

DESIGN AND DEVELOPMENT OF ROXITHROMYCIN FAST DISSOLVING TABLETS

Malkhan Singh*, Dr. Arun Patel, Mr. Shailendra Patel

Shri Ram Group of Institution, Faculty of Pharmacy near Iti Madhotal Jabalpur.

Article Received on 15 August 2026,
Article Revised on 05 Sept. 2026,
Article Published on 16 Sept. 2026,

<https://doi.org/10.5281/zenodo.22767883>

*Corresponding Author

Malkhan Singh

Shri Ram Group of Institution, Faculty
of Pharmacy near Iti Madhotal
Jabalpur.



How to cite this Article: Malkhan Singh*, Dr. Arun Patel, Mr. Shailendra Patel (2026). Design And Development Of Roxithromycin Fast Dissolving Tablets. World Journal of Pharmaceutical Research, 15(18), 700–715. This work is licensed under Creative Commons Attribution 4.0 International license.

ABSTRACT

Background: Roxithromycin is a semi-synthetic macrolide antibiotic with very low aqueous solubility, making dissolution an important formulation challenge. Fast dissolving tablets (FDTs) can provide rapid disintegration in the oral cavity without water and may improve convenience for patients who have difficulty swallowing conventional tablets. **Objective:** The study aimed to develop and evaluate Roxithromycin fast dissolving tablets using a solid-dispersion approach with PEG 4000 and different superdisintegrants, including sodium starch glycolate, croscarmellose sodium and Gum Karaya. **Methods:** Preformulation studies included organoleptic examination, solubility testing, loss on drying, melting-point determination, UV spectrophotometry and FTIR analysis. Roxithromycin–PEG 4000 physical mixtures and solid dispersions were

prepared at drug: polymer ratios of 1: 1, 1: 2 and 1: 3. Tablets equivalent to 150 mg Roxithromycin were prepared by direct compression and evaluated for powder-flow properties, thickness, hardness, friability, weight variation, drug content, disintegration and in-vitro dissolution. Results: Roxithromycin was soluble in methanol and ethanol and sparingly soluble in water, phosphate buffer pH 6.8, 0.1 N HCl, 0.1 N NaOH and chloroform. Loss on drying was $0.175 \pm 0.005\%$ and melting point was 118–120°C. The reported 1: 1 drug: PEG 4000 solid dispersion was selected for subsequent tablet development. Powder blends showed bulk density of 0.354–0.368 g/mL, tapped density of 0.458–0.472 g/mL, Carr's index of 20.306–23.377% and Hausner's ratio of 1.255–1.305. Tablet hardness was 3.2–3.4 kg/cm², friability 0.685–0.821%, thickness 2.8–2.9 mm and drug content 98.45–99.74%. Formulation F5 showed the shortest reported disintegration time (62 ± 4 s). The

source document reports a release-kinetic analysis for batch F7, with R^2 values of 0.992, 0.946, 0.999 and 1.000 for zero-order, first-order, Higuchi and Korsmeyer–Peppas models, respectively. **Conclusion:** The study demonstrates the feasibility of combining PEG 4000 solid dispersion with rapid-disintegrating excipients to develop a Roxithromycin FDT. The formulation showed acceptable physical quality and rapid disintegration. However, the source document contains a batch-label discrepancy between the optimized F5 formulation and the subsequent F7 release-kinetic section; this should be verified against the original laboratory records before publication.

KEYWORDS: Roxithromycin; fast dissolving tablet; orally disintegrating tablet; solid dispersion; PEG 4000; superdisintegrant; Gum Karaya; dissolution.

1. INTRODUCTION

Oral administration remains one of the most convenient and economical routes for drug delivery. Nevertheless, conventional tablets and capsules can be difficult to swallow in pediatric and geriatric populations and in patients experiencing nausea, dysphagia or limited access to water. Fast dissolving or orally disintegrating tablets are designed to disintegrate rapidly in saliva and can therefore be administered without water. The uploaded study describes FDTs as dosage forms intended to disintegrate generally within seconds and identifies improved convenience, patient acceptance and potentially faster drug dissolution as important advantages.

