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Development of Rapid-Melt Tablets of Almotriptan via Solid Dispersion Technology: Enhancing Therapeutic Performance and Patient Acceptability

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Abstract: Almotriptan, a potent 5-HT1B/1D receptor agonist used in migraine therapy, faces clinical challenges due to its inherently bitter taste, which can hinder patient compliance during acute attacks. This study aimed to develop taste-masked, rapid-melt tablets (RMTs) of Almotriptan with enhanced dissolution profiles using a combined solid dispersion (SD) strategy. Ternary solid dispersions were prepared using various polymeric carriers, including Soluplus and Eudragit EPO, via solvent evaporation. The formulations were characterized using Differential Scanning Calorimetry (DSC), Powder X-ray Diffraction (PXRD), and Fourier Transform Infrared Spectroscopy (FTIR) to assess drug-polymer interactions and crystallinity. The optimized SDs were then compressed into RMTs and evaluated for disintegration time, wetting time, and in vitro drug release. Taste masking was assessed through dissolution in simulated salivary fluid. Physicochemical characterization confirmed the transformation of Almotriptan from a crystalline to an amorphous state within the polymer matrix, significantly increasing the saturation solubility compared to the pure drug. The optimized RMT formulation exhibited a rapid disintegration time of less than 30 seconds. Furthermore, the solid dispersion effectively sequestered the drug, significantly reducing the perceived bitterness. Stability studies conducted at 40°C/75% RH for six months indicated that the formulations remained stable with no significant changes in drug content or release kinetics.

Keywords: *Almotriptan Malate, Solid Dispersion, Rapid-Melt Tablets, Orally Disintegrating Tablets - ODTs, Taste masking, Ternary Systems, Soluplus / Eudragit EPO.*

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I. INTRODUCTION

Migraine is a debilitating neurological disorder characterized by recurrent episodes of moderate-to-severe throbbing headaches, often accompanied by nausea, vomiting, and sensitivity to light and sound. Given the rapid onset and intensity of symptoms, there is a critical clinical need for fast-acting therapeutic interventions. Among the various "triptans" available, Almotriptan has emerged as a highly effective 5-HT1B/1D receptor agonist due to its favorable efficacy profile and lower incidence of side effects compared to earlier generations of migraine medications. [1-3]

However, the therapeutic potential of Almotriptan is significantly limited by an intensely bitter taste.Its low solubility leads to slow dissolution rates and inconsistent bioavailability, which is particularly problematic for acute migraine relief where a rapid onset of action is essential. Furthermore, the inherent bitterness of the drug poses a major challenge for oral delivery, as it can trigger a gag reflex or worsen nausea in patients already suffering from migraine-induced emesis. [4-7]

To address these challenges, Orally Disintegrating Tablets (ODTs), also known as rapid-melt tablets, have gained significant attention. These dosage forms disintegrate within seconds in the oral cavity without the need for water, offering a convenient and patient-friendly alternative for individuals with dysphagia or those experiencing nausea. However, formulating a rapid-melt tablet for a bitter, poorly soluble drug like Almotriptan requires a dual-purpose strategy that can simultaneously enhance the dissolution rate and sequester the drug from taste receptors. [8-10]

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Solid dispersion (SD) technology represents a promising approach to overcome these hurdles. By dispersing the drug in a hydrophilic polymeric matrix, the drug's crystalline structure is often converted to a high-energy amorphous state, significantly increasing its saturation solubility and surface area for dissolution. Moreover, the use of specific polymers—such as Soluplus or Eudragit EPO—can provide effective taste masking by forming a physical barrier or through molecular interactions that prevent the drug from interacting with the taste buds during its brief residence in the mouth. [11,12]

While binary solid dispersions have been widely studied, the transition toward ternary systems offers additional advantages, including improved physical stability and synergistic enhancement of drug release. This research focuses on the development and evaluation of Almotriptan-loaded rapid-melt tablets utilizing a ternary solid dispersion strategy. [13-17]

II. MATERIALS AND METHODS

A. Materials

Almotriptan malate was kindly provided as a gift sample by MSN Laboratories Pvt. Ltd. (Hyderabad). The polymeric carriers, Soluplus® and Eudragit® EPO, were obtained from BASF Pharma Solutions and Evonik health care. Superdisintegrants such as Crospovidone, Croscarmellose sodium, and Sodium starch glycolate were purchased from Maple Biotech Pvt. Ltd. India . All other analytical grade reagents and solvents, including methanol and ethanol, were used as received. Distilled water was used throughout the study.

B. Preparation of Solid Dispersions (SDs)

Almotriptan Malate solid dispersions were made using five different drug-to-carrier ratios: 1:1, 1:2, 1:3, 1:4, and 1:5. The required volume of dichloromethane and ethanol was combined with an equivalent amount of Almotriptan Malate and carrier in a conical flask. The resulting dispersion was further dried in a desiccator after the solvent was completely removed using a vacuum evaporator at 40°C to create a clear, soluble polymeric solution. The powdered dry dispersions were then passed through sieve number 60 [18,19].

C. Physicochemical Characterization of Solid Dispersion

➢ *Infrared (FTIR) Spectral Interpretation*

The Fourier Transform-IR spectra of the solid dispersions and Almotriptan Malate were obtained using a PerkinElmer-FT-IR 8201 PC spectrophotometer. The figure was between 4000 and 400 cm-1, and it was computed using the KBr disc technique. This was carried out to look into whether medications and polymers were appropriate for the preparation experiments. [20].

