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Research

Development and In Vitro Evaluation of Rizatriptan Benzoate Oral Disintegrating Tablets Using Superdisintegrants for Enhanced Patient Compliance

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Abstract:

Background: Migraine is a prevalent neurological disorder characterized by recurrent attacks of moderate to severe headache, often accompanied by nausea, vomiting, and sensitivity to light and sound. Oral drug administration during migraine attacks is frequently compromised due to dysphagia, nausea, and delayed gastric emptying. Oral disintegrating tablets (ODTs) provide a patient-friendly dosage form that rapidly disintegrates in the oral cavity without the need for water, thereby improving convenience and compliance. Rizatriptan benzoate, a selective 5-hydroxytryptamine (5-HT1B/1D) receptor agonist, is widely prescribed for the acute treatment of migraine and is an ideal candidate for ODT formulation. **Objective:** The present study aimed to formulate and evaluate oral disintegrating tablets of rizatriptan benzoate using different superdisintegrants to achieve rapid tablet disintegration, enhanced dissolution, and improved patient acceptability. **Materials and Methods:** Oral disintegrating tablets were prepared by the direct compression method employing various concentrations of crospovidone, croscarmellose sodium, and sodium starch glycolate. The prepared formulations were evaluated for pre-compression parameters, including angle of repose, bulk density, tapped density, Carr's compressibility index, and Hausner's ratio. Post-compression evaluation included weight variation, hardness, thickness, friability, drug content uniformity, wetting time, water absorption ratio, disintegration time, in vitro dissolution studies, Fourier-transform infrared spectroscopy (FTIR), and accelerated stability studies. **Results:** The powder blends exhibited satisfactory flow properties suitable for direct compression. All tablet formulations complied with pharmacopeial specifications for physical quality attributes. Formulations containing crospovidone demonstrated the shortest disintegration time, rapid wetting, and superior dissolution characteristics. The optimized formulation disintegrated within approximately 20–30 seconds and released more than 90% of the drug within 15 minutes. FTIR analysis confirmed the absence of significant drug–excipient interactions, while accelerated stability studies indicated that the optimized formulation remained physically and chemically stable throughout the study period. **Conclusion:** The optimized rizatriptan benzoate oral disintegrating tablet demonstrated excellent pharmaceutical performance with rapid disintegration and enhanced dissolution. The developed formulation offers a promising alternative to conventional tablets by improving patient convenience, compliance, and

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the potential for a faster onset of therapeutic action in migraine management.

Keywords: Rizatriptan benzoate; Oral disintegrating tablets, Superdisintegrants; Crospovidone; Direct compression; Migraine; Patient compliance; Dissolution studies.

1. Introduction

Migraine is a chronic neurovascular disorder affecting millions of individuals worldwide and represents one of the leading causes of disability among adults. The condition is characterized by recurrent episodes of unilateral pulsating headache that are frequently associated with nausea, vomiting, photophobia, and phonophobia. These symptoms substantially impair quality of life and often interfere with normal daily activities. Effective migraine therapy requires rapid onset of action to relieve symptoms as early as possible after the onset of an attack.

Rizatriptan benzoate is a selective serotonin (5-hydroxytryptamine; 5-HT1B/1D) receptor agonist belonging to the triptan class of antimigraine agents. Following oral administration, the drug produces cranial vasoconstriction, inhibits neuropeptide release, and suppresses trigeminal nerve activation, thereby relieving migraine symptoms. Rizatriptan has demonstrated rapid therapeutic efficacy and is widely recommended for the acute treatment of migraine attacks. However, conventional oral tablets may be difficult to administer during migraine episodes because patients frequently experience dysphagia, nausea, vomiting, or limited access to drinking water.