FDT development is strongly influenced by the physicochemical properties of the active pharmaceutical ingredient and the selection of excipients. Important formulation challenges include poor aqueous solubility, unpleasant taste, moisture sensitivity, mechanical strength and the need to maintain rapid disintegration while retaining adequate tablet integrity. Superdisintegrants such as sodium starch glycolate, croscarmellose sodium and crospovidone promote rapid water uptake and tablet breakup, while natural polymers may provide additional formulation functionality.

Roxithromycin is a semi-synthetic macrolide antibiotic. The source document reports a molecular weight of 837.0465 and molecular formula $C_{41}H_{76}N_2O_{15}$. Its antibacterial action is attributed to binding to the 50S ribosomal subunit and inhibition of peptide translocation. The drug is described as very slightly soluble in water and as having dissolution-rate-limited absorption, making dissolution enhancement a rational formulation objective.

Solid dispersion is a commonly used strategy for improving the apparent dissolution of poorly water-soluble drugs. In the present study, PEG 4000 was selected as the carrier. Physical mixtures and solid dispersions were compared at different drug-to-polymer ratios before incorporation into FDTs. The tablet formulations were then prepared by direct compression using different superdisintegrants.

2. AIM AND OBJECTIVES

The principal aim was to formulate and evaluate Roxithromycin fast dissolving tablets using a solid-dispersion approach and selected disintegrants.

- To characterize Roxithromycin by organoleptic, solubility, loss-on-drying, melting-point, UV and FTIR studies.
- To investigate Roxithromycin–PEG 4000 physical mixtures and solid dispersions at different drug: polymer ratios.
- To select a suitable solid-dispersion ratio for tablet formulation.
- To prepare Roxithromycin FDTs by direct compression using different superdisintegrants.
- To evaluate pre-compression powder characteristics and post-compression tablet quality.
- To investigate in-vitro dissolution and release kinetics of the reported optimized batch.

3. MATERIALS AND METHODS

3.1 Materials and Instruments

Roxithromycin was procured from Bioplus Life Science, Bangalore. Methanol, ethanol, chloroform, hydrochloric acid, potassium dihydrogen phosphate, sodium hydroxide, HPMC, sodium starch glycolate, croscarmellose sodium, citric acid and crospovidone were obtained from the suppliers listed in the source document. The study also used PEG 4000, Gum Karaya, mannitol, microcrystalline cellulose, talc and magnesium stearate for formulation development.

Instrument	Manufacturer/Source
FTIR	Bruker Alpha, Germany
Dissolution apparatus	Labindia DS 8000
UV-visible spectrophotometer	Labindia
Disintegration apparatus	Electronic India
pH meter	Electronic India
Hardness tester	PharmaChem Machineries
Melting-point apparatus	Chemi line CL 725
Karl Fischer / moisture system	Chemi line CL 510
Electronic balance	Wensor

3.2 Preformulation Studies

Organoleptic properties were assessed for colour, odour, taste and appearance. Solubility was examined by adding 5 mg Roxithromycin to 10 mL of methanol, ethanol, chloroform or distilled water and shaking at approximately room temperature. Loss on drying was measured using an IR moisture balance after exposure of 5 g powder to 100–105°C for 15 min. Melting point was determined by the open-capillary method.

For UV analysis, a 10 mg stock solution was prepared in 10 mL methanol and diluted to a working concentration of 10 µg/mL. Aliquots were transferred to 10 mL volumetric flasks and made up with phosphate buffer pH 6.8. The source document reports analysis at 278 nm. For FTIR, approximately 10 mg drug was triturated with 100 mg dried KBr, compressed into a pellet and scanned from 400 to 2000 cm⁻¹.

3.3 Preparation of Roxithromycin–PEG 4000 Systems

Physical mixtures were prepared by accurately weighing Roxithromycin and PEG 4000, gently grinding them together for 2 min, passing the mixture through a sieve and storing the resulting powder in a desiccator. Drug: PEG 4000 ratios of 1: 1, 1: 2 and 1: 3 were investigated.

For solid dispersion, PEG 4000 was melted at 58 ± 1°C and Roxithromycin was incorporated with stirring. After cooling and solidification at room temperature, the mass was pulverized and sieved. A 1: 1 solid dispersion containing 150 mg Roxithromycin and 150 mg PEG 4000 was subsequently used for further formulation work.

