

## Formulation Optimization and Evaluation of Orodispersible Tablet of Rupatadine Fumarate by Effervescent Method

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Date of Submission: 25-05-2026

Date of Acceptance: 02-06-2026

**ABSTRACT:** This study aimed to develop and optimize Orodispersible Tablets (ODTs) of Rupatadine Fumarate using the effervescent method for rapid disintegration and improved drug release in allergic rhinitis and urticaria treatment. Tablets were prepared by direct compression using Pregelatinized Starch as a superdisintegrant and sodium bicarbonate with citric acid as effervescent agents. A Central Composite Design (CCD) was used to evaluate the effect of formulation variables on disintegration time and drug release. The optimized batch (B2) showed rapid disintegration (13.65 sec) and high drug release (97.94%). FTIR and DSC studies confirmed drug–excipient compatibility, while stability studies proved the formulation remained stable for 30 days. Overall, the study demonstrated that effervescent ODTs of Rupatadine Fumarate can provide fast disintegration, enhanced dissolution, and better patient compliance.

**KEYWORDS:** Rupatadine Fumarate, Orodispersible Tablets (ODTs), Effervescent Method, Pregelatinized Starch, Central Composite Design (CCD), Disintegration Time, Drug Release, Direct Compression, FTIR, DSC, Stability Study.

**INTRODUCTION:** The oral route continues to be the ideal method for administering therapeutic agents despite significant advancements in drug delivery due to its low cost of therapy, ease of administration, accurate dosage, self-medication, pain avoidance, and versatility, which results in high patient compliance. Up to 50–60% of all dose forms are accepted, with tablets and capsules being the most widely used. Tablets are currently the most widely used conventional dosage form due to their ease of administration, compact size, convenience of manufacturing, and ability to administer precise doses.

In particular, for pediatric, geriatric, psychiatric, paralyzed, and bedridden patients, the need for quick disintegration, quick onset of action, and patient compliance led to the development of ODTs in the 1980s. Watanabe et al. published the first articles on the formulation of ODTs using cellulose derivatives

in 1995. In order to formulate a Orodispersible Tablet (ODT) that is acceptable, taste-covering is an essential step. Because it is believed that the dosage will not dissolve until it enters the oral cavity, traditional tablet formulations typically do not address the problem of flavor masking. By coating the pills with sugar, it is possible to delay the bitter taste of the medication. Additionally, a lot of FDDT technologies combine flavor masking. Oral medication continues to be the best option for marketers despite the remarkable advancements in pill delivery because it is inexpensive, easy to administer, self-medicating, pain-free, versatile, and leads to high levels of patient compliance.

Because of its quick disintegration and ability to be administered by mouth without the need for water or chewing, the oral fast dissolving drug delivery system (OFDDS) is one such innovative strategy to boost consumer adoption. Orally disintegrating tablets (ODTs) are solid dosage forms similar to regular tablets, but they contain super disintegrants that enable them to dissolve quickly in saliva without the need for water and no suffocation or choking. Drug absorbed through “oral cavity” directly goes into systemic circulation by a jugular vein ensure quick action, prevent first pass metabolism and drug degradation in gastric region and enzymatic hydrolysis in intestine.

Effervescent Orodispersible Tablets (ODTs) are tablets that rapidly disintegrate in the mouth without the need for water. They contain effervescent agents such as sodium bicarbonate and citric or tartaric acid, which react with saliva to release carbon dioxide gas. This fizzing action helps the tablet break down quickly and improves drug dissolution. Effervescent ODTs provide faster onset of action, better patient compliance, and are especially useful for pediatric, geriatric, and dysphagic patients. However, they are sensitive to moisture and require proper packaging for stability.

Rupatadine fumarate is a long-acting, non-sedating, second-generation antihistamine. A dual antagonist acting on both Histamine H1 receptors and PAF receptors, which reduces allergy symptoms and

inflammation respectively. Rupatadine relieves the symptoms of allergic rhinitis such as sneezing, runny nose, itching in the eyes and nose. Rupatadine is also used to relieve the symptoms associated with urticaria (an allergic skin rash) such as itching and hives (localized skin redness and swelling) in adults and children aged over 12 years.

#### **Materials and Methods:**

Rupatadine Fumarate was purchased from SM Pharma and Chemicals; Mumbai, Superdisintegrants Such as Pregelatinized Starch and MCC PH 102, Pearlitol SD 200 were procured From Medley Pharma Ltd; Andheri, Sodium Bicarbonate and Citric Acid was used as Effervescent agent, other Excipients Aspartame, Talc, Orange Flavour, Magnesium Stearate were of analytical Grade and used as received. All chemicals and reagents used were of analytical or pharmaceutical grade.

#### **Pre- Formulation studies of Rupatadine Fumarate:**

##### **Organoleptic properties:**

The sample of Rupatadine Fumarate was studied for organoleptic properties like color, odor and taste.

##### **Determination of Melting Point:**

A thin capillary of about 5cm in length with uniform bore was sealed at one end by bringing it near the flame. The dry and fine powder of rupatadine fumarate was filled through open end of the capillary tube was gently tapping the close end. The capillary was placed in digital melting point apparatus. The risk in temperature was noted. The temperature at which drug melts to a clear liquid and then off the apparatus.