Oral disintegrating tablets (ODTs) have emerged as an attractive alternative to conventional solid oral dosage forms. According to the United States Food and Drug Administration (FDA), an ODT is a solid dosage form that rapidly disintegrates on the tongue, usually within seconds, without requiring water for swallowing. These formulations improve convenience of administration and are particularly beneficial for pediatric, geriatric, bedridden, and dysphagic patients. ODTs also improve patient adherence and may facilitate a faster onset of action because rapid tablet disintegration accelerates drug dissolution.

Rapid tablet disintegration is primarily achieved through the incorporation of superdisintegrants. Superdisintegrants absorb saliva rapidly and promote tablet breakup by mechanisms including swelling, capillary action (wicking), deformation recovery, and particle repulsion. Among the most commonly used superdisintegrants are crospovidone, croscarmellose sodium, and sodium starch glycolate. Crospovidone acts predominantly through capillary action and possesses a highly porous structure, whereas croscarmellose sodium and sodium starch glycolate primarily promote tablet disintegration through swelling combined with water uptake. The type and concentration of superdisintegrant significantly influence tablet disintegration time and dissolution performance.

Direct compression remains one of the most widely employed manufacturing techniques for ODTs because it is simple, economical, and suitable for moisture- and heat-sensitive drugs. The process requires fewer manufacturing steps, minimizes processing time, and facilitates large-scale production using conventional pharmaceutical equipment. Successful direct compression depends on excellent powder flow, adequate compressibility, and uniform distribution of the active pharmaceutical ingredient and excipients.

The present study was undertaken to develop oral disintegrating tablets of rizatriptan benzoate using different superdisintegrants and to evaluate their influence on tablet performance. The prepared formulations were assessed for pre-compression flow properties, tablet quality parameters, wetting time, disintegration time, drug content, dissolution behavior, compatibility by FTIR spectroscopy, and accelerated stability. The optimized formulation was selected based on rapid disintegration, superior dissolution characteristics, and compliance with pharmacopeial quality standards. The findings are expected to contribute to the development of a patient-friendly dosage form capable of improving convenience, therapeutic performance, and treatment adherence in patients with acute migraine.

2. Materials and Methods

2.1 Materials

Rizatriptan benzoate was obtained as a gift sample from SMS Pharmaceuticals Ltd., India. Mannitol, microcrystalline cellulose (Avicel PH 102), colloidal silicon dioxide, magnesium stearate, and aspartame

were procured from commercial pharmaceutical suppliers and used as received. The superdisintegrants employed in the study included crospovidone, croscarmellose sodium, and sodium starch glycolate. All chemicals and reagents were of analytical or pharmaceutical grade and complied with the specifications of the Indian Pharmacopoeia (IP) and the United States Pharmacopeia (USP).

2.2 Preformulation Studies

Preformulation studies were carried out to evaluate the physicochemical characteristics of rizatriptan benzoate and to establish its suitability for oral disintegrating tablet formulation. The studies included:

- Organoleptic evaluation
- Solubility studies
- Determination of λmax using UV–Visible spectrophotometry
- Preparation of the calibration curve
- Drug–excipient compatibility studies using Fourier-transform infrared spectroscopy (FTIR)
- Evaluation of powder flow properties

These investigations provided the necessary information for selecting suitable excipients and optimizing the formulation.

2.3 Drug–Excipient Compatibility Study

Compatibility between rizatriptan benzoate and the selected excipients was evaluated by Fourier-transform infrared spectroscopy (FTIR). The spectra of the pure drug, individual excipients, and the optimized formulation were recorded over an appropriate scanning range. Characteristic absorption peaks were compared to detect any possible chemical interaction.

The absence of significant peak shifts or disappearance of characteristic functional groups indicated compatibility between the drug and formulation excipients.

2.4 Preparation of Calibration Curve

A standard stock solution of rizatriptan benzoate was prepared in the selected solvent system. Serial dilutions were prepared to obtain solutions of different concentrations. The absorbance of each solution was measured at the predetermined wavelength (λmax) using a UV–Visible spectrophotometer.