3.4 Preparation of Fast Dissolving Tablets

FDTs containing 150 mg Roxithromycin equivalent were prepared by direct compression. Three superdisintegrant systems were investigated: sodium starch glycolate (10 or 20 mg), croscarmellose sodium (10 or 20 mg), and Gum Karaya (10 or 20 mg). Mannitol was maintained at 10 mg, microcrystalline cellulose at 19 or 29 mg according to batch, talc at 5 mg and magnesium stearate at 6 mg. The powder blend was mixed geometrically, passed through mesh 60 and compressed using 8-mm punches. Six formulations, F1–F6, each with a total tablet weight of 360 mg, were prepared.

Table 1: Composition of Roxithromycin FDT formulations.

Ingredient (mg)	F1	F2	F3	F4	F5	F6
Roxithromycin–PEG 4000 solid dispersion (equiv. 150 mg ROX)	300	300	300	300	300	300
Sodium starch glycolate	10	20	–	–	–	–
Croscarmellose sodium	–	–	10	20	–	–
Gum Karaya	–	–	–	–	10	20
Mannitol	10	10	10	10	10	10
Microcrystalline cellulose	29	19	29	19	29	19
Talc	5	5	5	5	5	5
Magnesium stearate	6	6	6	6	6	6
Total weight	360	360	360	360	360	360

3.5 Evaluation of Powder and Tablets

Pre-compression properties included angle of repose, loose bulk density, tapped bulk density, Carr's compressibility index and Hausner's ratio. Post-compression evaluation included tablet appearance, thickness, weight variation, hardness, friability and drug content. For drug-content analysis, powdered tablets were extracted with phosphate buffer pH 6.8 and assayed spectrophotometrically at 278 nm.

In-vitro dissolution was performed using USP paddle apparatus in 900 mL dissolution medium at $37 \pm 0.2^\circ\text{C}$ and 75 rpm. Samples were withdrawn at defined intervals, replaced with fresh medium and analyzed at 278 nm. The source document additionally describes mathematical fitting to zero-order, first-order, Higuchi and Korsmeyer–Peppas models.

4. RESULTS

4.1 Preformulation Findings

Parameter	Observed result
Colour	White
Odour	Odourless
Taste	Bitter
Appearance	Crystalline powder
Solubility in methanol	Soluble
Solubility in ethanol	Soluble
Solubility in chloroform	Sparingly soluble
Solubility in distilled water	Sparingly soluble
Solubility in phosphate buffer pH 6.8	Sparingly soluble
Solubility in 0.1 N HCl	Sparingly soluble
Solubility in 0.1 N NaOH	Sparingly soluble
Loss on drying	$0.175 \pm 0.005\%$
Melting point	118–120°C

The drug was described as a white, odourless, bitter crystalline powder. The low aqueous solubility was consistent with the formulation rationale for use of a solid-dispersion carrier. The reported calibration data at 278 nm were 0.183, 0.385, 0.568, 0.751 and 0.962 mean absorbance units at 5, 10, 15, 20 and 25 µg/mL, respectively. FTIR analysis was performed to characterize the drug; the source document provides the spectrum but does not provide a complete peak-assignment table in the extracted text.

4.2 Comparison of Physical Mixtures

Time (min)	1: 1 (%)	1: 2 (%)	1: 3 (%)	Pure drug (%)
30	22.25	24.56	26.65	9.12
60	32.14	35.56	39.98	11.23
120	36.65	39.38	42.23	16.65
240	45.56	48.89	55.56	18.89
360	48.89	50.56	62.23	20.23
480	48.96	50.23	69.98	22.32

The physical-mixture data showed higher cumulative release with increasing PEG 4000 ratio, but the source document characterized the release as erratic and reported a bursting effect. On this basis, solid dispersion was selected as the preferred approach. The document further states that the 1: 1 solid dispersion provided a more controlled release than the 1: 2 and 1: 3 systems and was therefore selected for subsequent tablet development.

4.3 Pre-compression Properties

Batch	Bulk density (g/mL)	Tapped density (g/mL)	Carr index (%)	Hausner ratio
F1	0.365	0.458	20.306	1.255
F2	0.358	0.465	23.011	1.299
F3	0.362	0.472	23.305	1.304
F4	0.368	0.465	20.860	1.264
F5	0.358	0.465	23.011	1.299
F6	0.354	0.462	23.377	1.305

Bulk density ranged from 0.354 to 0.368 g/mL and tapped density from 0.458 to 0.472 g/mL. Carr's index ranged from 20.306 to 23.377%, while Hausner's ratio ranged from 1.255 to 1.305. The source document interpreted the blends as having acceptable flow and compressibility for tablet manufacture.

