ISSN: 2231-3656

International Journal of Pharmacy and Industrial Research (IJPIR)

IJPIR |Vol. 16 | Issue 3 | Jul – Sep 2026

www.ijpir.com

DOI: https://doi.org/10.61096/ijpir.v16.iss3.2023.1285.1291

Formulation and Characterization of Rimegepant-Loaded Polymeric Nanoparticles for Enhanced Solubility and Oral Delivery

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Published on:

14.08.2026

Published by:

Futuristic Publications

Abstract: The present study was aimed at the formulation and characterization of Rimegepant (RMG)-loaded polymeric nanoparticles (NP) for enhanced solubility and oral delivery. RMG-loaded NP were prepared by the nanoprecipitation method using Eudragit RL100 as polymer and PVA as stabilizer. Preformulation studies confirmed the limited aqueous solubility of RMG and compatibility with selected excipients. The λmax of RMG was found to be 264 nm, and the calibration curve showed good linearity in the range of 2–12 µg/mL. Six formulations were prepared by varying polymer concentration. Among them, F3 showed optimum performance with satisfactory drug content, entrapment efficiency, redispersibility and in vitro drug release. F3 released 85.42% drug within 20 minutes compared with 50.72% release from pure drug. Release kinetics indicated first-order release with anomalous diffusion. Stability studies showed no significant changes during storage. Thus, polymeric NP improved the dissolution behaviour of RMG.

Keywords: Rimegepant; Polymeric nanoparticles; Eudragit RL100; Oral drug delivery; Migraine.

INTRODUCTION

Migraine is a recurrent neurological disorder that frequently requires rapid, convenient, self-administered treatment. Oral therapy remains important, but nausea, gastric stasis, and variability in gastrointestinal conditions can influence administration and drug release during an acute attack [1–4].

Rimegepant is a calcitonin gene-related peptide receptor antagonist used for acute treatment and prevention of migraine. It is available as an oral product, but its limited aqueous solubility provides a formulation rationale for investigating systems that improve dispersion and dissolution rather than assuming inadequate clinical oral bioavailability [5–8].

Polymeric nanoparticles can improve pharmaceutical performance of poorly soluble drugs by increasing effective surface area, improving wettability, maintaining drug in a finely dispersed state, and modifying release from a carrier matrix. Their performance depends on polymer concentration, stabilizer level, organic-to-aqueous phase ratio, drug loading, entrapment, redispersibility, and physical stability [9–12].

Eudragit RL100 is a permeable polymethacrylate that can form polymeric particles and modify drug release, while polyvinyl alcohol is commonly used to stabilize nanoparticle dispersions. Nanoprecipitation is particularly suitable when drug and polymer are soluble in a water-miscible organic phase that is introduced into an aqueous stabilizer phase [13–16].

Published nanoparticle studies support the use of polymeric carriers to improve dissolution of poorly soluble compounds [17–20]. Accordingly, the present study prepared six rimegepant-loaded Eudragit RL100 nanoparticle formulations and evaluated their physical appearance, yield, drug content, entrapment efficiency, drug loading, redispersibility, in vitro release, and accelerated stability.

MATERIALS AND METHODS

Chemicals

Rimegepant was obtained from To be obtained from API supplier. Eudragit RL100 was obtained from Evonik Industries AG, Germany. Polyvinyl alcohol was obtained from S.D. Fine-Chem Ltd., Mumbai. Acetone was obtained from Merck Life Science Pvt. Ltd., India. Ethanol was obtained from S.D. Fine-Chem Ltd., Mumbai. Potassium dihydrogen phosphate was obtained from Loba Chemie Pvt. Ltd., Mumbai. Sodium hydroxide was obtained from S.D. Fine-Chem Ltd., Mumbai. Hydrochloric acid was obtained from S.D. Fine-Chem Ltd., Mumbai. Methanol was obtained from Merck Life Science Pvt. Ltd., India. Dialysis membrane was obtained from HiMedia Laboratories Pvt. Ltd., Mumbai.

Preformulation and analytical studies

Rimegepant was evaluated for appearance, apparent solubility, UV absorbance at 264 nm, and FTIR compatibility with Eudragit RL100.

Formulation design

Six nanoparticle formulations, F1–F6, were prepared with 25 mg rimegepant and 1% w/v PVA while the Eudragit RL100 concentration was progressively increased. The acetone:ethanol ratio, organic-phase volume, and aqueous-phase volume were maintained as shown in Table 1.

Table 1: Formulation composition of rimegepant-loaded Eudragit RL100 polymeric nanoparticles

Formulation	RMG	Eudragit RL100	PVA (w/v)	Acetone: Ethanol	Organic Phase Volume	Aqueous Phase Volume
F1	25 mg	25 mg	1%	7:3	5 mL	25 mL
F2	25 mg	50 mg	1%	7:3	5 mL	25 mL
F3	25 mg	75 mg	1%	7:3	5 mL	25 mL
F4	25 mg	100 mg	1%	7:3	5 mL	25 mL
F5	25 mg	125 mg	1%	7:3	5 mL	25 mL
F6	25 mg	150 mg	1%	7:3	5 mL	25 mL

Preparation method

Rimegepant and Eudragit RL100 were dissolved in a 7:3 acetone:ethanol organic phase. This phase was added dropwise to 25 mL of 1% w/v aqueous PVA under continuous magnetic stirring at room temperature. The organic solvent was removed to obtain the nanoparticle dispersion.