A calibration curve was constructed by plotting absorbance against concentration, and linear regression analysis was performed to determine the correlation coefficient (R^2), confirming the linearity of the analytical method.

2.5 Formulation of Oral Disintegrating Tablets

Nine formulations (F1–F9) of rizatriptan benzoate oral disintegrating tablets were prepared by varying the type and concentration of superdisintegrants while maintaining a constant drug content.

The superdisintegrants investigated were:

- Crospovidone (CP)
- Croscarmellose sodium (CCS)
- Sodium starch glycolate (SSG)

Other excipients, including mannitol, microcrystalline cellulose, aspartame, colloidal silicon dioxide, and magnesium stearate, were incorporated to improve compressibility, palatability, and flow characteristics.

2.6 Preparation of Tablets by Direct Compression

All ingredients were accurately weighed according to the formulation design and passed through a suitable sieve to achieve uniform particle size. Rizatriptan benzoate was blended with the diluents and superdisintegrants using geometric dilution to ensure uniform distribution.

After thorough mixing, colloidal silicon dioxide and magnesium stearate were added as glidant and lubricant, respectively. The final powder blend was compressed using a rotary tablet compression machine equipped with suitable punches to produce oral disintegrating tablets of uniform weight and hardness. Direct compression was selected because of its simplicity, cost-effectiveness, and suitability for moisture- and heat-sensitive materials.

2.7 Evaluation of Powder Blend (Pre-compression Parameters)

The prepared powder blends were evaluated for flow properties prior to compression.

Angle of Repose

The angle of repose was determined using the fixed funnel method according to the following equation:

$$\theta = \tan^{-1}\left(\frac{h}{r}\right)$$

where:

- θ = Angle of repose
- h = Height of powder cone
- r = Radius of powder cone

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Bulk Density

Bulk density was determined by gently pouring a known weight of powder into a graduated measuring cylinder.

$$Bulk\ Density = \frac{Weight}{Bulk\ Volume}$$

Tapped Density

Tapped density was measured after mechanically tapping the measuring cylinder until a constant volume was obtained.

$$Tapped\ Density = \frac{Weight}{Tapped\ Volume}$$

Carr's Compressibility Index

The compressibility index was calculated using the following equation:

$$Carr's\ Index = \frac{Tapped\ Density - Bulk\ Density}{Tapped\ Density} \times 100$$

Hausner's Ratio

Hausner's ratio was calculated using:

$$Hausner's\ Ratio = \frac{Tapped\ Density}{Bulk\ Density}$$

The obtained values were interpreted according to standard pharmacopeial limits to assess powder flow and compressibility.

2.8 Evaluation of Oral Disintegrating Tablets (Post-compression Parameters)

The prepared tablets were evaluated according to Indian Pharmacopoeia and USP guidelines.

Weight Variation

Twenty tablets were individually weighed, and the percentage deviation from the average weight was calculated.

Thickness

Tablet thickness was measured using a digital Vernier caliper.

Hardness

Tablet hardness was determined using a tablet hardness tester and expressed as kg/cm².

Friability

Friability was evaluated using a Roche friabilator operating at 25 rpm for 4 minutes.

$$Friability(\%) = \frac{W_1 - W_2}{W_1} \times 100$$

where:

- W_1 = Initial weight
- W_2 = Final weight

A friability value below 1% was considered acceptable.

Drug Content Uniformity

An accurately weighed quantity of powdered tablets equivalent to one tablet was dissolved in the selected solvent, filtered, diluted appropriately, and analyzed spectrophotometrically. Drug content was calculated using the calibration curve.

Wetting Time

Wetting time was determined by placing a tablet on a folded tissue paper saturated with distilled water in a Petri dish. The time required for complete wetting was recorded.

Water Absorption Ratio

The water absorption ratio was calculated using:

$$R = \frac{W_a - W_b}{W_b} \times 100$$

where:

- (W_b) = Weight before wetting
- (W_a) = Weight after wetting

Disintegration Time

Disintegration testing was performed using the USP disintegration apparatus containing distilled water maintained at **37 ± 0.5°C**. The time required for complete tablet disintegration was recorded.