4.4 Post-compression Properties

Batch	Hardness (kg/cm ²)	Friability (%)	Weight (mg)	Thickness (mm)	Drug content (%)
F1	3.2 ± 0.2	0.756 ± 0.004	465 ± 5	2.9 ± 0.1	99.85 ± 0.25
F2	3.3 ± 0.1	0.745 ± 0.003	460 ± 4	2.8 ± 0.1	98.85 ± 0.32
F3	3.4 ± 0.1	0.821 ± 0.007	458 ± 6	2.8 ± 0.2	99.12 ± 0.14
F4	3.2 ± 0.2	0.774 ± 0.003	462 ± 3	2.9 ± 0.1	98.45 ± 0.15
F5	3.4 ± 0.1	0.685 ± 0.005	465 ± 2	2.8 ± 0.1	99.74 ± 0.38
F6	3.3 ± 0.1	0.745 ± 0.006	463 ± 5	2.9 ± 0.2	99.02 ± 0.25

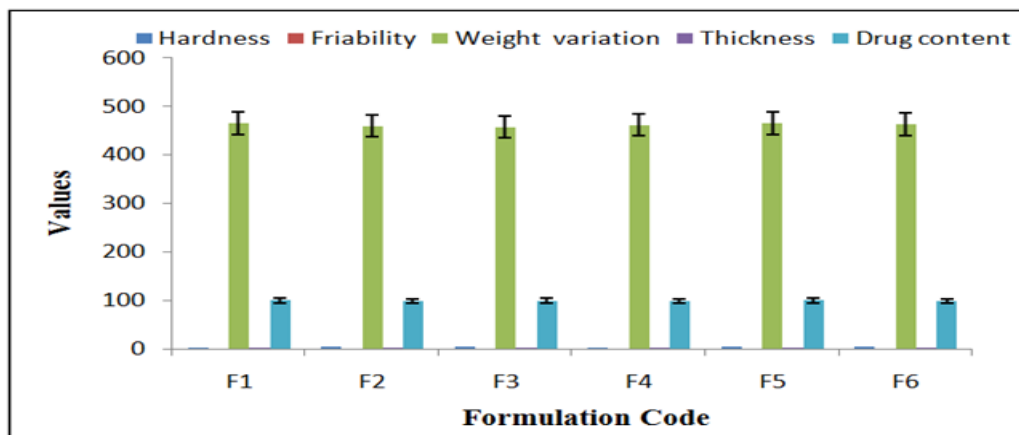


Fig 4.1 Results of Post-Compression parameters of all formulations.

4.5 Disintegration and Release-Kinetic Findings

Formulation	Disintegration time (s)
F1	120 ± 5
F2	105 ± 4
F3	95 ± 6
F4	85 ± 5
F5	62 ± 4
F6	75 ± 3

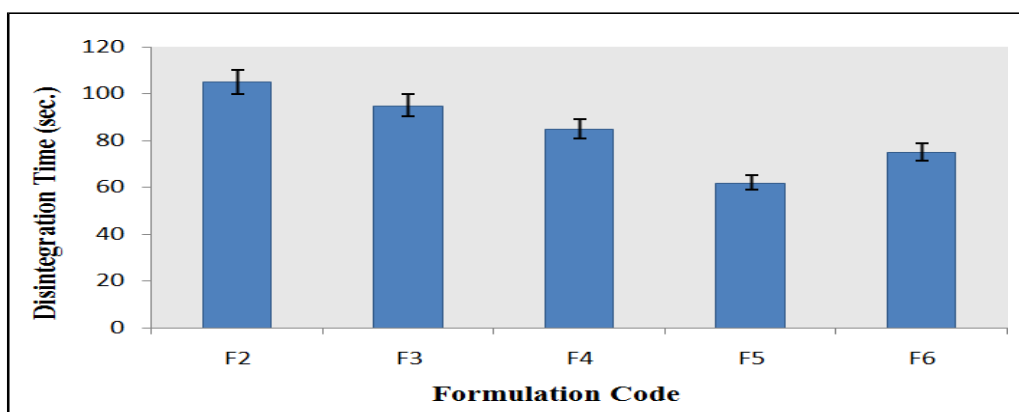


Fig 4.2: Results of Disintegration Time of all formulations.