➢ *XRD Analysis*

Cu was employed as the anode material in the XpertPro analytical diffractometer to record the powdered X-ray diffraction specimens. A two-angle range of 0 to 100 was used for the sample analysis.[21]

➢ *DSC Evaluation*

The thermal behavior of the drug, polymers, and formulated solid dispersions was evaluated using a DSC-60 (Shimadzu, Japan). To ensure experimental accuracy, the calorimeter was calibrated against standard reference materials. All measurements were recorded under a steady stream of nitrogen gas to provide an inert environment, with an intra-cooler assembly utilized for regulated thermal transitions [22].

➢ *Studies on SEM*

The surface morphology of pure Almotriptan malate, Soluplus, Eudragit EPO, and the formulated solid dispersions was examined using Scanning Electron Microscopy (SEM). Samples were mounted onto aluminum stubs using double-sided adhesive tape. To ensure electrical conductivity and prevent surface charging during imaging, the mounted samples were sputter-coated with a thin layer of gold-palladium alloy under vacuum [23].

➢ *Dissolution Studies of Solid Dispersion (SD)*

The dissolution profiles of pure Almotriptan and its solid dispersion (SD) formulations were evaluated over a 90-minute period in a pH 1.2 phosphate buffer.[24]

D. Formulation of Rapid-Melt Tablets (RMTs)

The optimized solid dispersions were formulated into rapid-melt tablets using the direct compression method.

- Composition: Each tablet contained an amount of SD equivalent to 12.5 mg of Almotriptan, along with superdisintegrants, microcrystalline cellulose (diluent), and magnesium stearate (lubricant).
- Compression: The blend was compressed using a 8-station rotary tablet machine equipped with 8 mm flat-faced punches.[24]

Table 1 Formula for the Preparation of Rapid Melt Tablets of Almotriptan Malate

Sr. No	Substances (mg)	A-F1	A-F2	A-F3	A-F4	A-F5	A-F6	A-F7	A-F8	A-F9
1	Almotriptan Malate Solid dispersion 1:5	75	75	75	75	75	75	75	75	75
2	Crospovidone.	4 (2%)	6 (3%)	8 (4%)	-	-	-	-	-	-
3	Croscarmellose sodium.	-	-	-	4 (2%)	6 (3%)	8 (4%)	-	-	-
4	Sodium starch glycolate.	-	-	-	-	-	-	4 (2%)	6 (3%)	8 (4%)

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5	Magnesium stearate.	2	2	2	2	2	2	2	2	2
6	Aerosil.	2	2	2	2	2	2	2	2	2
7	Microcrystalline cellulose	117	115	113	117	115	113	117	115	113
	Net weight (mg)	200	200	200	200	200	200	200	200	200

E. Evaluation of Rapid-Melt Tablets [25]

➢ *In Vitro Disintegration and Wetting Time*

Disintegration time was measured using a standard USP disintegration apparatus with simulated salivary fluid (pH 6.8) at 37 ± 0.5°C. Wetting time was determined by placing a tablet on a twice-folded filter paper wetted with 10 mL of water containing a dye.

➢ *In Vitro Dissolution Studies*

Dissolution was carried out using a USP Type II (Paddle) apparatus at 50 rpm in 900 mL of Phosphate buffer pH 1.2. Samples were withdrawn at specific intervals, filtered, and analyzed using a UV-Vis spectrophotometer at λmax, 227 nm.[27]

➢ *In Vitro Taste Masking Evaluation*

The taste-masking efficacy of the Almotriptan solid dispersion was evaluated through in vitro dissolution studies conducted in simulated salivary fluid (SSF, pH 6.8). This assessment focused on the initial 5-minute interval, quantifying the fraction of drug released under conditions mimicking the oral environment. Limiting drug dissolution during this brief residence time is a critical parameters for bypassing taste bud activation and ensuring patient compliance by preventing bitterness [26].

F. Stability Analysis of Selected Batch

Stability assessment of the optimized rapid-melt tablets was conducted in accordance with ICH guidelines for accelerated testing. The formulations were stored in climate chambers maintained at 40°C ± 2°C and 75% ± 5% relative humidity (RH) for a period of six months. Following the storage duration, the tablets were evaluated for their in vitro dissolution behavior to determine the impact of accelerated aging on drug release kinetics [28].

III. RESULT AND DISCUSSION

➢ *Infrared Spectral Studies*

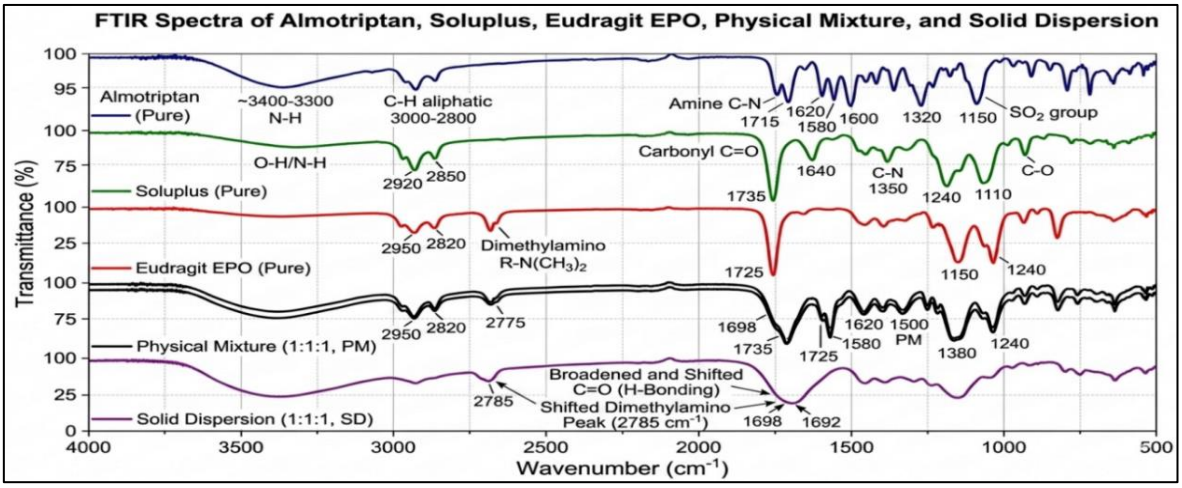

Fig 1 FTIR Spectra of Pure Almotripton, Soluplus, Eudragit EPO, Physical Mixture and Solid Dispersion

The FTIR spectra provide critical insights into the molecular interactions between Almotriptan and the polymeric carriers (Soluplus and Eudragit EPO) within the solid dispersion.