2.9 In Vitro Dissolution Study

Drug release studies were performed using the **USP Type II (Paddle) dissolution apparatus**.

Experimental conditions included:

- Dissolution medium: 900 mL phosphate buffer (pH appropriate for the study)
- Temperature: **37 ± 0.5°C**
- Paddle speed: **50 rpm**

Samples were withdrawn at predetermined time intervals and replaced with fresh dissolution medium maintained at the same temperature. The samples were filtered, suitably diluted, and analyzed using a UV–Visible spectrophotometer at the predetermined wavelength. The cumulative percentage drug release was calculated and plotted against time.

2.10 Accelerated Stability Study

The optimized formulation was subjected to accelerated stability testing according to **ICH Q1A(R2)** recommendations. Tablets were stored under accelerated conditions (e.g., **40 ± 2°C/75 ± 5% RH**) for the specified study period. Samples

were periodically evaluated for physical appearance, drug content, disintegration time, and dissolution profile to assess formulation stability.

2.11 Statistical Analysis

All experimental studies were performed in triplicate, and the results were expressed as **mean ± standard deviation (SD)**. Comparative analysis among formulations was performed to identify the optimized oral disintegrating tablet based on rapid disintegration, maximum drug release, and compliance with pharmacopeial quality requirements.

3. Results and Discussion

3.1 Preformulation Studies

Preformulation investigations were performed to characterize rizatriptan benzoate and assess its suitability for oral disintegrating tablet (ODT) formulation. The drug was obtained as a white crystalline powder and exhibited physicochemical properties consistent with pharmacopeial standards. UV spectrophotometric analysis demonstrated a well-defined absorption maximum at the selected analytical wavelength. The calibration curve showed excellent linearity over the concentration range studied, with a correlation coefficient (R^2) close to 1.0, confirming the suitability of the analytical method for quantitative estimation of rizatriptan benzoate during formulation development.

Fourier-transform infrared (FTIR) spectroscopy confirmed the compatibility of rizatriptan benzoate with the selected excipients. The characteristic absorption bands corresponding to the functional groups of the drug were retained in the optimized formulation without significant peak shifts or disappearance, indicating the absence of chemical interaction during formulation and compression. These findings support the suitability of the selected excipients for developing stable oral disintegrating tablets.

3.2 Evaluation of Powder Blend (Pre-compression Parameters)

The powder blends prepared for direct compression were evaluated for flowability and compressibility. The values of angle of repose, bulk density, tapped density, Carr's compressibility index, and Hausner's ratio were within acceptable pharmacopeial limits, demonstrating satisfactory flow characteristics.

The angle of repose indicated good powder flow, ensuring uniform die filling during tablet compression. Carr's index values below 20% and Hausner's ratio values below 1.25 suggested good compressibility and minimal interparticle friction. These results confirmed that all powder blends were suitable for direct compression without requiring granulation, thereby simplifying the manufacturing process.

3.3 Evaluation of Oral Disintegrating Tablets

All prepared formulations were evaluated for physical quality parameters, including weight variation, hardness, thickness, friability, drug content, wetting time, water absorption ratio, and disintegration time.

The tablets showed uniform appearance and satisfactory mechanical strength. Weight variation for all batches remained within the pharmacopeial acceptance limits, indicating consistent die filling during compression. Hardness values were sufficient to withstand handling while allowing rapid tablet disintegration. Friability values were below 1%, confirming adequate resistance to abrasion during packaging and transportation.

Drug content analysis demonstrated uniform distribution of rizatriptan benzoate in all formulations, indicating efficient mixing of the powder blend and reproducible manufacturing. The observed drug content complied with pharmacopeial specifications, ensuring dose uniformity and therapeutic reliability.