Disintegration time decreased across the formulation series, with F5 showing the shortest reported value of 62 ± 4 s. The source document therefore identifies F5 as the optimized formulation. The relatively low disintegration time of F5 was accompanied by the lowest reported friability ($0.685 \pm 0.005\%$) and the highest reported drug content ($99.74 \pm 0.38\%$) among the six batches.

An important reporting issue is present in the source: the release-kinetic section labels the analyzed optimized batch as F7, although the formulation-composition and disintegration sections contain only F1–F6 and identify F5 as optimized. The release table reports 38.56% drug release at 2 min, 65.5% at 5 min and 98.45% at 10 min for the batch labeled F7. Because the original experimental record is not available here, these labels should not be silently changed.

Model	R ² for reported F7 batch
Zero order	0.992
First order	0.946
Higuchi	0.999
Korsmeyer–Peppas	1.000

Based on the reported regression coefficients, the source document concludes that the release data best fit the Korsmeyer–Peppas model. The high R² value should be interpreted as a model-fit observation rather than evidence of a specific in-vivo release mechanism.

4.5 Release kinetics of Roxithromycin fast dissolving tablets

4.6: In-vitro drug release data for optimized formulation F7.

Time (min)	Square Root of Time(h) ^{1/2}	Log Time	Cumulative*% Drug Release	Log Cumulative % Drug Release	Cumulative % Drug Remaining	Log Cumulative % Drug Remaining
2	1.414	0.301	38.56	1.586	61.44	1.788
5	2.236	0.699	65.5	1.816	34.5	1.538
10	3.162	1	98.45	1.993	1.55	0.190

Zero order release kinetics of formulation F7

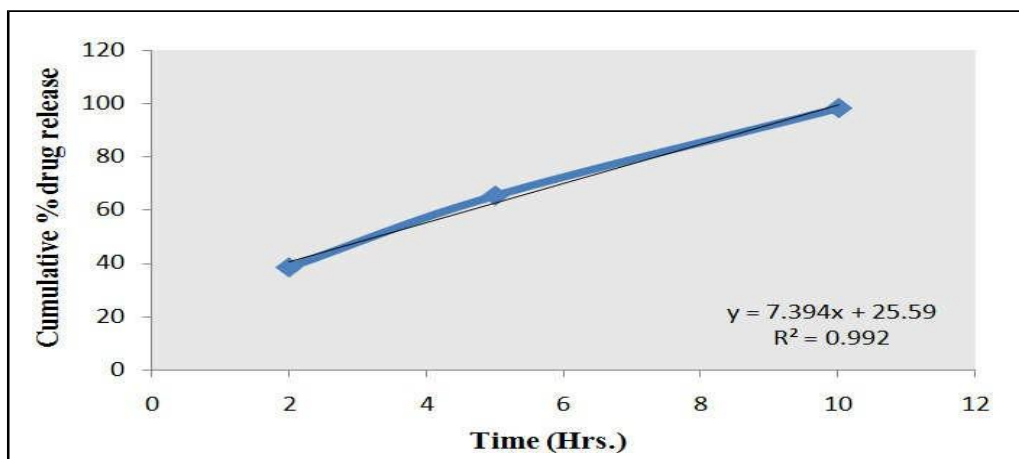


Figure 4.3: Graph of zero order release Kinetics of formulation F7.

