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Research

FORMULATION DEVELOPMENT AND EVALUATION OF ORAL DISINTEGRATING TABLETS OF RIZATRIPTAN BENZOATE

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Abstract

In this work Rizatriptan benzoate oral disintegrating tablets were formulated utilizing compression approach. a thorough evaluation was conducted for stability dissolution, hardness, and disintegration time characteristics of various ODT formulations, interestingly friability tests came up with results lower than1%. In accordance with USPs 3-minutesdisintegration time requirement for ODTs all tablet formulations dissolved entirely within 1 minute. In addition, the optimized formulation dissolved more than 85%of the Rizatriptan benzoate, labeled content in under 15 minutes. The FTIR examination did not reveal any changes or between the excipients and the active component interaction. The use of superdisintegrants in ODT formulations is therefore a promising approach.

Key words: Rizatriptan benzoate, ODT formulations, FTIR

INTRODUCTION

Oral Disintegrating Tablet: Oral drug delivery has been known for decades as the most widely utilized route of administration among all the routes that have been explored for the systemic delivery of drugs via various pharmaceutical products of different dosage forms. The reason that the oral route achieved such popularity may be attributed to its ease of administration as well as the traditional belief that by oral administration the drug is well absorbed as the food stuffs ingested daily. In fact, the development of pharmaceutical products for oral delivery, irrespective of physical form involves varying extents of optimization of dosage form within the inherent constraints of GI physiology. Therefore, a fundamental understanding of various disciplines, including GI physiology, pharmacokinetics, Pharmacodynamic and formulation design are essential to achieve a systemic approach to the successful development of an oral dosage form.

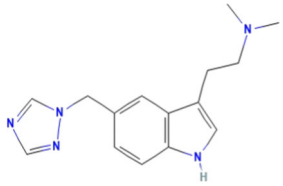
The orally disintegrating tablets are also called as Orodispersible tablets, quick disintegrating tablets, fast disintegrating tablets, porous tablets, and rapid melts. However of all the above terms, United States Pharmacopoeia (USP) approved these dosage forms as ODTs. Recently, European Pharmacopoeia has used the term "Orodispersible tablet" for tablets that disperse readily and within three minutes before swallowing.

METHODOLOGY

Material and Methods: Rizatriptan Benzoate, Hypromellose, Microcrystalline Cellulose, Aspartame Magnesium Stearate

Instruments: U.V. visible spectrophotometer, FT-IR spectrophotometer Disintegration Apparatus Digital pH meter Digital weighing balance DSC Melting Point Apparatus Friability Apparatus Hardness Tester Stability Chamber Scanning Electron Microscope Rotary Tablet Compression Machine Dissolution Apparatus

DRUGPROFILE: Rizatriptan Benzoate: Molecular Formula: $C_{22}H_{25}N_5O_2$ Rizatriptan is a medicine that narrows the blood vessels around the brain. Rizatriptan also reduces substances in the body that can trigger head ache pain, nausea, sensitivity to light and sound, and other migraine symptoms.



Rizatriptan in migraine can most likely beat tribute to agonist effects at 5-$HT_{1B/1D}$receptors on the extra cerebral, intracranial blood vessels that become dilated during a migraine attack and on nerve terminals in the trigeminal system.

RESULTS&DISCUSSION:

PREFORMULATIONSTUDIES:

Melting Point Determination, Solubility Studies, Compatibility study of drug and excipients using FT-IR: Rizatriptan and excipients compatibility were evaluated using FT-IR. The compatibility between the pure drug and Excipients was detected by FT-IR spectra obtained on Jasco FT/IR-4X. The potassium bromide pellet method was used for solid samples followed by recording the spectra over the wave number of 4000 to 500cm^{-1}.

FORMULATION OF RIZATRIPTAN ORAL DISINTEGRATING TABLETS.

All the ingredients were weighed according to the quantities specified inTable5 and passed through #60mesh separately. Then the ingredients were mixed in geometrical order and compressed into tabletsof70 mg byusing8-stationrotaryminipresstablet machine using 5mmpunch. The dose of each tablet is 10mg and the tablet weight is 70mg.