3.4 Wetting Time, Water Absorption Ratio, and Disintegration Time

Rapid wetting and disintegration are essential characteristics of oral disintegrating tablets because they directly influence the onset of drug dissolution and patient acceptability.

Among the investigated formulations, tablets containing crospovidone exhibited the shortest wetting time and the highest water absorption ratio. The highly porous structure of crospovidone facilitated rapid penetration of saliva into the tablet matrix through capillary action, resulting in faster tablet breakup.

Formulations containing croscarmellose sodium also demonstrated satisfactory disintegration owing to combined swelling and wicking mechanisms. Sodium starch glycolate effectively promoted tablet swelling; however, higher concentrations occasionally delayed complete disintegration

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because excessive swelling may produce a viscous gel layer around the tablet particles.

The optimized formulation disintegrated within approximately **20–30 seconds**, meeting the desired characteristics of oral disintegrating tablets and providing rapid drug availability for dissolution.

3.5 In Vitro Dissolution Studies

The dissolution profiles of all formulations demonstrated that the type and concentration of superdisintegrant significantly influenced drug release.

All formulations released rizatriptan benzoate rapidly; however, notable differences were observed in dissolution efficiency. Tablets prepared with crospovidone exhibited the highest cumulative drug release, exceeding **90% within 15 minutes**. This rapid dissolution can be attributed to the efficient capillary action of crospovidone, which accelerates water penetration into the tablet matrix and promotes rapid disintegration.

Formulations containing croscarmellose sodium showed slightly slower dissolution but still achieved acceptable drug release within the specified time. Sodium starch glycolate formulations demonstrated comparatively lower dissolution efficiency at higher concentrations because extensive swelling may reduce the effective diffusion of dissolution medium into the tablet matrix.

Comparison with the marketed formulation indicated that the optimized ODT exhibited an equivalent or improved dissolution profile, suggesting that the developed formulation is capable of providing rapid drug release suitable for acute migraine therapy.

3.6 Comparative Performance of Superdisintegrants

A comparative evaluation of the investigated superdisintegrants demonstrated clear differences in formulation performance.

Crospovidone consistently produced:

- The shortest wetting time
- Rapid water uptake
- Fast tablet disintegration
- Highest cumulative drug release
- Superior overall tablet performance

Croscarmellose sodium produced satisfactory disintegration through combined swelling and capillary action, whereas sodium starch glycolate primarily relied on swelling. Although all three superdisintegrants improved tablet performance, crospovidone was identified as the most effective for the development of rizatriptan benzoate ODTs.

3.7 Accelerated Stability Studies

The optimized formulation was subjected to accelerated stability testing under ICH-recommended storage conditions.

Throughout the study period, no significant changes were observed in tablet appearance, hardness, friability, drug content, disintegration time, or dissolution profile. Drug release remained within acceptable limits, and the tablets retained their rapid disintegration characteristics.

These findings indicate that the optimized formulation possesses satisfactory physical and chemical stability and is suitable for long-term storage under recommended conditions.

3.8 Discussion

The present investigation successfully demonstrated that oral disintegrating tablets of rizatriptan benzoate can be developed by the direct compression technique using suitable superdisintegrants. Direct compression proved to be a simple, economical, and reproducible manufacturing method while maintaining acceptable tablet quality attributes.

Among the investigated superdisintegrants, crospovidone exhibited superior performance because of its highly porous structure and capillary action mechanism, which facilitated rapid water penetration and efficient tablet disintegration. The optimized formulation disintegrated within approximately **20–30 seconds** and released more than **90% of the drug within 15 minutes**, making it particularly suitable for rapid relief of migraine symptoms.

The absence of drug–excipient incompatibility confirmed by FTIR analysis and the favorable accelerated stability results further support the pharmaceutical suitability of the optimized formulation. Overall, the developed ODT fulfilled pharmacopeial quality requirements and demonstrated enhanced dissolution performance compared with conventional tablet formulations. These characteristics suggest that the optimized formulation has the potential to improve patient convenience, adherence, and therapeutic outcomes in the management of acute migraine attacks.