First order release Kinetics of formulation F7

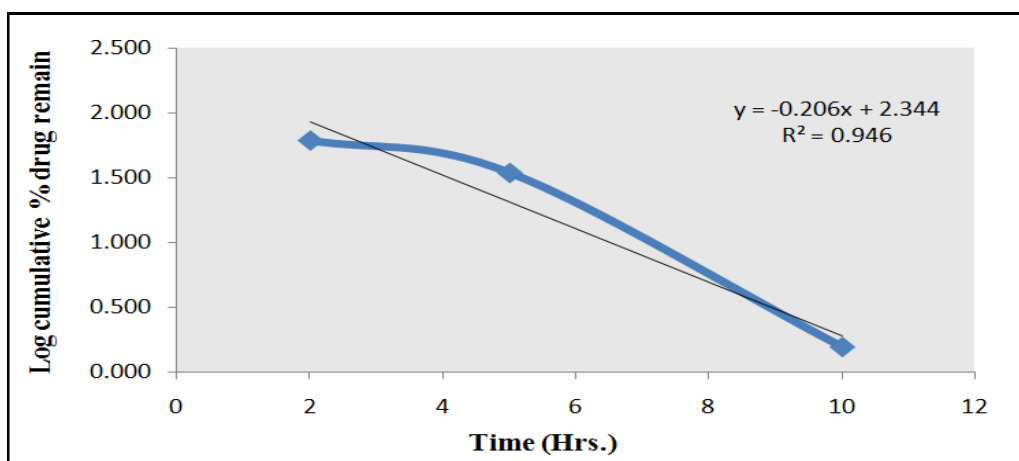


Figure 4.4: Graph of first order release kinetics of formulation F7.

Higuchi release Kinetics of formulation F7

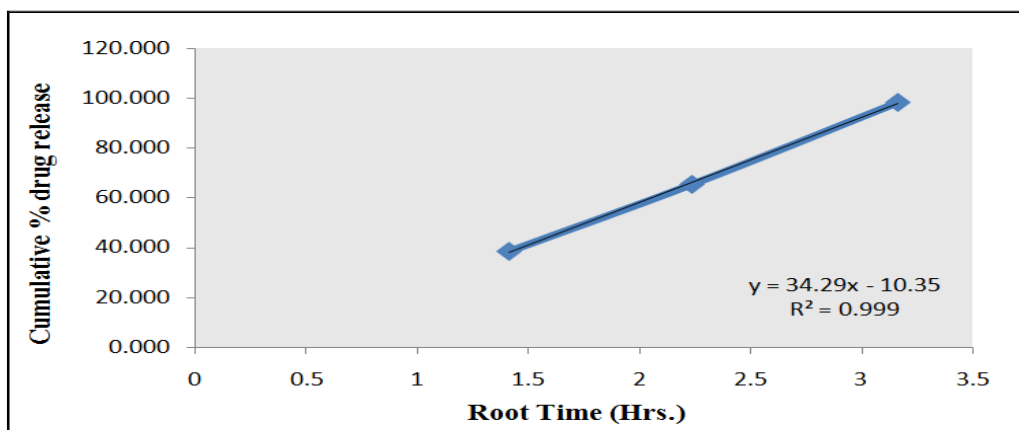


Figure 4.5: Graph of Higuchi release Kinetics of formulation F7.

Korsmeyer-Peppas release Kinetics of formulation F7

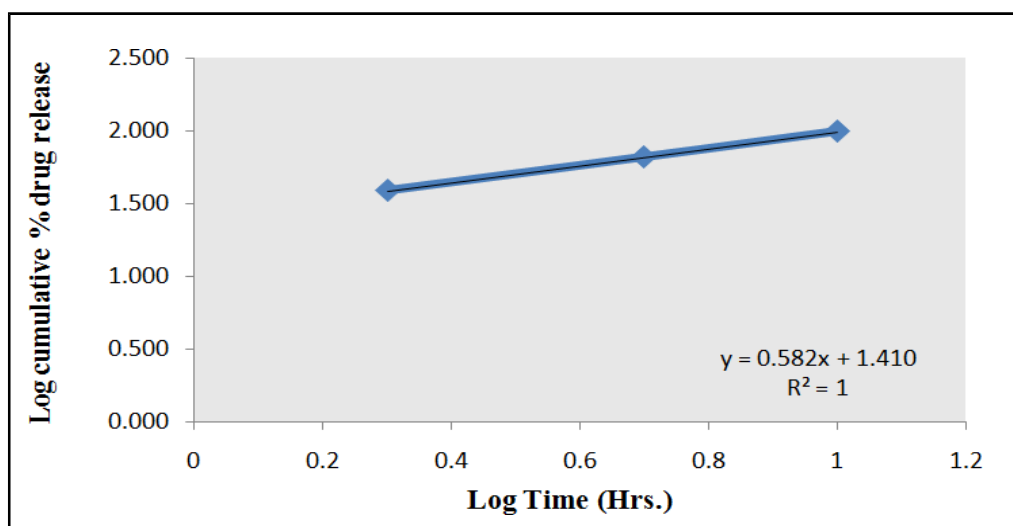


Figure 4.6: Graph of Korsmeyer-Peppas release Kinetics of formulation F7.