Table: Rizatriptan ODT Formulations

S.No	Ingredients	RF1	RF2	RF3	RF4	RF5	RF6	RF7	RF8	RF9
1	Rizatriptan	10	10	10	10	10	10	10	10	10
2	Sodium Starch Glycolate	2.63	2.63	1.50	2.63	1.50	3.75	3.75	1.50	3.75

3	Hypromellose	3.75	2.63	3.75	1.50	1.50	2.63	1.50	2.63	3.75
4	MCC	37.87	39.0	39.0	40.1	41.2	37.8	39.0	40.1	36.7
5	Aspartame	15	15	15	15	15	15	15	15	15
6	Magnesium Stearate	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75
7	Total Weight of Tablet (mg)	70	70	70	70	70	70	70	70	70

Pre-compression evaluation of Oral disintegrating Tablets: Bulk density, Tapped density, Angle of repose, Compressibility Index and Hausner's ratio were evaluated according to USP General repose to assess the flow property of the blend before compression.

Post compression evaluation of Oral disintegrating Tablets: Compressed tablets were evaluated for post compression parameters according to the procedure mentioned in the following USP general chapters Weight Variation & Drug Content <905>[88], Hardness, Thickness & Friability <1217>.

In-Vitro dissolution was performed according to the procedure mentioned in Mirtazapine USFDA dissolution database. Oral disintegrating tablets of Rizatriptan were subjected for dissolution while maintaining dissolution conditions (Type II apparatus, 0.1NHCLBuffer (Hydrochloric Acid); 900mL, 50 RPM; 37°± 5°C; 30 Minutes) at sampling intervals of 5, 10,15,20,&30minutes.The samples obtained were determined by UV-visible spectrophotometer at226nm.

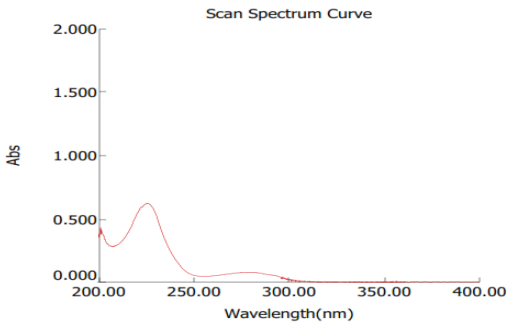
Stability Studies: Stability studies were performed according to the ICH guidelines Q1A (R2) for optimized formulation. The stability study is an indicative method for determination of durability of quality and quantity of therapeutic agents with the passes of time under the influence of various atmospheric conditions such as temperature, humidity, light and to establish a re- test period for the drug substance or a shelf life for the drug product and recommended storage conditions at 40°C ± 2°C/75% RH ± 5% RH. (ICH Q1C). Further stability studies were confirmed by Differential Scanning Colorimetry. Thermal analysis of Optimized Formulation before and after stability was performed using thermal analyzer (Mettler Toledo-DSC 3) Temperature axis and cell constant were calibrated by utilizing indium (In). This technique allows a rapid assessment of possible interaction by disclosing transition in exhibition, dissipation of endothermic or exothermic peaks, and transition in the pertinent enthalpy standards in thermal curves of drug-excipients combinations.

Determination of Melting Point: The melting point of Rizatriptan Benzoate was determined by using melting point apparatus**.** Melting point of Rizatriptan was found to be180℃. Reference range of Rizatriptan melting point is 178-180 ℃.

Solubility Studies: Based on the solubility study of Rizatriptan, it was observed that Rizatriptan is freely soluble in water. Rizatriptan is categorized as BCS Class III drug. The aqueous solubility of Rizatriptan was found to be 40.89 mg/ml.

Determination of Absorption Maxima &Linearity of Rizatriptan: It is evident from the figure, that the graph is linear with regression co-efficient value of R^2=0.9999andslope0.12369atλmaxof226nm**.**

Spectrum Scan of Rizatriptan



No.	ID	Type	Conc [µg/mL]	Abs	226.00 nm
1	Blank	Standard	0.0	0.000	0.000
2	Standard 1	Standard	1.0	0.128	0.128
3	Standard 2	Standard	2.0	0.250	0.250
4	Standard 3	Standard	3.0	0.368	0.368
5	Standard 4	Standard	4.0	0.495	0.495
6	Standard 5	Standard	5.0	0.622	0.622

Linearity for Rizatriptan

Compatibility study of drug and polymer using FT-IR:

IR spectrum of rizatriptan succinate shows a broad peak at The possible interaction between the drug and the carrier was studied by FTIR spectroscopy. IR spectra of pure rizatriptan showed characteristic peaks at CH_3 stretch at 2950 cm^{-1}, C=C stretch at 1628$cm^{-1,}$ NH bend at 1243 cm^{-1}, C-N stretch at 1123 cm^{-1}. From IR overlay Spectra interpretation of drug was done with individual excipients and formulation mixture and observed that there is no appreciable change in the positions of the characteristic bands. Since there is no change in the nature and position of the bands in the formulation, it can be concluded that the drug maintains its identity without going any chemical interaction with the excipients used.