4. Conclusion

The present study successfully developed and evaluated oral disintegrating tablets (ODTs) of rizatriptan benzoate using the direct compression technique with different superdisintegrants. All formulations demonstrated satisfactory pre-compression flow properties and post-compression quality attributes, including acceptable weight variation, hardness, friability, thickness, and drug content uniformity. The results confirmed that the selected excipients and manufacturing process were suitable for producing robust ODT formulations.

Among the superdisintegrants investigated, **crospovidone** produced the most desirable pharmaceutical performance, exhibiting the shortest wetting time, rapid tablet disintegration, and the highest dissolution rate. The optimized formulation disintegrated within approximately **20–30 seconds** and released **more than 90% of rizatriptan benzoate within 15 minutes**, indicating excellent immediate-release characteristics.

FTIR compatibility studies demonstrated no significant interaction between rizatriptan benzoate and the selected excipients, confirming formulation compatibility. Accelerated stability studies further established that the optimized formulation maintained its physical integrity, drug content, and dissolution characteristics under stress conditions.

Overall, the optimized rizatriptan benzoate ODT offers a promising patient-friendly dosage form with improved convenience, enhanced dissolution, and the potential for a faster onset of therapeutic action. Such a formulation may improve treatment adherence, particularly in patients experiencing dysphagia, nausea, or difficulty swallowing during acute migraine attacks. Further **in vivo pharmacokinetic and bioequivalence studies** are recommended to establish in vitro–in vivo correlation and confirm the clinical performance of the developed formulation.

Future Scope

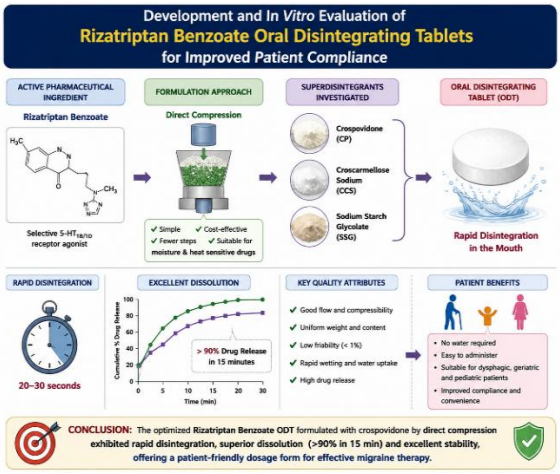
Future research may focus on:

- **In vivo pharmacokinetic evaluation** of the optimized ODT formulation.
- **Bioequivalence studies** comparing the optimized formulation with the marketed product.
- Establishment of **in vitro–in vivo correlation (IVIVC)**.
- Application of **Quality by Design (QbD)** for systematic formulation optimization.
- Scale-up studies and process validation for industrial manufacturing.
- Long-term stability studies under **ICH climatic conditions**.
- Development of taste-masked formulations with improved organoleptic properties.
- Exploration of advanced co-processed excipients and multifunctional superdisintegrants to further enhance tablet performance.

Abbreviations

Abbreviation	Full Form
API	Active Pharmaceutical Ingredient
ODT	Oral Disintegrating Tablet
CP	Crospovidone
CCS	Croscarmellose Sodium
SSG	Sodium Starch Glycolate
MCC	Microcrystalline Cellulose
FTIR	Fourier Transform Infrared Spectroscopy
UV	Ultraviolet
USP	United States Pharmacopeia
IP	Indian Pharmacopoeia
RH	Relative Humidity
SD	Standard Deviation
IVIVC	In Vitro–In Vivo Correlation
QbD	Quality by Design
ICH	International Council for Harmonisation