Table 7.10: Regression analysis data.

Batch	Zero Order	First Order	Higuchi	Korsmeyer-Peppas
	R ²	R ²	R ²	R ²
F7	0.992	0.946	0.999	1.000

When the regression coefficient values of were compared, it was observed that 'r²' values of Korsmeyer-Peppas was maximum i.e. 1.000 hence indicating drug release from formulations was found to follow Korsmeyer-Peppas kinetics.

5. DISCUSSION

The study addresses two linked formulation problems: the poor aqueous solubility of Roxithromycin and the need for a dosage form that rapidly disintegrates without water. The preformulation findings support the selection of a dissolution-enhancement strategy because Roxithromycin was only sparingly soluble in aqueous media while showing better solubility in methanol and ethanol. The reported melting point and low loss on drying additionally provide basic characterization data for the starting material.

PEG 4000 solid dispersion was used to improve the dissolution performance of Roxithromycin. The physical-mixture comparison showed that increasing PEG 4000 increased cumulative release; however, the source document reports an erratic or burst-like pattern for physical mixtures. Solid dispersion was therefore selected, and the 1: 1 ratio was carried forward. This selection reflects a balance between dissolution enhancement and

control of the release pattern rather than simply choosing the ratio with the highest cumulative release.

Direct compression was selected for the FDTs because it is a relatively simple manufacturing route and is well suited to the incorporation of superdisintegrants. Sodium starch glycolate, croscarmellose sodium and Gum Karaya were evaluated at two concentrations. The six formulations showed broadly comparable mechanical properties. Friability remained below 1%, and drug content was within the reported range of 98.45–99.74%, suggesting reasonably uniform drug distribution in the prepared batches.

The disintegration results indicate an effect of disintegrant type and concentration. F5, containing 10 mg Gum Karaya, produced the shortest disintegration time among the six batches at 62 ± 4 s, while F6 containing 20 mg Gum Karaya showed 75 ± 3 s. This observation is important because increasing disintegrant concentration did not necessarily produce a proportionally faster tablet breakup. Such behavior can arise from differences in swelling, wicking, powder packing and tablet microstructure.

The reported tablet thickness of 2.8–2.9 mm, hardness of 3.2–3.4 kg/cm² and friability below 1% indicate that the formulations achieved a compromise between mechanical integrity and rapid disintegration. For FDTs, excessive compression or excessive binder strength can slow liquid penetration, whereas insufficient mechanical strength can cause unacceptable friability. The observed values suggest that direct compression was feasible for the selected formulation composition.

The dissolution-kinetic analysis indicates the highest R^2 for the Korsmeyer–Peppas model. However, the dataset presented in the source contains only three time points for the batch labeled F7, and the batch identity conflicts with the F1–F6 formulation scheme. Therefore, the kinetic conclusion should be regarded as provisional until the original dissolution dataset and batch code are verified. A publication-quality article should report the complete dissolution profile, number of replicates, variability, fitted equations, kinetic constants and diffusional exponent.

6. Comparison with Previous Roxithromycin Formulation Studies

The literature summarized in the source document shows that Roxithromycin has previously been investigated using several dissolution- and palatability-enhancement approaches.

Dahiya *et al.* reported microsphere-based orodispersible Roxithromycin tablets prepared using solvent evaporation and direct compression; the reported optimized tablets had hardness of 4.7 ± 0.24 kg/cm², friability of $0.54 \pm 0.04\%$, disintegration time of 45 ± 0.51 s and $96.45 \pm 2.24\%$ drug release in one hour. Singh and co-workers investigated taste masking using solid dispersion and reported a 3.7-fold increase in solubility with a selected Roxithromycin: PEG 6000 system. Mohapatra *et al.* evaluated different superdisintegrants for Roxithromycin dispersible tablets, while Prasanthi investigated Roxithromycin–mannitol solid dispersions and reported improved dissolution compared with physical mixtures and conventional tablets.