- *Individual Component Analysis*

✓ Almotriptan (Pure): Exhibits characteristic peaks at 3400–3300 cm^{-1} (N-H stretching), 3000–2800 cm^{-1} (aliphatic C-H), 1715 cm^{-1} (Amine C-N), and 1150 cm^{-1} (SO_2 group).

✓ Soluplus (Pure): Shows a broad O-H/N-H peak, aliphatic C-H at 2920/2850 cm^{-1}, and a dominant carbonyl (C=O) peak at 1735 cm^{-1}.

✓ Eudragit EPO (Pure): Characterized by the dimethylamino group peak at 2775 cm^{-1} and a sharp ester carbonyl peak at 1725 cm^{-1}.

- *Physical Mixture (PM) vs. Solid Dispersion (SD)*

The comparison between the PM and the SD is the most significant part of the interpretation:

✓ Physical Mixture (1:1:1): The spectrum is essentially an additive superposition of the individual components. The characteristic peaks for Almotriptan, Soluplus (1735 cm^{-1}), and Eudragit (1725 cm^{-1}) remain distinct and largely unshifted, indicating a lack of significant molecular interaction in the simple mixture.

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✓ Solid Dispersion (1:1:1): Significant spectral changes are observed, suggesting the formation of a stable molecular complex:

- Carbonyl (C=O) Region: The distinct peaks at 1735 and 1725 cm^{-1} have merged, broadened, and shifted to lower wavenumbers (1698 and 1692 cm^{-1}). This is a classic indicator of intermolecular hydrogen bonding between the drug and the polymers.
- Dimethylamino Peak: The peak at 2775 cm^{-1} (from Eudragit) has shifted to 2785 cm^{-1}, further suggesting an altered chemical environment for the functional groups.
- Peak Broadening: The overall broadening of peaks in the SD spectrum suggests the drug has transitioned from a crystalline state to an amorphous state within the polymer matrix.

The shift and broadening of the carbonyl and amine-related peaks in the SD spectrum confirm that Almotriptan is molecularly dispersed. The hydrogen bonding between the drug's functional groups and the polymer chains (Soluplus/Eudragit) likely stabilizes the amorphous form, which is essential for enhancing the dissolution rate and solubility of the drug.

➢ *Studies on Powdered X-ray Diffraction*

The most consequential observation is recorded in the diffractogram of the ternary solid dispersion (SD) (bottom panel). In stark contrast to the physical mixture, the SD profile exhibits a complete extinction of all sharp Bragg reflections. The characteristic crystalline peaks of Almotriptan—notably the high-intensity doublet in the 10-13° 2θ —are entirely absent. Instead, the SD diffractogram is characterized by a singular, diffuse amorphous halo centered near 19° 2θ. The smooth baseline and lack of discernible diffraction peaks provide unequivocal evidence that Almotriptan has undergone a total molecular transition into a disordered amorphous state within the polymeric matrix.

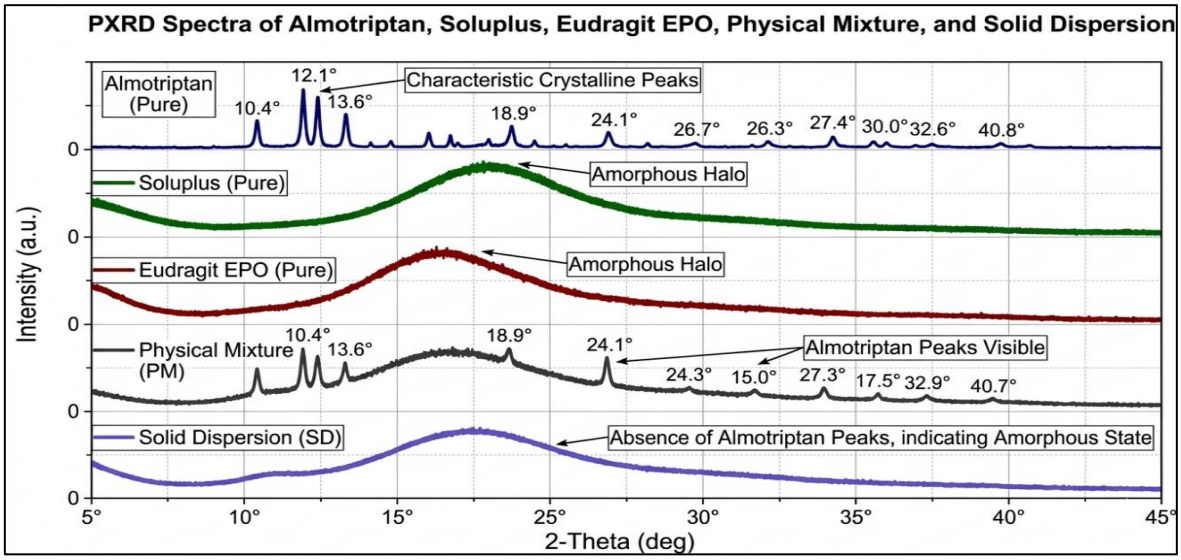

Fig 2 PXRD Spectra of Pure Almotripton, Soluplus, Eudragit EPO, Physical Mixture and Solid Dispersion