Figure 1. Graphical Abstract



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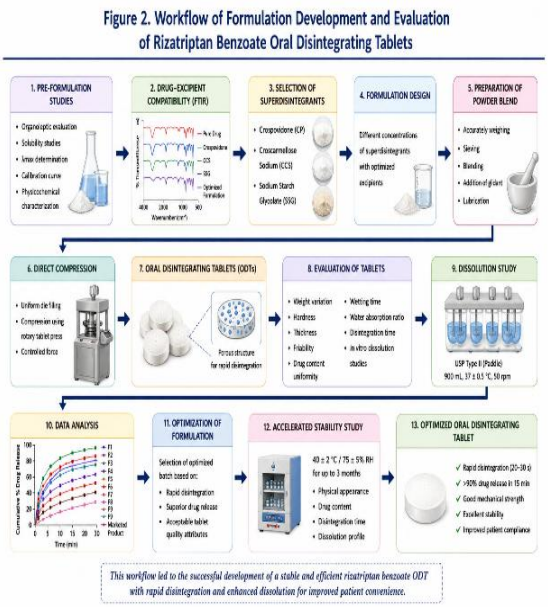

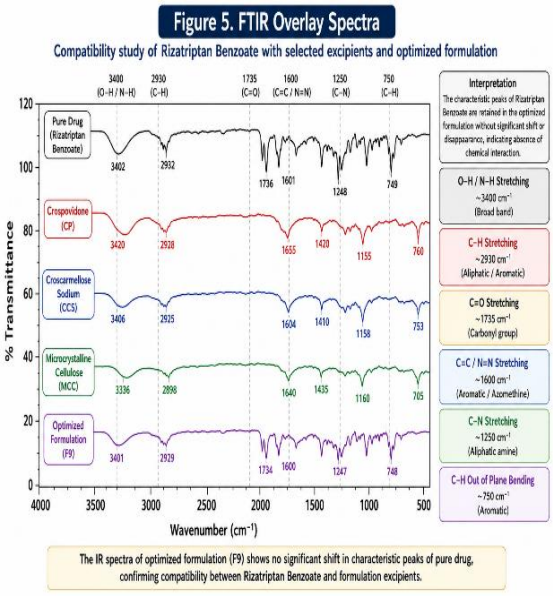

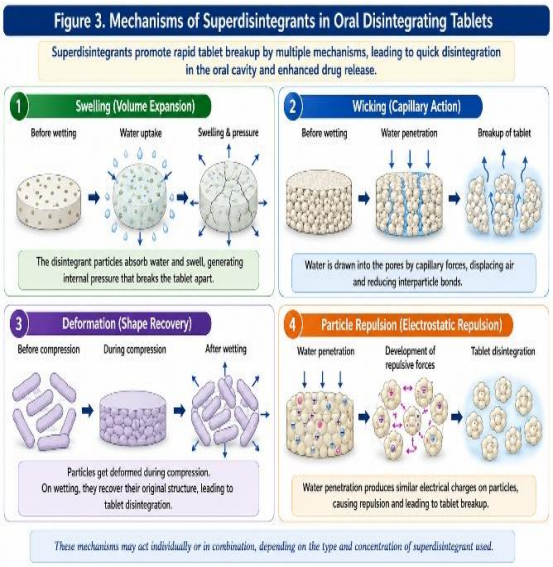