##### **Determination of Solubility:**

The concentration at which a solid phase and solution phase are in equilibrium at a specified temperature and pressure is known as the solubility of a solid material. The apparent solubility of Rupatadine Fumarate was determined in water, ethanol, methanol, 0.1N HCl, Phosphate buffer pH 6.8 and 0.1N NaOH at 37 °C. A small quantity of drug sample was taken in a test tube and the solubility was determined by dissolving the drug in 1ml of different solvents. Then the solubility was observed.

##### **Determination of UV spectra of Rupatadine Fumarate:**

Rupatadine Fumarate solution (10µg/ml) was prepared in phosphate buffer pH 6.8. This solution scanned under double beam UV visible Spectrophotometer (Shimadzu-1800) and spectrum

was recorded in the wavelength ranges between 200-400 nm.

##### **Calibration Curve of Rupatadine Fumarate:**

The stock solution of Rupatadine Fumarate was prepared by dissolving 10 mg Rupatadine Fumarate in phosphate buffer pH 6.8 and final volume was made up to 100 ml. The solutions in concentration ranges of 5-25 µg/ml were prepared by appropriate dilution of stock solution. The absorbance of this solution was measured spectrophotometrically at  $\lambda_{max}$  242 nm.

##### **DRUG EXCIPIENT COMPATIBILITY:**

###### ➤ **Fourier Transform Infrared Spectroscopy**

The FTIR analysis method scans test samples and looks at their chemical properties using infrared light. To determine whether there were any interactions between the drug and excipients, FTIR analyses were performed on the mixture. Using the Potassium bromide disk technique, the drug's FTIR absorption spectra assured drug excipients compatibility

###### ➤ **Differential Scanning Calorimetry**

DSC analysis was used to measure melting temperature and also to check the possibility of any interaction between drug and excipients used in the formulation of Orodispersible tablet. It also measured the amount of energy absorbed or released by a sample when it is heated or cooled, providing quantitative data on endothermic or exothermic processes.

##### **EXPERIMENTAL DESIGN:**

In the development of Orodispersible Tablets (ODTs), the Central Composite Design (CCD) is commonly applied for response surface optimization and is extensively used to evaluate the relationship between formulation variables and their influence on the desired responses. In the present study, the Central Composite Design was utilized to systematically investigate the effect of two independent variables (factors), namely concentration of Pregelatinized Starch (X1) and concentration of Effervescent Agent (X2), on the dependent variables, namely Disintegration Time (Y1) and Drug Release (Y2). The concentrations of Pregelatinized Starch and Effervescent Agent were selected as formulation variables and varied according to the experimental design, while the quantities of other excipients were maintained constant throughout the study. Disintegration Time and Percentage Drug Release were selected as the response variables for optimization of the ODT formulation. The experimental runs in the CCD consisted of factorial points, axial points, and center points, which enabled the evaluation of linear, interaction, and quadratic effects of the formulation variables on the responses. All experimental data and

statistical analyses were carried out using [Design-Expert software](#)

**Table 1: Independent Variables and their levels of Central Composite Design**

Independent Variable	Unit	Levels				
		- $\alpha$	Low	Medium	High	+ $\alpha$
Pregelatinized starch (X1)	%	3.96447	5	7.5	10	11.0355
Effervescent agent (X2)	%	11.1716	12	14	16	16.8284

**Table 2: Dependent (Response) Variable of Central Composite Design**

Response Variable	Actual Coded Values	Unit
Disintegration Time	Y1	sec
% Drug Release	Y2	%

**Table 3: Composition of Rupatadine Fumarate Effervescent ODT Batches**

Sr. No	Ingredients	Batches									
		B1	B2	B3	B4	B5	B6	B7	B8	B9	B10
1	Rupatadine Fumarate	10	10	10	10	10	10	10	10	10	10
2	MCC PH102	40	40	40	40	40	40	40	40	40	40
3	Perlitol SD 200	101.66	96	96	97	87	105	90.347	103.07	95	88.93
4	Sodium bicarbonate	7.45	9.33	9.33	10.67	10.67	8	11.22	9.33	8	9.33
5	Citric acid	14.90	18.67	18.67	21.33	21.33	16	22.44	18.67	16	18.67
6	Pregelatinized starch	15	15	15	10	20	10	15	7.93	20	22.071
7	Aspartame	5	5	5	5	5	5	5	5	5	5
8	Orange flavor	2	2	2	2	2	2	2	2	2	2
9	Talc	2	2	2	2	2	2	2	2	2	2
10	Magnesium stearate	2	2	2	2	2	2	2	2	2	2
	Total	200	200	200	200	200	200	200	200	200	200

\*All ingredients in mg

**PREPARATION OF RUPATADINE FUMARATE EFFERVESCENT ODT:**

1. Weigh all ingredients properly
2. Dry Sodium bicarbonate and citric acid at 40°C to 50°C for about 30 to 60 minutes. Then cool them.

3. Sift Rupatadine Fumarate, Perlitol SD 200, pregelatinized starch, aspartame and orange flavor through #60 mesh sieve to remove the lumps.
4. Sift MCC PH 102 through #22 mesh sieve

5. Mix sodium bicarbonate and citric acid together to prepare the effervescent mixture (1:2 ratio)
6. Take Rupatadine fumarate, MCC PH 102, Perlitol SD 200 and Pregelatinized starch. Mix them well.
7. Add the effervescent mixture, aspartame and orange flavor. Mix properly.
8. Add magnesium stearate and Talc into a above blend and mixed them gently for 2minutes.
9. Weigh 200 mg of the prepared tablet blend and compress it using a KBr Press fitted with an 8mm punch in low humidity environment to prevent premature effervescence.