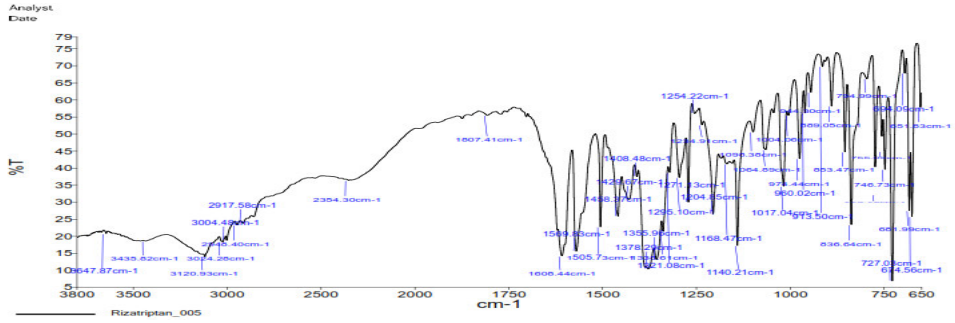


Figure 6: FT-IR Spectra of Rizatriptan

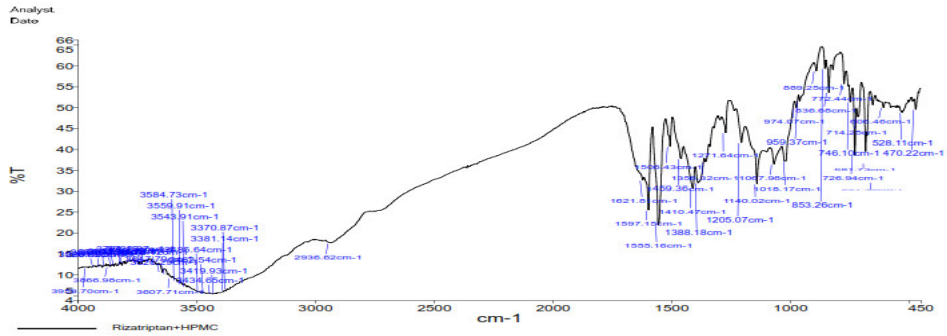


Figure 7: FT-IR Spectra of Rizatriptan + Hypromellose

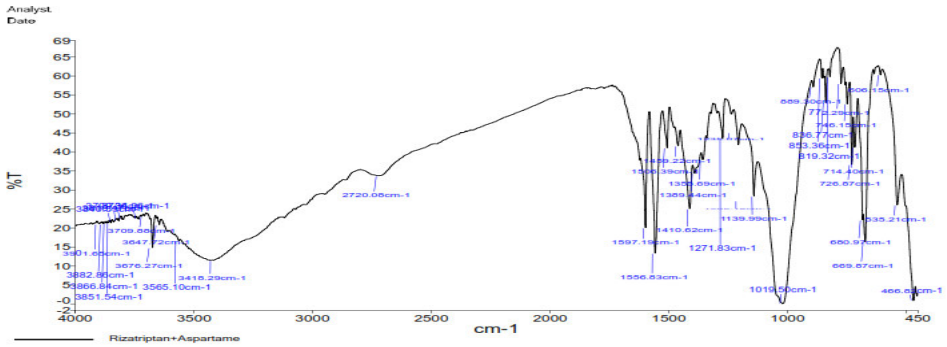


Figure 8: FT-IR Spectra of Rizatriptan + Aspartame

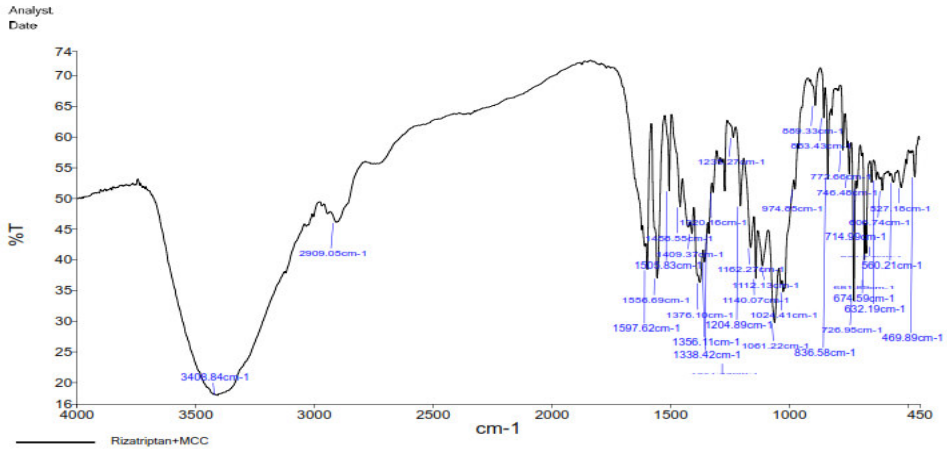


Figure 9: FT-IR Spectra of Rizatriptan + MCC

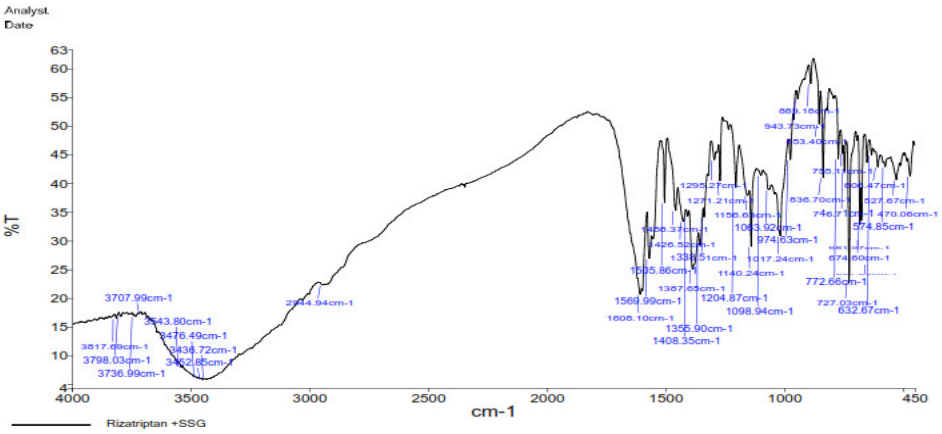


Figure 10: FT-IR Spectra of Rizatriptan + SSG

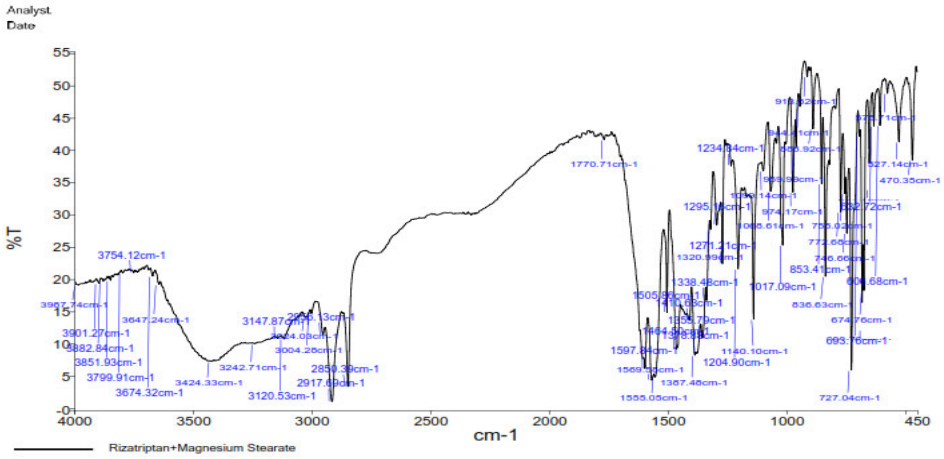


Figure 11: FT-IR Spectra of Rizatriptan + Magnesium Stearate

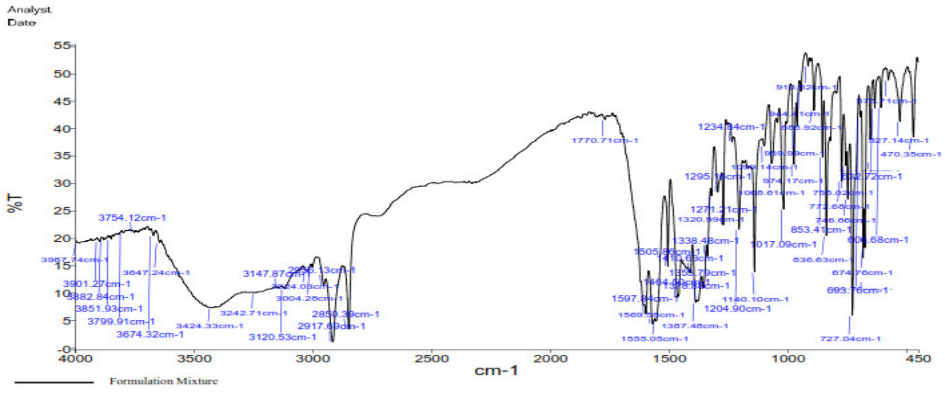


Figure 12: FT-IR Spectra of Rizatriptan ODT Formulation Mixture

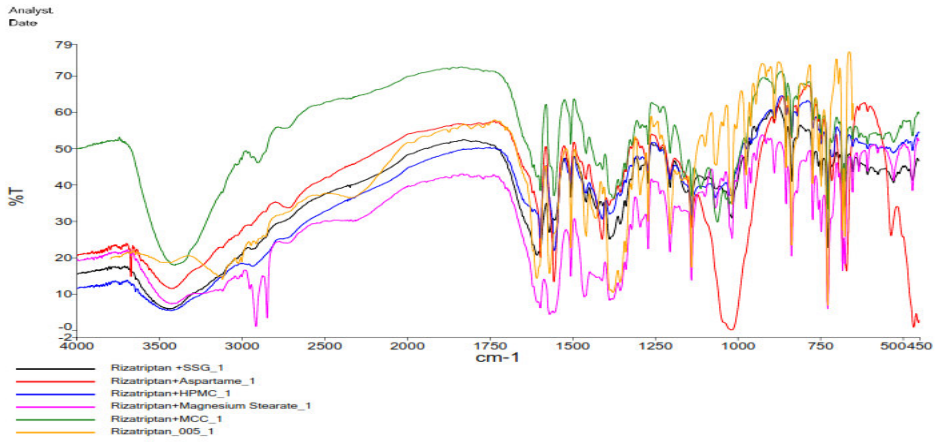


Figure 13: Overlay Spectra