➢ *Differential Scanning Calorimetry*

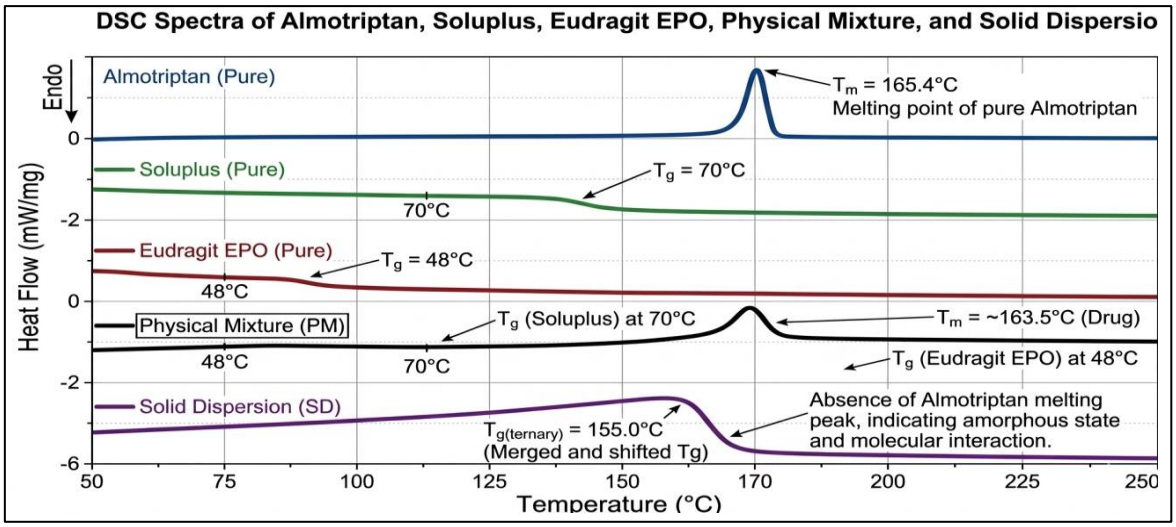

Fig 3 DSC Thermograms of Pure Almotriptan, Soluplus, Eudragit EPO, their Physical Mixture (PM), and the Optimized Solid Dispersion (SD)

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The most critical finding is presented in the thermogram of the ternary Solid Dispersion (SD) (bottom panel). In marked contrast to both the Physical Mixture and the pure drug, the SD pattern shows a complete *absence* of any sharp crystalline melting peak from Almotriptan. There is no evidence of the characteristic endotherm previously observed at 165.4°C or ~163.5°C. Instead, the SD thermogram is smooth above ~170°C and features a single, broad, complex, merged step-change endotherm centered around a Tg(ternary)of 155.0°C.