#### EVALUATION OF ODT:

##### ➤ Precompression Parameters:

##### 1. Bulk Density (B.D):

Bulk density was determined by dividing the total mass of powder by its bulk volume. The weighed powder, passed through sieve #20, was transferred into a measuring cylinder, and the initial volume was noted as the bulk volume. The value was calculated using the standard formula and expressed in g/mL.

##### 2. Tapped Density (T.D):

Tapped density is the ratio of the total mass of powder to its tapped volume. The powder was tapped 750 times, and if the difference between readings was less than 2%, the tapped volume was recorded. If the difference exceeded 2%, tapping was continued up to 1250 times until the variation became less than 2%.

##### 3. Carr's Index:

Carr's Index (Compressibility Index) is used to evaluate the flowability and compressibility of powder blends by comparing bulk density and tapped density. Lower values indicate good flow properties, while higher values suggest poor flow and the possible need for flow enhancers or granulation.

##### 4. Hausner's Ratio:

Hausner's Ratio is defined as the ratio of tapped density to bulk density and is used to assess the flow properties of powders.

##### 5. Angle of Repose:

The angle of repose was measured using the funnel method, where the powder blend was allowed to flow through a funnel to form a cone-shaped pile. The diameter of the cone was measured, and the angle of repose was calculated using the standard formula.

##### ➤ Post Compression Parameters:

##### 1. Hardness:

Hardness is an important parameter that helps prevent tablet breakage during handling, transportation, and storage. The hardness of tablets was measured using a Monsanto hardness tester and expressed in kg/cm<sup>2</sup>. For ODTs, hardness is generally maintained at a lower level to allow rapid disintegration in the mouth.

##### 2. Thickness:

Tablet thickness is an essential parameter affecting the appearance and counting of tablets during filling operations. It also helps in determining whether the quantity of filler used during tablet preparation is adequate. The thickness of tablets was measured using a Vernier Calliper and expressed in millimeters (mm).

##### 3. Weight Variation:

Twenty tablets were randomly selected and weighed individually. The difference between individual weight and average weight was compared to determine weight variation.

##### 4. Friability:

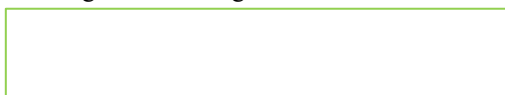
Friability indicates the loss of tablet weight due to surface particle removal and helps assess the tablet's ability to withstand handling, packaging, and transportation. The test was performed using a Roche friabilator, where 10 tablets were rotated at 25 rpm for 4 minutes, dedusted, and reweighed.

**5. Disintegration Time:**

ODTs generally disintegrate within less than one minute, with patient-perceived disintegration occurring within 5–30 seconds. The disintegration time was measured using a tablet disintegration apparatus with phosphate buffer pH 6.8 maintained at  $37^{\circ}\pm 2^{\circ}\text{C}$ , and the time for complete tablet disintegration was recorded.

**6. Drug Content:**

ODT containing 10mg of the drug was made to dissolve in 100ml of the buffer pH6.8 and then absorbance were measured at 242 nm using UV spectrophotometer and the amount of the drug present was calculated using the following Formula:



**7. Wetting Time:**

Wetting time was determined by placing the tablet on double-folded tissue paper soaked in 6 mL of methylene blue solution in a petri dish. The time required for complete wetting was recorded, and the average value of three tablets from each formulation was calculated.

**8. Dissolution Study**

Rupatadine Fumarate sample 5 ml were withdraw at time intervals. Sample which

has been withdraw were replaced by fresh buffer solution. Drug concentration was analysed by UV spectrophotometer at 242 nm. The graph was plotted taking percentage drug dissolve along Y – axis against Time X -axis and the dissolution pattern was observed.

**9. Uniformity of Dispersion:**

This test was performed to ensure disintegration of tablets in the salivary fluid, if it is to be used as an Oro-Dispersible Tablet. In vitro dispersion time was measured by dropping a tablet in a measuring cylinder containing 6 ml of simulated salivary fluid of phosphate buffer pH 6.8. Three tablets from each formulation were randomly selected and in vitro dispersion time was measured.

**10. Stability Study:**

Stability testing was performed under accelerated conditions at  $40^{\circ}\text{C}\pm 2^{\circ}\text{C}$  and  $75\%\pm 5\%$  Relative Humidity for 30 days. Rupatadine Fumarate ODTs were evaluated for weight, hardness, thickness, friability, disintegration, drug content, and release. No significant physical or chemical changes occurred. All values remained within limits, and formulation B5 retained its stability, integrity, and original characteristics throughout storage, showing consistent performance under stress test conditions.