Pre-compression parameters of ODT's powder blend

Table 6: Pre-compression Evaluation Parameters of Rizatriptan Succinate ODT's Powder Blend

Formulations	RF1	RF2	RF3	RF4	RF5	RF6	RF7	RF8	RF9
Angle of repose (°)	25.62	25.34	30.18	27.38	30.84	26.42	28.12	26.28	27.54
Bulk density (gm/cc)	0.32	0.35	0.32	0.38	0.35	0.38	0.34	0.33	0.36
Tapped density (gm/cc)	0.42	0.38	0.40	0.39	0.36	0.39	0.41	0.35	0.38
Compressibility Index (%)	6.45	8.29	4.85	5.67	10.12	7.29	8.44	6.82	11.58
Hausner's ratio	1.12	1.09	1.07	1.10	1.08	1.13	1.12	1.10	1.16

Results obtained in Table; were found within the pharmacopoeial limits and showed good flow properties for all the formulations.

Post-compression parameters of ODTs

Table 7: Post compression Evaluation Parameters of Oral Disintegrating Tablets

Formulation	Weight Variation (mg)	Thickness (mm)	Hardness (N)	Friability (%)	Drug Content (%)	Disintegration in Seconds
RF1	68.74	3.12	58	0.12	100.04	44
RF2	67.18	2.94	46	0.30	101.12	35
RF3	73.36	3.28	52	0.51	99.38	45
RF4	69.12	2.86	48	0.18	98.22	26
RF5	72.64	3.30	60	0.34	100.54	31
RF6	70.38	2.74	56	0.26	97.38	28
RF7	68.56	3.08	52	0.18	98.26	19
RF8	70.20	2.95	50	0.42	100.64	43
RF9	69.82	2.68	46	0.16	97.16	38

Results obtained in Table; were found within the acceptable limits for friability and weight variation. Thickness was found in the range of 2.68-3.28 mm; Hardness was found in the range of 46-60 N and Drug content was found in the range of 97.16-101.12 %.