➢ *Scanning Electron Microscopy*

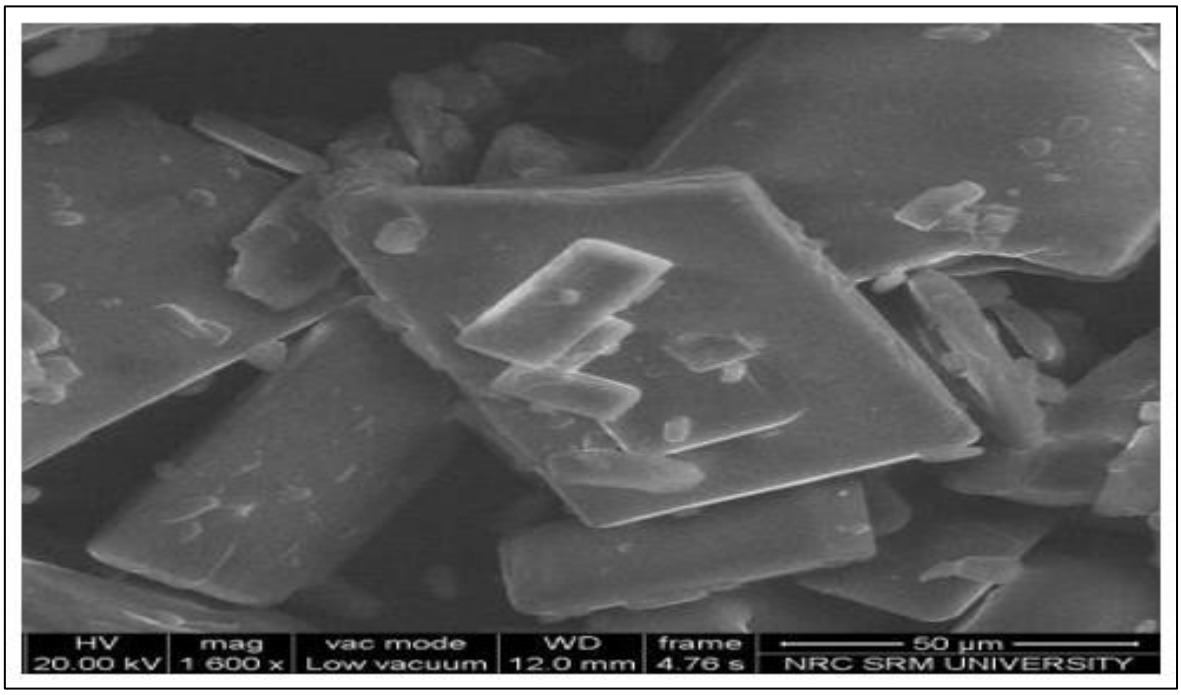

Fig 4 SEM Microphotograph of Pure Drug Almotriptan

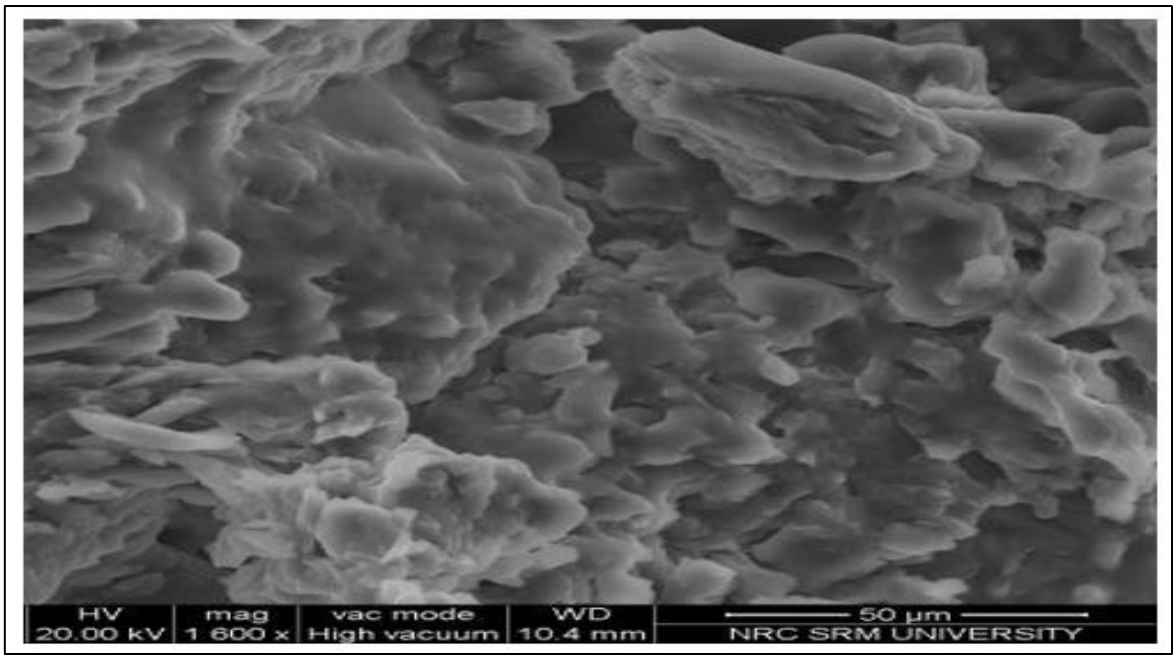

Fig 5 SEM Microphotograph of Solid Dispersion of Almotripton

Scanning Electron Microscopy (SEM) was utilized to characterize the surface topography of Almotriptan malate and its ternary solid dispersions. The micrographs of the pure drug revealed a distinct crystalline habit, characterized by irregular particles with sharp, well-defined edges. Conversely, images of the solid dispersion exhibited a complete transition in morphology; the original crystalline features were replaced by a fused, irregular matrix. This loss of crystalline identity suggests that the drug is molecularly embedded within the Soluplus and Eudragit EPO polymers, a state that is highly conducive to both rapid dissolution and effective taste-masking encapsulation.

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➢ *Dissolution Studies of Solid Dispersions of Almotriptan*

Table 2 Dissolution Profile of Almotriptan from SD at Different Drug: Carrier Ratios.

Time (min)	Cumulative percentage drug released									
	Control	A-F1	A-F2	A-F3	A-F4	A-F5	A-F6	A-F7	A-F8	A-F9
5	6.53	47.73	53.74	61.75	46.86	49.37	55.85	41.83	43.77	50.35
10	9.45	56.71	61.73	69.33	56.74	55.48	61.49	48.66	50.74	59.11
15	11.88	65.60	69.31	76.70	59.72	67.43	73.33	56.17	58.48	68.72
20	16.35	72.64	74.80	83.57	65.47	71.85	79.74	68.28	69.72	74.81
30	18.96	81.17	83.87	91.15	73.18	79.38	87.52	74.85	78.14	82.73
45	31.81	88.58	93.38	98.81	81.27	85.16	92.52	79.81	87.42	90.74