**RESULT AND DISCUSSION:**

**Organoleptic properties of Rupatadine Fumarate:**

**Table 4: Organoleptic properties of Rupatadine Fumarate**

Sr. No.	Properties	Specification	Observation
1	Colour	White or slightly pinkish powder	White or slightly pinkish powder
2	Odour	Odourless	Odourless

**Melting point determination:**

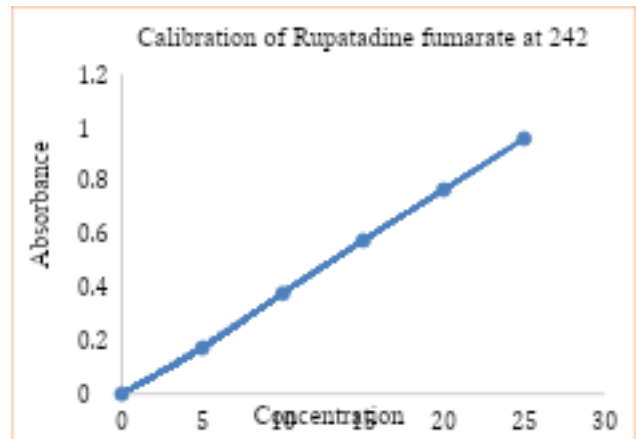
**Table 5: Melting point of Rupatadine Fumarate**

Drug (Itraconazole)	Melting point apparatus
Standard	$194^{\circ}\text{C} - 201^{\circ}\text{C}$
Observed	$193^{\circ}\text{C} - 204^{\circ}\text{C}$

**Solubility of Rupatadine Fumarate:**

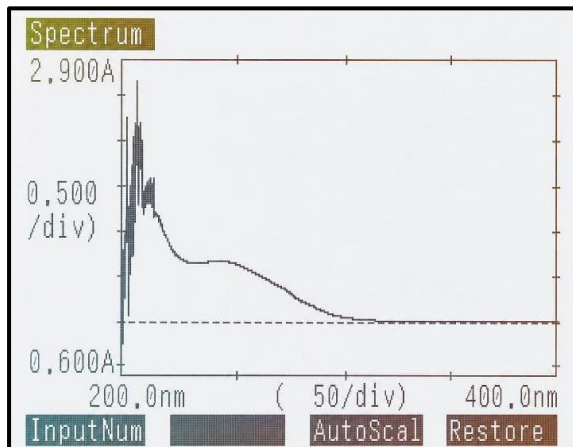
**Table No. 6: solubility of Rupatadine Fumarate**

Sr.No.	Media	Solubility status
1	Water	Very slightly soluble
2	Ethanol	Freely Soluble
3	Phosphate Buffer pH 6.8	Slightly soluble
4	0.1N HCl	Freely soluble
5	0.1N NaOH	Practically insoluble



**Fig. 2: Calibration curve of Rupatadine Fumarate in Phosphate Buffer pH 6.8**

**Determination of UV Spectra of Rupatadine Fumarate**

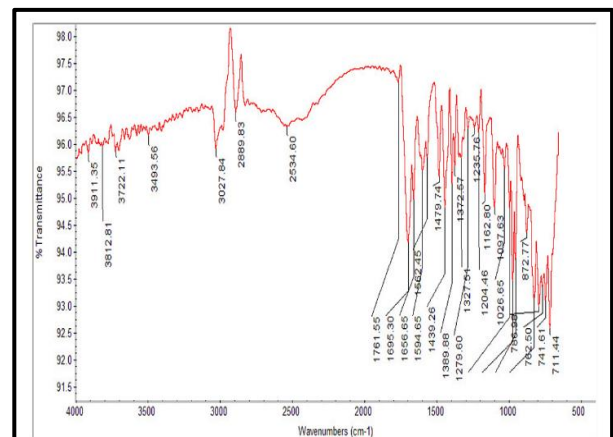


**Fig. 1: UV Spectrum of Rupatadine Fumarate in phosphate buffer pH 6.8**

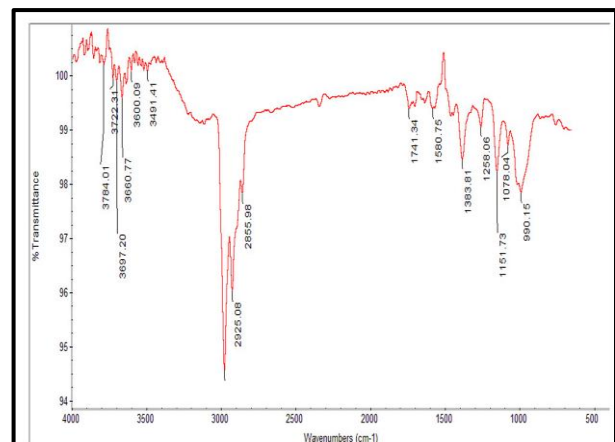
**Calibration Curve of Rupatadine Fumarate**

The calibration curve of Rupatadine Fumarate was plotted as absorbance versus concentrations. The  $\lambda_{max}$  of Rupatadine Fumarate in phosphate buffer pH 6.8 was found to be 242 nm. The standard calibration curve of Rupatadine Fumarate was plotted between 5 and 25 µg/ml, as shown in fig no.2.

