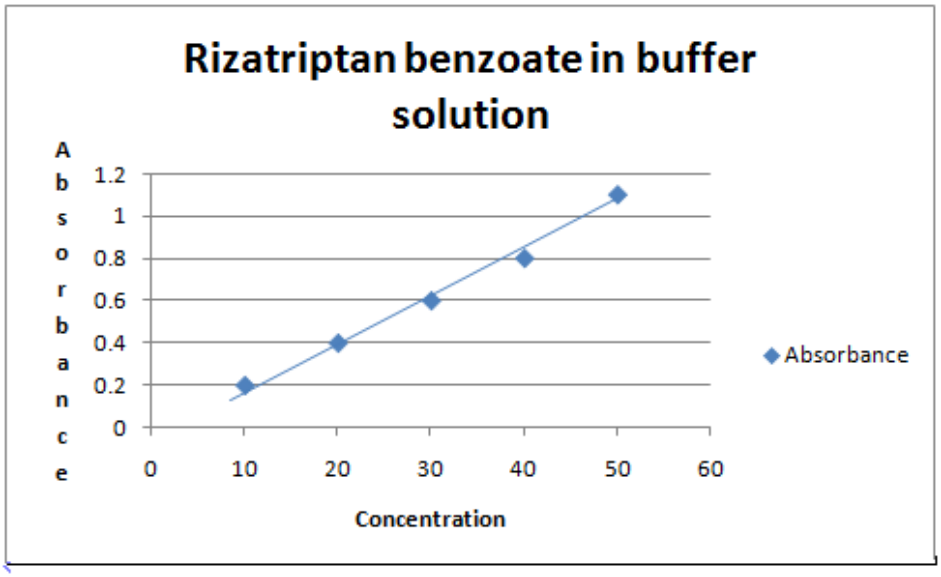

Figure-5: Standard Graph of Rizatriptan benzoate in pH 6.8 Phosphate Buffer (λ_{max} 281 nm).

RESULTS

Table-9: Precompression parameters of formulations prepared by Direct Compression Method.

Parameters	Formulation code					
	DCR_1	DCR_2	DCR_3	DCR_4	DCR_5	DCR_6
Angle of repose (º)	30.96	27.63	29.20	25.56	27.85	26.55
Bulk density (gm/cc)	0.440	0.440	0.473	0.455	0.475	0.455
Tapped density (gm/cc)	0.528	0.528	0.550	0.528	0.596	0.535
Carr's Index (%)	16.39	15.49	15.70	14.78	19.10	17.16
Hausner's ratio	0.80	0.82	0.80	0.84	0.83	0.83

Table-10: Post compression parameters of formulations prepared by direct compression method.

Parameters	Formulation code					
	DCR_1	DCR_2	DCR_3	DCR_4	DCR_5	DCR_6
Hardness* (kg/cm^2)±SD	2.73±0.16	2.70±0.11	2.83±0.12	2.76±0.15	2.96±0.20	3.03±0.21
Thickness (mm)	3.10	3.30	3.15	3.20	3.10	3.30
Friability (%)	0.43	0.39	0.45	0.46	0.43	0.48
In vitro dispersion time* (sec) ±SD	16.85±0.58	12.4±0.20	8.10±0.18	9.89±0.10	8.17±0.16	7.49±0.23
Wetting time* (sec) ±SD	14.22±0.43	13.23±0.39	7..83±0.35	9.49±0.54	7.29±0.06	6.99±0.10
Water absorption ratio* (%) ±SD	53.29±0.42	56.29±0.34	68.86±0.36	66.79±0.42	74.26±0.39	74.26±0.38
Drug content*	102.71±0.390	104.39±0.811	102.14±1.53	101.15±1.09	101.75±0.93	104.5±2.84

(%) ±SD						
Weight variation	119-126 mg within the IP limits of ±7.5%.					

* Average of three determinations.

Table-11: In vitro dissolution data of tablet formulations of Rizatriptan benzoate and Formulation in pH 6.8 Phosphate Buffer.