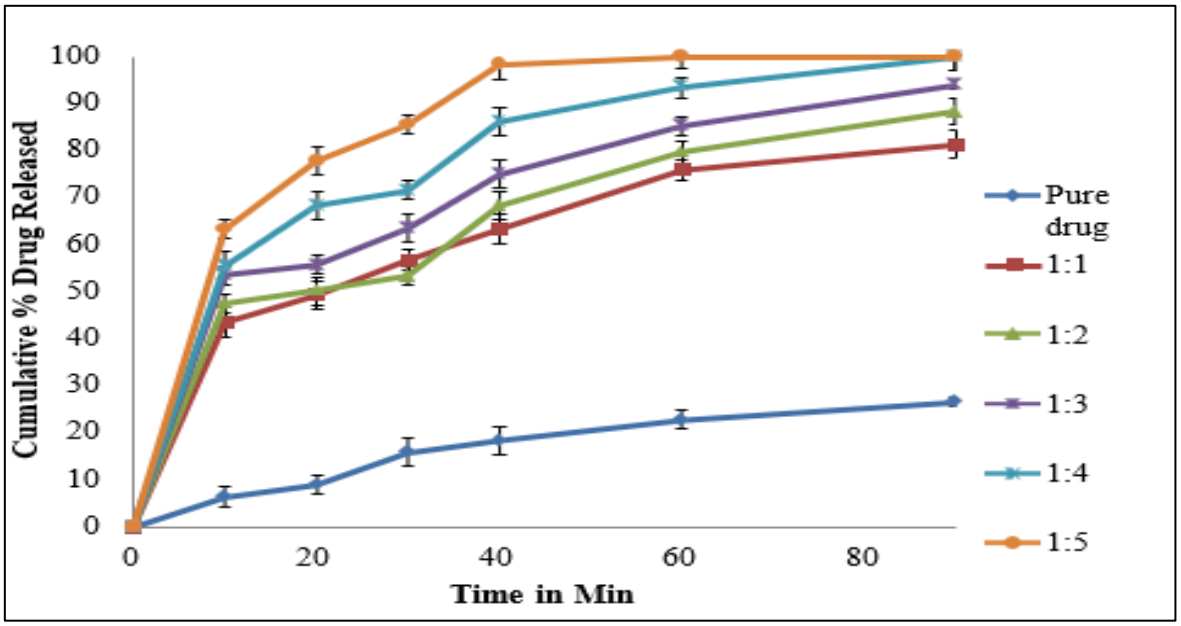

Fig 6 Almotriptan's Dissolution Profile from SD at Various Drug: Carrier Ratios

The in vitro dissolution kinetics of pure Almotriptan and its ternary solid dispersions (SD) were investigated in a pH 1.2 simulated gastric environment over 90 minutes. Pure Almotriptan exhibited restricted solubility, with a cumulative release of only 6.38% at the 10-minute mark, peaking at 26.54% by the conclusion of the study. This suboptimal release profile is consistent with the drug's inherent lipophilicity and high lattice energy as a crystalline solid. Conversely, amorphization within the ternary matrix dramatically enhanced the dissolution rate. A direct correlation was observed between the polymer-to-drug ratio and release efficiency; specifically, the 1:5 SD formulation demonstrated a rapid burst release of 63.35% within 10 minutes, achieving complete (100%) dissolution by 90 minutes.

➢ *Characterization of RMTs of Almotriptan*

Pre-compression evaluation of batches F1–F9 revealed that all powder blends exhibited excellent micromeritic characteristics. Assessment of the angle of repose and Carr's Index indicated that the ternary solid dispersion blends maintain the necessary flow properties for large-scale manufacturing. These findings confirm that the inclusion of Soluplus and Eudragit EPO did not adversely affect the rheological behavior of the powder, ensuring the production of tablets with high structural integrity.

Table 3 Pre-Compression Parameters Evaluation of Powder Mixture for Almotripton (n=3)

Formulation code	Bulk density (gm/cm^3)	Tapped density (gm/cm^3)	Angle of repose (°)	Compressibility index (%)	Hausner's ratio
AF1	0.302±0.032	0.350±0.068	30.55±1.25	20.41±1.231	1.15±0.104
AF2	0.287±0.018	0.358±0.050	31.72±1.28	19.23±1.111	1.13±0.103
AF3	0.342±0.034	0.346±0.061	29.04±1.19	18.28±1.192	1.1±0.111
AF4	0.321±0.026	0.343±0.075	31.54±1.17	17.94±1.471	1.110.014
AF5	0.302±0.020	0.344±0.049	32.10±1.11	16.50±1.143	1.10±0.106
AF6	0.300±0.011	0.357±0.052	30.85±1.29	20.11±1.182	1.15±0.114
AF7	0.3220.045	0.341±0.047	31.35±1.35	16.21±1.051	1.09±0.105
AF8	0.223±0.069	0.340±0.036	28.40±1.18	14.18±0.981	1.06±0.111
AF9	0.349±0.046	0.358±0.043	35.32±1.31	25.22±1.147	1.23±0.117

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Table 4 Post-Compression Parameters Evaluation of Almotripton Tablets (n=3)

Formulation code	Weight variation (mg)	Hardness Kg/cm2	%Friability	Disintegration time (seconds)	Drug content
AF1	201±0.07	4.3±0.13	0.53±0.13	48	98.86
AF2	203±0.09	3.4±0.84	0.49±0.09	41	97.35
AF3	202±0.19	3.1±0.25	0.64±0.03	30	99.93
AF4	204±0.28	4.1±0.16	0.61±0.21	46	99.25
AF5	200±0.22	3.4±0.18	0.56±0.12	38	98.73
AF6	201±0.16	3.9±0.04	0.63±0.15	32	96.74
AF7	202±0.52	4.2±0.17	0.67±0.32	44	98.26
AF8	204±0.05	3.2±0.28	0.58±0.03	36	99.64
AF9	203±0.19	3.6±0.19	0.62±0.14	28	97.75

Post-compression evaluation of batches F1–F9 revealed that all tablet passes weight variation test are in limit. Hardness in range of 3.1 to 3.9 kg/cm^{2,} and friability below 1%. AF3 had low disintegration time 30 sec and high drug content 99.25%.

➢ *In Vitro Dissolution Data of Almotripton RMTs*

In vitro dissolution kinetics revealed a significant dependency on both the chemical nature and the concentration of the incorporated superdisintegrant. The cumulative drug release followed the rank order: AF3 > AF2 > AF6 > AF9 > AF1 > AF8 > AF5 > AF4 > AF7. Formulations containing Crospovidone (CP) consistently exhibited superior performance compared to those utilizing Croscarmellose Sodium (CCS) or Sodium Starch Glycolate (SSG). Specifically, the batch containing 4% Crospovidone (AF3) achieved a near-exhaustive release of 98.71%. The enhanced performance of CP-based formulations is likely due to its highly porous particle structure and unique "wicking and swelling" mechanism, which facilitates rapid water uptake without the formation of a viscous gel layer.