**Drug Excipient Compatibility Study: FTIR Study-**



**Fig. 3: FTIR Spectra of Rupatadine Fumarate**



**Fig. 4: FTIR Spectra of Pregelatinized**

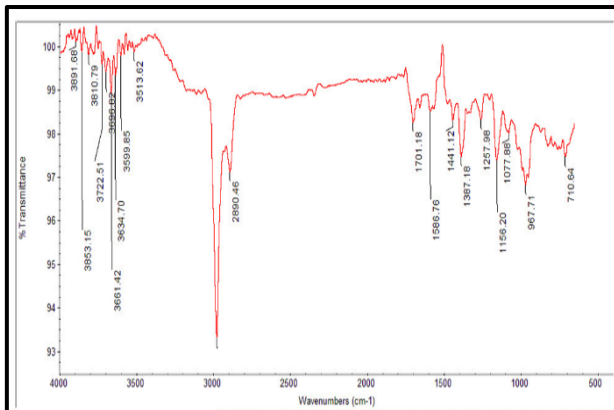


Fig. 5: FTIR spectra of Drug + Pregelatinized

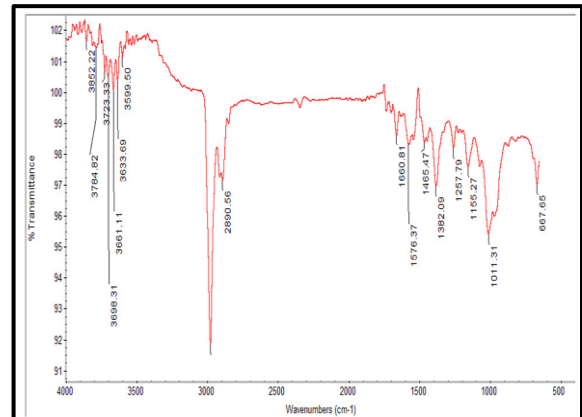


Fig. 6: FTIR spectra of Drug + All excipients

DSC Studies-

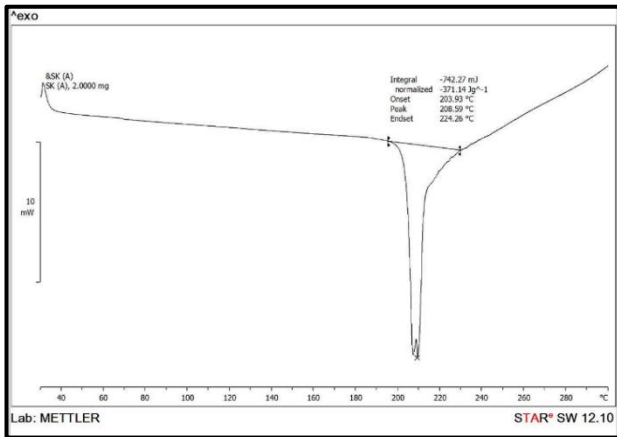


Fig. 7: DSC Thermogram of Rupatadine Fumarate

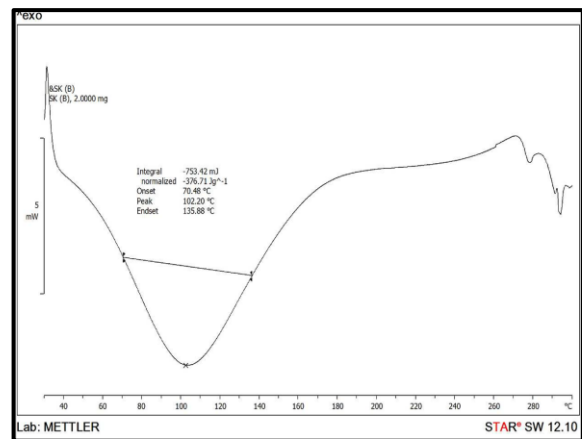


Fig. 8: DSC Thermogram of Pregelatinized

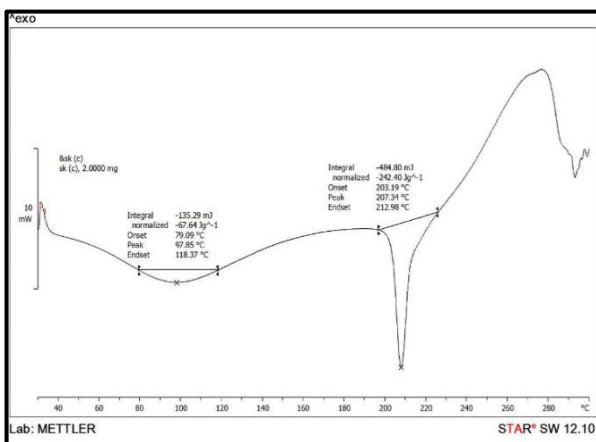


Fig. 9: DSC Thermogram of Drug + Pregelatinized starch

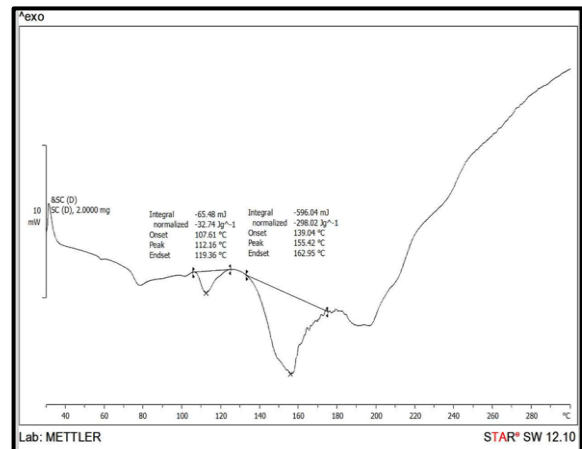


Fig. 10: DSC Thermogram of Drug + All Excipients

EVALUATION PARAMETERS OF OPTIMIZED BATCHES OF RUPATADINE FUMARATE ODT (B1 – B10)