Time (min)	Cumulative Percent Drug Released					
	DCR_1	DCR_2	DCR_3	DCR_4	DCR_5	DCR_6
2	2.17±0.72	4.20±0.92	58.04±1.20	6.20±0.71	62.03±0.91	54.20±0.79
4	2.90±0.72	6.29±1.20	74.38±1.81	9.16±1.20	74.31±1.21	62.69±1.11
6	5.57±1.10	9.12±0.82	84.38±1.11	13.20±0.78	82.31±1.14	79.20±1.23
8	8.72±0.73	14.09±1.18	92.67±2.85	18.39±1.29	92.91±2.01	85.16±2.12
10	13.56±1.51	18.06±0.69	99.75±1.44	24.31±0.64	97.20±1.0	98.23±2.70
15	16.71±0.72	21.24±1.89	--	28.21±0.98	--	--
30	23.01±1.11	--	--	--	--	--

DISCUSSION

In the present study an attempt has been made to design and optimize fast disintegrating tablets of Rizatriptan benzoate by direct compression method. In direct compression method the formulations were prepared using superdisintegrants such as Crospovidone (CP) along with microcrystaline cellulose (MCC) (PH. 102) in different ratios.

The hardness of the tablet formulations made by the direct compression method was found to be in the range of 2.7 to 3.00 Kg/cm, indicating good, mechanical strength with an ability to withstand physical and mechanical stress conditions while handling (table 5). In all the formulations, friability value was found to be less than 1%. The weight of all the tablets were found to be uniform with low values of standard deviation and within the prescribed IP limits. The percent drug content of all the tablets was found to be in the range of 102.65 to 105.73 of the expected Rizatryptan benzoate content, which was within the acceptable limits (table-5).

In vitro dispersion time, wetting time and water absorption ratio for all the Rizatriptan benzoate tablet formulations prepared by direct compression method were determined and the results are shown in table-3.

Among the tablets prepared by direct compression method using crospovidone (CP) and microcrystalline cellulose (MCC) as disintegrates, formulation DCR_3 containing 2% w/w crospovidone and 15% w/w microcrystalline cellulose was found to be promising and has shown *in vitro* dispersion time of 8 s, wetting time of 8.83 s and water absorption ratio of 74.38%.

In Vitro Dissolution Study

In vitro dissolution studies were performed in phosphate buffer of pH 6.8, on the above promising formulations, namely $DCR_{3,}$ The results are shown in table-6.

From the above data it is evident that among the promising formulations, DCR_3 (prepared by direct compression method), released 99.75% and 89% drug in 10 minutes (pH 6.8 phosphate buffer).

Drug-Excipient Interaction Studies (by FT-IR)

The IR spectrum of the pure drug shows characteristic peaks at 3508cm^{-1} and 1718 cm^{-1} due to –OH and carboxyl groups respectively. Formulations DCR_3 exhibited similar peaks at 3508 and 1718 cm^{-1} respectively for the above groups. This confirms undisturbed structure of the drug in the formulations. Hence, there are no drug-excipients interactions.

CONCLUSION

In the present work, fast disintegrating tablets of Rizatriptan benzoate were prepared by direct compression method using super-disintegrants such as crospovidone and microcrystalline cellulose.

All the tablets of Rizatriptan benzoate were subjected to weight variation, drug content-uniformity, hardness, friability, water absorption ratio, wetting time, *in vitro* dispersion time, dissolution and drug-excipient interactions.

Based on the above studies, following conclusions can be drawn.

- Tablets prepared by direct compression technique were found to be good without any chipping, capping and sticking.
- The hardness of the prepared tablets were found to be in the range of 2.70 to 3.00 Kg/cm^2 for direct compression method The friability value of the prepared batches of tablets were found to be less than 1%.
- The low values of standard deviation for average weight and drug content of the prepared tablets indicate weight and drug content uniformity within the batches prepared.
- The *in vitro* dispersion time of Rizatriptan benzoate tablets prepared by direct compression found to be in the range of 8-13 s.

- Based on the *in vitro* dispersion time, formulations DCR_3 was found to be promising and displayed a dispersion time of approximately 8 s. Wetting time of promising formulations was found to be 8.83 s, which facilities their faster dispersion in the mouth.
- The promising formulations (DCR_3) have displayed good water absorption of about 74.38%, which indicates better and faster swelling ability of the disintegrants in presence of little amount of water.
- IR-spectroscopic studies indicated that there are no drug-excipient interactions in the optimized formulation.

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