In-Vitro drug release studies

The cumulative percentage drug release from oral disintegrating tablets was studied in USP-II dissolution apparatus with following conditions (0.1N Hydrochloric Acid; 900mL, 50RPM; 37°± 5°C; 30 Minutes) and the outcome of the release profile was depicted in Table . The optimized formulation was found to be RF7 suffice the Q point criteria as per USP.

According to the USP monograph of Rizatriptan oral disintegrating tablets, the Q point criteria was given as NMT 85% at 15 minutes.

Formulation was designed targeting the criteria of Q point by altering the ratios of superdisintegrants.

Table 8: In-Vitro Drug Release Studies of Rizatriptan Oral Disintegrating Tablets.

Dissolution (Minutes)	RF1	RF2	RF3	RF4	RF5	RF6	RF7	RF8	RF9
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
5	10.15	16.38	9.85	23.26	18.52	20.33	34.28	14.68	14.25
10	16.38	27.12	15.29	50.48	33.14	42.62	76.54	17.3	21.42
15	39.29	64.28	33.45	84.32	69.72	79.29	94.18	46.88	54.28
20	60.54	78.11	52.42	96.28	82.29	88.18	101.52	60.19	70.29
30	74.12	90.28	69.12	101.2	99.86	96.32	100.28	83.42	88.54

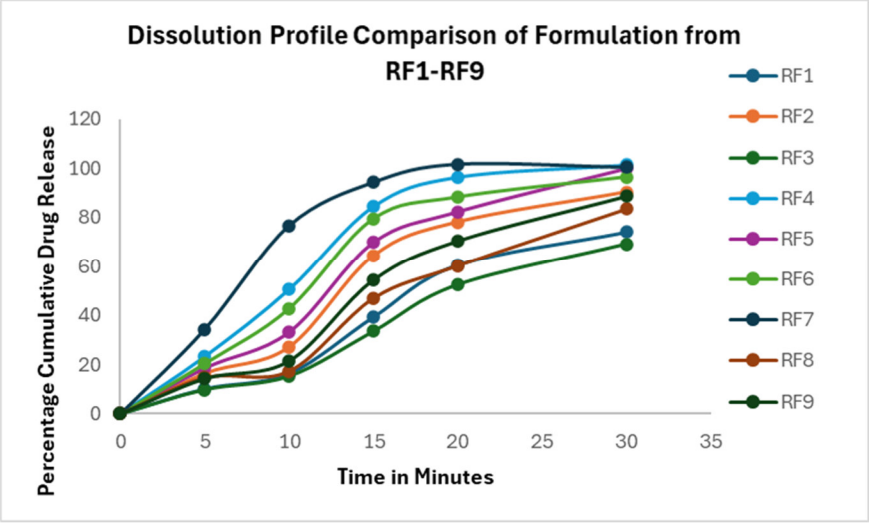


Figure 14: Dissolution Profile Comparison of Formulation from RF1-RF9

Stability studies:

The findings on the improved formulation's short-term accelerated stability (RF7) showed that the drug content and in-vitro dissolution, as shown in table, remained within acceptable ranges.

Table 15: Stability studies of Rizatriptan ODT Optimized Formulation (RF7)

Stability Conditions	**40°C ± 2°C/75% RH ± 5% RH**	
Formulation	**Optimized Trial (RF7)**	
	Initial	**After 3 months**
Dissolution Time (Hours)	**% Cumulative Drug Release**	
0	0.00	0.00
5	34.28	33.68
10	76.54	77.12
15	94.18	93.42
20	101.52	100.28
30	100.28	100.40
Average Drug Content %	98.26	99.08

SUMMARY

The optimized formulations was found to be RF7suffice the Q point criteria as per USP, according to the USP monograph of Rizatriptan benzoate ODT the Q point criteria was given as NMT 85% at 15 minutes. Formulation was designed targeting the criteria of Q point by altering the ratio of sodium starch glycolate.

CONCLUSION

The ODTs were developed and optimized based on evaluation parameters. The DC, IVD and stability of the optimized formulation RF7 were all inside acceptable ranges. Thus it can be stated that the formulation can be further studied for stability and assessment of pharmacokinetic parameters ODTs proves to be a possible method for carrying medications for instant release.

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