Table 7: Pre-compression Evaluation of Optimized Batches of Rupatadine Fumarate ODT (B1 – B10)

Micromeritics Properties	Batches									
	B1	B2	B3	B4	B5	B6	B7	B8	B9	B10
Bulk Density	0.47 ± 0.01	<b>0.45 ± 0.01</b>	0.45 ± 0.07	0.48 ± 0.05	0.45 ± 0.01	0.43 ± 0.01	0.43 ± 0.03	0.48 ± 0.02	0.42 ± 0.01	0.49 ± 0.04
Tapped Density	0.50 ± 0.02	<b>0.53 ± 0.02</b>	0.53 ± 0.05	0.52 ± 0.01	0.51 ± 0.01	0.5 ± 0.01	0.51 ± 0.01	0.54 ± 0.02	0.53 ± 0.02	0.54 ± 0.01
Carr's Index	11.17 ± 0.9	<b>14.23 ± 0.6</b>	14.36 ± 0.7	12.68 ± 0.4	11.57 ± 1.21	14.25 ± 0.6	15.51 ± 0.13	13.49 ± 0.8	15.30 ± 0.38	12.61 ± 1.08
Hausner's Ratio	1.14 ± 0.04	<b>1.13 ± 0.02</b>	1.14 ± 0.01	1.12 ± 0.06	1.13 ± 0.08	1.17 ± 0.04	1.20 ± 0.02	1.16 ± 0.06	1.18 ± 0.03	1.12 ± 0.10
Angle of Repose (degree)	29.62 ± 1.05	<b>31.75 ± 0.18</b>	31.95 ± 0.20	31.17 ± 0.61	33.66 ± 0.45	32.27 ± 0.5	33.96 ± 0.48	31.21 ± 0.24	33.02 ± 0.46	30.93 ± 1.03

\*Each value represents the mean ±SD n=3

Post-compression Evaluation of Optimized Batches of Rupatadine Fumarate ODT (B1-B10)

Table 8: Evaluation of Batches of Rupatadine Fumarate ODT Generated by CCD:

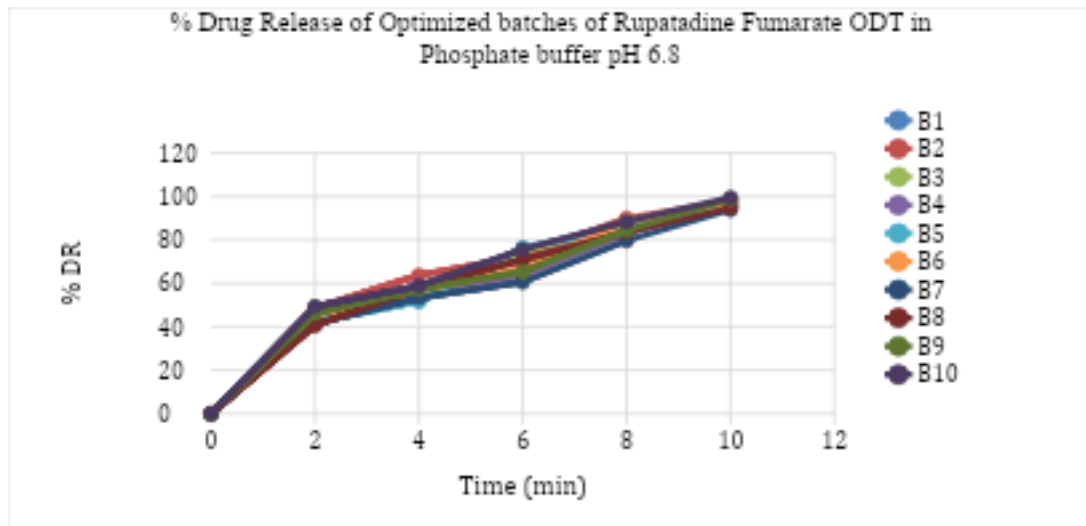
Evaluation Parameters	Batches									
	B1	B2	B3	B4	B5	B6	B7	B8	B9	B10
Weight Variation (mg)	197.3 ± 0.7	<b>199 ± 1</b>	198.3 ± 0.7	197.3 ± 0.7	197 ± 1	198.3 ± 0.7	198.7 ± 1.3	198.3 ± 0.7	197 ± 1	199 ± 1
Hardness (kg/cm <sup>2</sup> )	1.9 ± 0.2	<b>1.8 ± 0.1</b>	1.8 ± 0.1	1.7 ± 0.2	1.6 ± 0.4	1.7 ± 0.2	1.5 ± 0.1	1.6 ± 0.15	1.5 ± 0.4	1.7 ± 0.3
Thickness (mm)	3.65 ± 0.01	<b>3.6 ± 0.01</b>	3.61 ± 0.03	3.59 ± 0.04	3.62 ± 0.01	3.64 ± 0.02	3.65 ± 0.01	3.63 ± 0.02	3.62 ± 0.05	3.63 ± 0.02
Friability (%w/w)	0.50 ± 0.03	<b>0.51 ± 0.02</b>	0.51 ± 0.01	0.54 ± 0.03	0.56 ± 0.04	0.55 ± 0.02	0.6 ± 0.02	0.57 ± 0.06	0.61 ± 0.01	0.59 ± 0.05
Drug content (%)	97.34	<b>98.23</b>	98.23	96.46	97.34	98.23	95.57	96.46	100.8	99.11
Wetting Time (sec)	25.06	<b>17.54</b>	18.05	19.45	20.56	22.39	22.07	23.27	19.34	18.3
Disintegration Time (sec)	14.5	<b>13.65</b>	13.8	12.05	11.4	15.25	14.1	15.2	14.3	12.2
% Drug Release	96.35	<b>97.94</b>	97.14	95.55	96.35	97.14	93.96	94.75	98.73	99.53