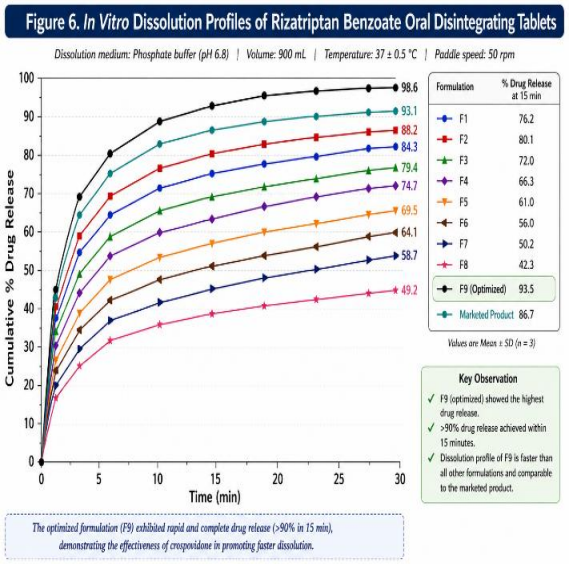

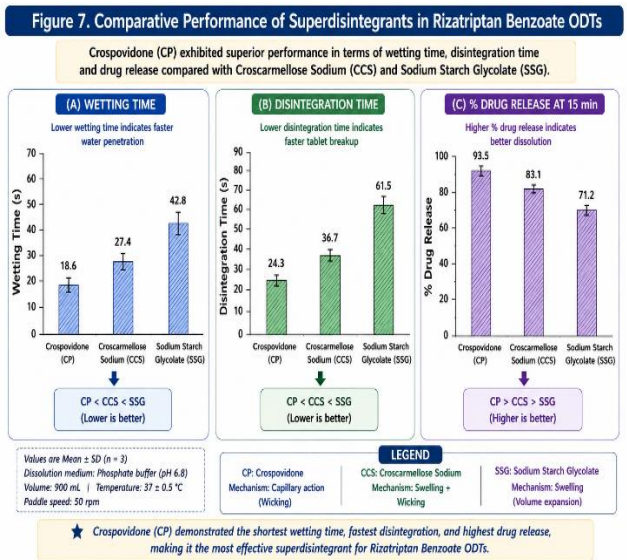

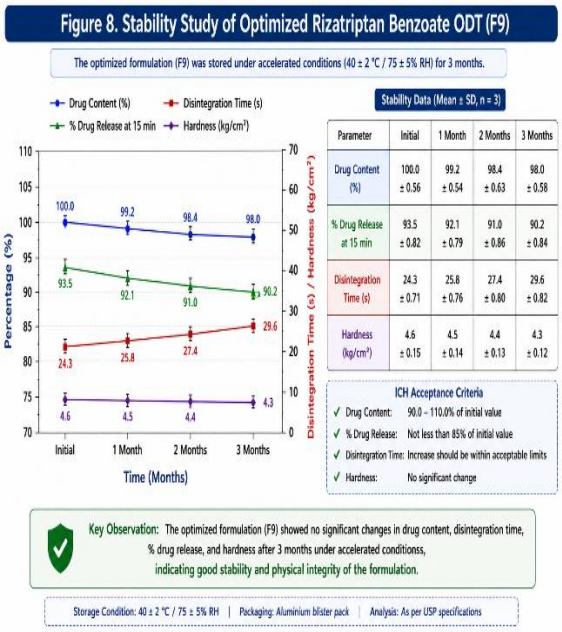

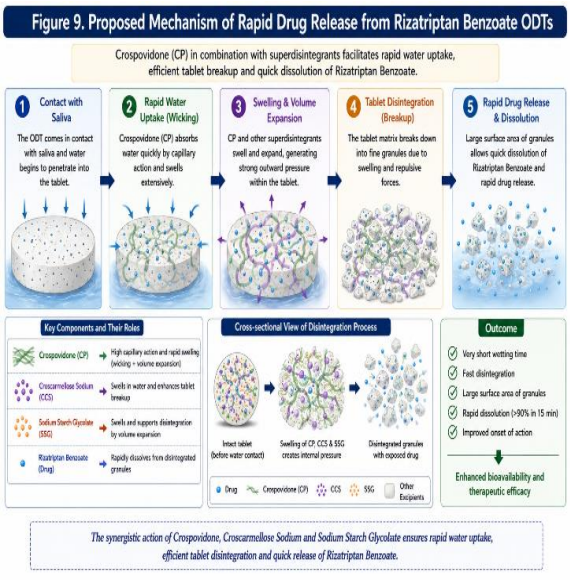

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