Study in source literature	Approach	Reported key outcome
Dahiya <i>et al.</i>	Microspheres + orodispersible tablets	45.0 s disintegration; 96.45% release at 1 h
Singh <i>et al.</i>	Taste masking + PEG 6000 solid dispersion	Selected 1: 2 system; reported 3.7-fold solubility increase
Mohapatra <i>et al.</i>	Dispersible tablets + superdisintegrants	Superdisintegrant concentration/type influenced performance
Prasanthi	Roxithromycin–mannitol solid dispersions	Melt-method dispersion gave highest dissolution rate
Present study	PEG 4000 solid dispersion + FDT	F5 reported 62 ± 4 s disintegration

These studies collectively support the use of formulation engineering to address Roxithromycin's poor aqueous solubility and the practical limitations of conventional tablets. The present study adds a specific comparison of three disintegrant systems within a PEG 4000 solid-dispersion FDT platform. The use of Gum Karaya is particularly relevant because it provides a natural-polymer option within the formulation strategy.

7. Strengths of the Study

- The formulation strategy addresses both dissolution limitation and ease of administration.
- Multiple preformulation tests were performed before tablet development.
- Three disintegrant systems were compared at two levels, allowing formulation-level comparison.
- Both pre-compression and post-compression quality attributes were assessed.
- The study used direct compression, a relatively straightforward manufacturing approach.
- The source provides numerical results for key tablet-quality parameters rather than only descriptive observations.

8. Limitations and Reporting Issues

- The uploaded document does not provide a complete quantitative FTIR peak-assignment table in the extracted results.
- The complete dissolution profile and replicate variability for the selected tablet batch are not presented in the extracted source text.
- The release-kinetic section uses batch code F7, whereas the formulation study describes F1–F6 and identifies F5 as optimized. This must be verified before submission.
- The source text does not provide a clearly documented statistical comparison among formulations.
- The article cannot independently verify assay validation characteristics such as linearity, accuracy, precision, LOD or LOQ beyond the calibration data reported in the source.
- The source reports a stability study in the plan of work, but the extracted results section does not provide a complete stability dataset.
- The source contains some inconsistent or duplicated reference details and numbering; references should be checked against the original publications before journal submission.

9. CONCLUSION

Roxithromycin fast dissolving tablets were developed using a PEG 4000 solid-dispersion strategy and direct compression with selected superdisintegrants. Preformulation testing confirmed the poor aqueous solubility of Roxithromycin and supported the need for dissolution enhancement. The reported 1: 1 Roxithromycin: PEG 4000 solid dispersion was selected for tablet formulation. All six prepared formulations showed acceptable physical characteristics, with hardness of 3.2–3.4 kg/cm², friability below 1%, thickness of 2.8–2.9 mm and drug content of 98.45–99.74%. F5, containing 10 mg Gum Karaya, showed the shortest reported disintegration time of 62 ± 4 s and was identified as the optimized formulation in the source document.

The formulation approach demonstrates the potential of combining solid dispersion with rapid-disintegrating excipients to improve the performance of a poorly water-soluble drug in an orally convenient dosage form. Nevertheless, the manuscript should not be considered publication-ready until the F5/F7 batch-label discrepancy, complete dissolution data, statistical analysis, stability results and reference accuracy are verified against the original experimental records.

10. Future Scope

- Repeat and fully document dissolution testing of the confirmed optimized batch with sufficient replicates and statistical analysis.
- Verify the identity of the batch used for release-kinetic analysis and correct the F5/F7 labeling discrepancy.
- Determine the Korsmeyer–Peppas diffusional exponent from the appropriate portion of the dissolution curve.
- Conduct accelerated and long-term stability studies according to applicable ICH conditions and report assay, disintegration, dissolution and physical appearance over time.
- Evaluate taste masking or palatability because the drug is reported to be bitter.
- Compare Gum Karaya directly with established synthetic superdisintegrants using a statistically designed formulation study.
- Where appropriate, conduct in-vivo or biopharmaceutical studies to establish whether improved in-vitro dissolution translates into improved systemic exposure.

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Source note

1. This article was prepared from the uploaded file “roxithromycin fdt.docx” and deliberately retains the experimental values and formulation labels reported there. No unsupported experimental values have been added. Before journal submission, the authors should verify the original laboratory notebook, formulation sheet, dissolution records and reference list, especially the F5/F7 batch designation.