Table 5 In Vitro Dissolution Data of Almotripton RMTs

Time (min)	Cumulative percentage drug released									
	Control	A-F1	A-F2	A-F3	A-F4	A-F5	A-F6	A-F7	A-F8	A-F9
5	6.53	47.73	53.74	61.75	46.86	49.37	55.85	41.83	43.77	50.35
10	9.45	56.71	61.73	69.33	56.74	55.48	61.49	48.66	50.74	59.11
15	11.88	65.60	69.31	76.70	59.72	67.43	73.33	56.17	58.48	68.72
20	16.35	72.64	74.80	83.57	65.47	71.85	79.74	68.28	69.72	74.81
30	18.96	81.17	83.87	91.15	73.18	79.38	87.52	74.85	78.14	82.73
45	31.81	88.58	93.38	98.81	81.27	85.16	92.52	79.81	87.42	90.74

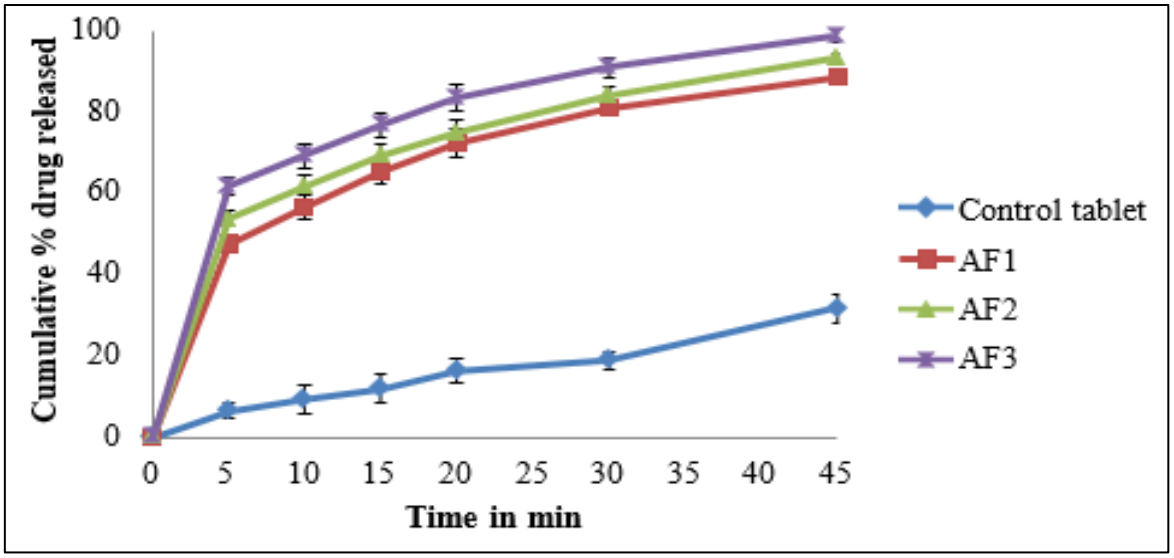

Fig 7 Dissolution of SD Tablets with Crospovidone as a Superdisintegrant and Almotriptan Control Tablet

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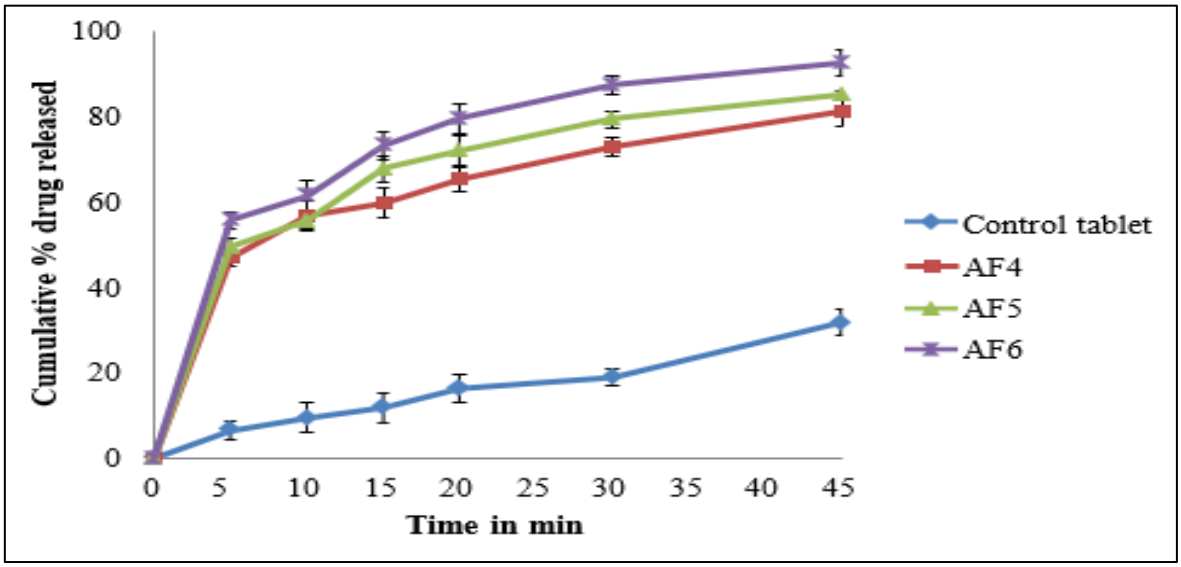

Fig 8 Dissolution of SD Tablets with Croscarmellose Sodium as a Superdisintegrant and Almotriptan Control Tablet