Each Value represents the mean ±SD n=3

**In vitro Dissolution Study of Optimized Formulation (B1-B10)**

**Table 9: In vitro Dissolution Study of Optimized Formulation (B1-B10)**

Sr. No.	Time (min)	Batches (%)									
		B1	B2	B3	B4	B5	B6	B7	B8	B9	B10
1	0	0	0	0	0	0	0	0	0	0	0
2	2	45.39	<b>48.57</b>	44.59	42.99	42.20	45.38	41.40	40.61	46.18	49.36
3	4	51.75	<b>63.7</b>	54.94	53.35	51.75	56.54	53.35	58.13	57.33	58.92
4	6	73.26	<b>72.46</b>	74.85	63.70	76.44	66.89	60.52	70.86	65.29	75.64
5	8	85.99	<b>89.98</b>	87.59	82.81	85.99	88.39	79.62	83.6	84.41	88.38
6	10	96.35	<b>97.94</b>	97.14	95.55	96.35	97.14	93.96	94.75	98.73	99.53



**Fig. 11: In vitro %Drug Release Study of Optimized Batches (B1-B10)**

**Table 10: Result of Analysis of Variance for Batches by CCD of Rupatadine Fumarate ODT**

	DF*	SS*	MS*	F*	p-value	
<b>Y1=Disintegration Time</b>						
<b>Model</b>	2	9.82	4.91	5.51	0.0365	significant
<b>Residual</b>	7	6.24	0.8909	--	--	--
<b>Total</b>	9	16.06				
<b>Y2=% DR</b>						
<b>Model</b>	2	17.22	8.61	6.22	0.0281	significant
<b>Residual</b>	7	9.69	1.38	--	--	--
<b>Total</b>	9	26.91				

\* DF indicates degree of freedom; SS sum of square; MS mean sum of square and F is Fischer's ration.

**Data Analysis:**

**A) Disintegration Time (Y1)**

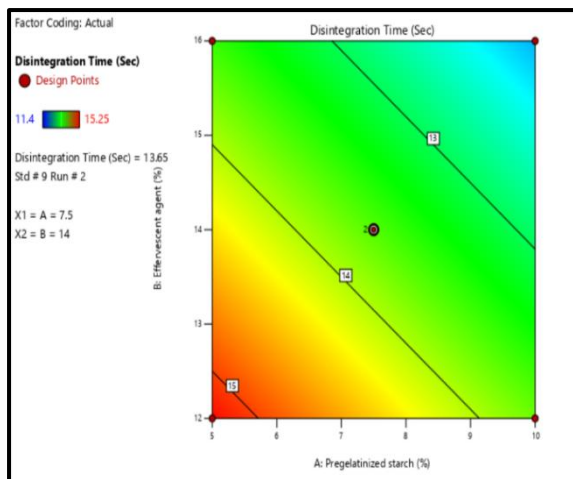
Final equation in terms of coded form,  
 Disintegration Time = +13.65-0.7303X1-0.8332X2  
 Concerning disintegration, the results of multiple linear regression analysis showed that the coefficients X1 bear negative sign and X2 bear a negative sign. It revealed that Disintegration time decreases with increase in Pregelatinized starch and Effervescent agent. Large amount of Pregelatinized starch and Effervescent agent were expected to decrease the disintegration time due to faster disintegration of tablet. ANOVA was used to identify the significant effect. The result was found to be significant at the level of probability (p=0.0365).

**B) % Drug Release (Y2)**

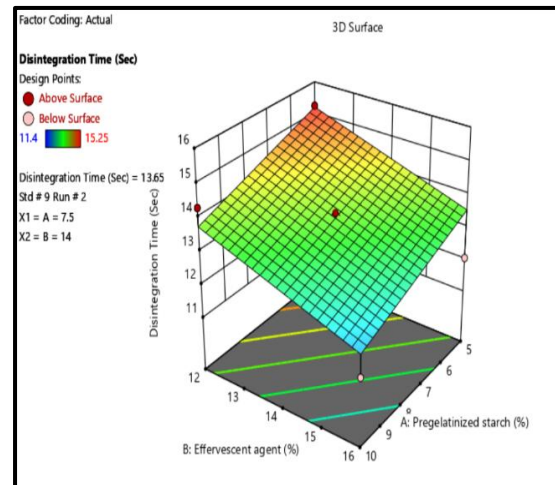
Final equation in terms of coded form,  
 $\% DR = +96.74+1.14X1-0.9187X2$   
 Concerning % Drug Release, the results of multiple linear regression analysis showed that the coefficients X1 bear positive sign and X2 bear a negative sign. It revealed that % DR increase with increase in Pregelatinized starch % w/w were selected as optimum concentration that showed the maximum % DR. It was observed that further increase in concentration of effervescent agent to the decrease the %DR. ANOVA was used to identify the significant effect. The result was found to be significant at that level of probability (p= 0.0281).