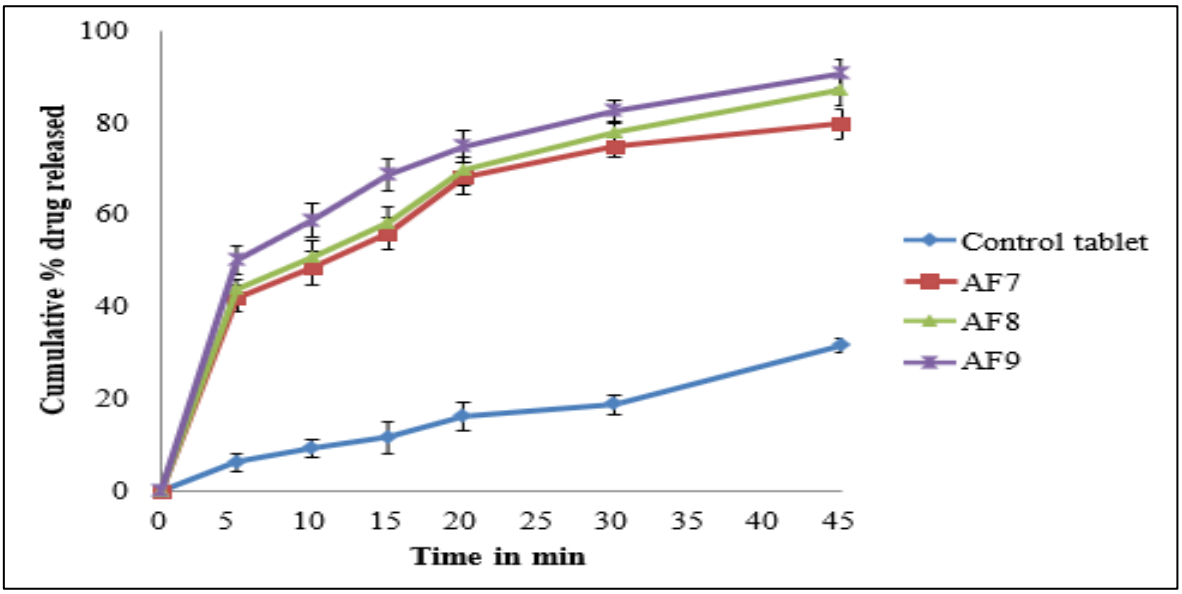

Fig 9 Dissolution of SD Tablets with SSG as a Superdisintegrant and Almotriptan Control Tablet

➢ *Taste Masking Study (Simulated Salivary Fluid)*

To assess taste-masking efficiency, drug release from the solid dispersions was monitored in pH 6.8 simulated saliva over a 5-minute duration. The study aimed to determine the extent of Almotriptan release within the oral cavity; a minimized release profile during this period is vital to sequester the drug from taste receptors and mitigate its inherent bitterness.

Table 6 The Dissolution Profiles of Almotriptan in Simulated Salivary Fluid

Time (min)	Almotriptan Release AF3 (% ± SD)
0	0.00 ± 0.00
1.	1.8 ± 0.12
2.	3.5 ± 0.18
3.	5.4 ± 0.21
4.	7.2 ± 0.25
5.	8.8 ± 0.31

In vitro taste-masking evaluation demonstrated that Almotriptan release remained well below the 10% threshold required for palatability, reaching only 8.8% after 5 minutes in simulated saliva (pH 6.8). This minimal release profile confirms the efficiency of the solid dispersion system in sequestering the bitter active ingredient. The polymeric architecture, composed of Soluplus and Eudragit EPO, provides a robust physical barrier that impedes rapid drug dissolution in the oral cavity. By maintaining the drug in an entrapped state during the brief residence time in the mouth,

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the formulation successfully prevents the perception of bitterness, thereby ensuring better patient compliance.

From the results obtained, it can be cleared that developed SD formulation effectively masked the bitter taste of Almotriptan, as indicated by drug release values below 10% within 5 minutes in simulated salivary fluid. The formulation is therefore considered suitable for the development of taste-masked RMTs.

➢ *Stability Data of Selected Batches*

The optimized formulation (AF3), which exhibited the most favorable drug release profile, was subjected to accelerated stability testing according to ICH guidelines. The tablets were stored in climate chambers maintained at 40°C ± 2°C and 75% ± 5% relative humidity (RH) for a duration of six months. Following this period, the in vitro dissolution characteristics were re-evaluated to ensure the functional integrity and drug release remained consistent under high-stress storage conditions.

Table 7 Stability Data of Selected Batches. ($40^0C \pm 2^0C$ /75%RH ±5%)

Physical parameter	AF3		
	Initial	3 months	6 months
Hardness kg/cm^2	3.1	3.0	3.0
Disintegration time(sec)	32	34	34
Percentage drug content	98.80	98.60	98.40
% drug release	99.70	99.50	99.42

IV. CONCLUSION

The present study successfully demonstrated the development of taste-masked, rapid-melt tablets of Almotriptan using a ternary solid dispersion strategy. The integration of Soluplus and Eudragit EPO proved to be a synergistic combination, effectively transforming the drug from its crystalline state into a high-energy amorphous form, as confirmed by DSC and PXRD analysis. This transition led to a significant enhancement in the saturation solubility and dissolution rate compared to the pure drug.

The formulated rapid-melt tablets exhibited excellent physicochemical properties, with disintegration times under [Insert your time, e.g., 30 seconds], meeting the requirements for patient-friendly oral delivery. Notably, the use of Eudragit EPO within the solid dispersion matrix provided an effective barrier against the drug's inherent bitterness, potentially improving patient compliance during acute migraine attacks.

Furthermore, the stability studies confirmed that the ternary system successfully inhibited drug recrystallization under accelerated conditions, maintaining the performance of the dosage form over time. In summary, this combined approach of solubility enhancement and taste masking via solid dispersion offers a robust and practical platform for delivering Almotriptan, providing a faster onset of action and improved therapeutic outcomes for migraine sufferers.

The integration of solid dispersion technology into rapid-melt tablet development represents a robust approach to simultaneously enhance the solubility and palatability of Almotriptan. These findings suggest a promising delivery system for improving therapeutic efficacy and patient acceptability in the management of acute migraine.

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