**Graphical Representation:**

**A) Disintegration Time -**

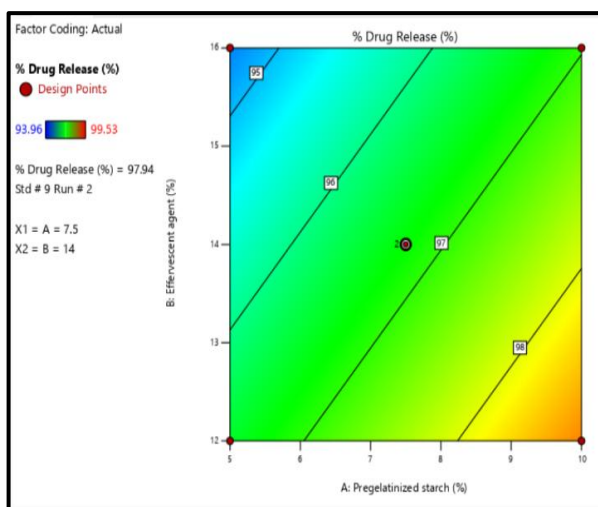


**Fig. 12: Response Surface Contour Graph Showing the Influence of Pregelatinized starch(X1) and Effervescent agent(X2) on Disintegration Time of Rupatadine Fumarate ODT**

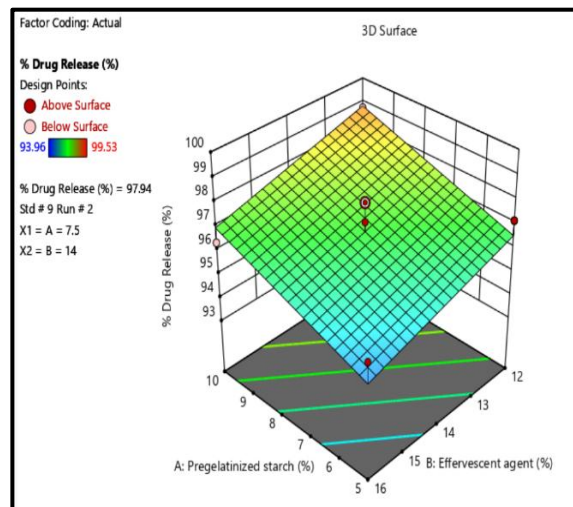


**Fig. 13: 3D Response Surface Graph Showing the Influence of Pregelatinized starch(X1) and Effervescent agent(X2) on Disintegration Time of Rupatadine Fumarate ODT**

**B) % Drug Release**



**Fig. 15: Response Surface Contour Graph Showing the Influence of Pregelatinized starch(X1) and Effervescent agent(X2) on% Drug Release of Rupatadine Fumarate ODT**



**Fig. 16: 3D Response Surface Graph Showing the Influence of Pregelatinized starch(X1) and Effervescent agent(X2) on% Drug Release of Rupatadine Fumarate ODT**

**Stability Study:**

**Table 11: Stability Study of Optimized Batch (B2) of Rupatadine Fumarate ODT**

Parameters		Condition 40±2°C/75%±5 RH		
		Initial	15 days	30 days
Physical	Avg. Wt. (mg)	199	199	198
	Thickness	3.60	3.60	3.58
	Hardness (kg/cm <sup>2</sup> )	1.8	1.6	1.6
	Friability (%w/w)	0.51	0.52	0.53
Chemical	DT (sec)	13.65	13.52	15.42
	% Drug Release	97.94	97.14	97.14
	Drug Content	98.23	98.21	98.19

**II. CONCLUSION:**

The present research successfully developed and optimized effervescent Orodispersible Tablets (ODTs) of Rupatadine Fumarate using the direct compression method. The study demonstrated that the concentrations of Pregelatinized Starch and Effervescent Agent significantly influenced the disintegration time and percentage drug release of the formulations. Pre-compression parameters indicated satisfactory flow properties of the powder blends,

while post-compression evaluation confirmed that all batches complied with acceptable pharmacopeial limits for hardness, friability, weight variation, thickness, drug content, and wetting time. FTIR and DSC studies revealed no significant interaction between Rupatadine Fumarate and the selected excipients, confirming the compatibility and stability of the formulation components. Among all the prepared batches, formulation B2 was identified as the optimized formulation based on its rapid

disintegration time (13.65 sec), high percentage drug release (97.94%), acceptable mechanical strength, and satisfactory physicochemical characteristics. Statistical analysis through Central Composite Design and ANOVA confirmed the significant effect of formulation variables on the response parameters. The accelerated stability study indicated that the optimized formulation remained stable under specified storage conditions without any significant changes in physical appearance, drug content, disintegration time, or drug release profile. Therefore, the developed effervescent ODT formulation of Rupatadine Fumarate can be considered a promising dosage form for rapid onset of action, improved dissolution, enhanced patient compliance, and convenient administration, especially for pediatric and geriatric patients who experience difficulty in swallowing conventional tablets.

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