FTIR compatibility study

FTIR spectra of pure rimegepant, Eudragit RL100, and the optimized formulation were compared for preservation of the principal functional-group regions and possible drug–polymer interaction.

Evaluation

The nanoparticle dispersions were evaluated for appearance, homogeneity, pH, percentage yield, drug content, entrapment efficiency, drug loading, and redispersibility.

In vitro drug release

In vitro release of pure rimegepant and the nanoparticle formulations was compared over 20 min.

Stability study

The optimized nanoparticle formulation was stored under accelerated conditions for three months and reassessed for appearance, pH, drug content, and release behaviour.

RESULTS AND DISCUSSION

Preformulation and FTIR compatibility

Rimegepant showed limited aqueous solubility. The optimized formulation retained the principal rimegepant and Eudragit RL100 FTIR regions with modest shifts and broadening, consistent with physical incorporation of the drug within the polymeric system.

Table 2: Solubility profile of rimegepant

Solvent	Observed Solubility	Inference
Distilled water	Slightly soluble	Poor aqueous solubility
Phosphate buffer pH 6.8	Slightly soluble	Limited dissolution in buffer
Phosphate buffer pH 6.8 + 0.5% w/v SLS	Soluble	Suitable release medium
Methanol	Soluble	Suitable for stock solution
Ethanol	Sparingly soluble	Useful as co-solvent
Acetone	Soluble	Suitable organic solvent
Acetone:Ethanol 7:3	Soluble	Suitable organic phase for nanoprecipitation

Table 3: Comparative FTIR peak assignments of rimegepant and Eudragit RL100 system

Functional group	Pure Rimegepant (cm^{-1})	Eudragit RL100 (cm^{-1})	Rimegepant + Eudragit RL100 (cm^{-1})
O–H stretching and N–H stretching	3390	3435	3385
Aliphatic C–H stretching	2930	2990, 2948	2990, 2948
Carbonyl C=O stretching	1715	1728	1720
Amide C=O stretching	1650	—	1652
C–N stretching	1260	—	1264
Ester C–O stretching	—	1265, 1190, 1145	1170, 1142
C–O–C stretching	1170	1100	1100
Aromatic C–H out-of-plane bending	760	752, 842	758

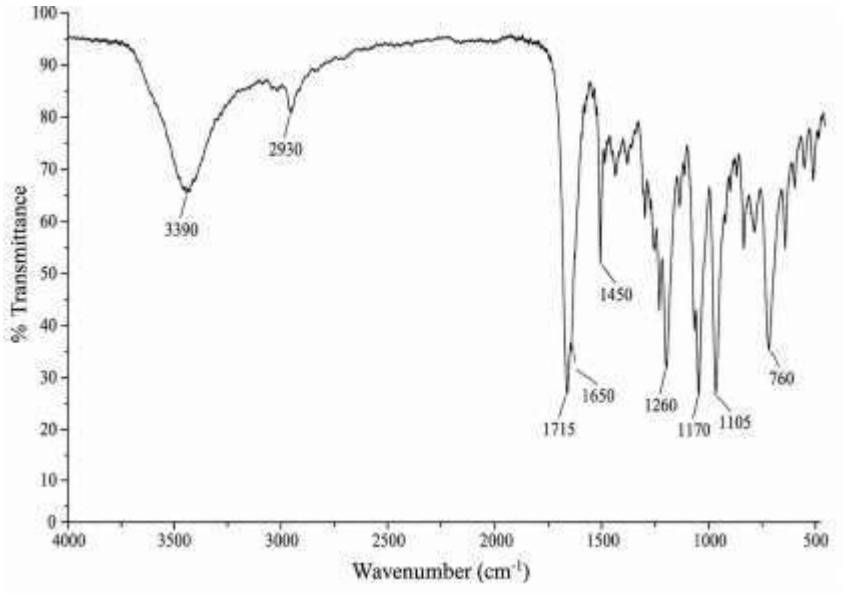

Fig 1: FTIR spectrum of pure rimegepant.

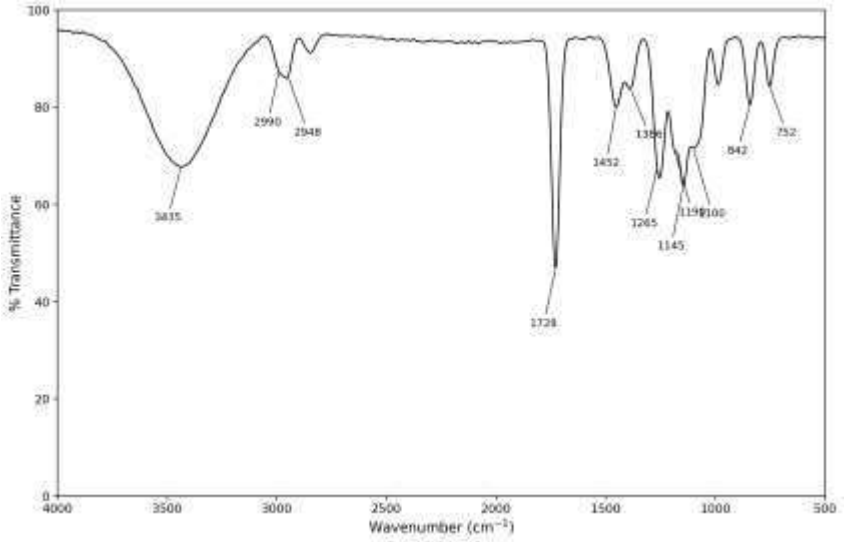

Fig 2: FTIR spectrum of Eudragit RL100.

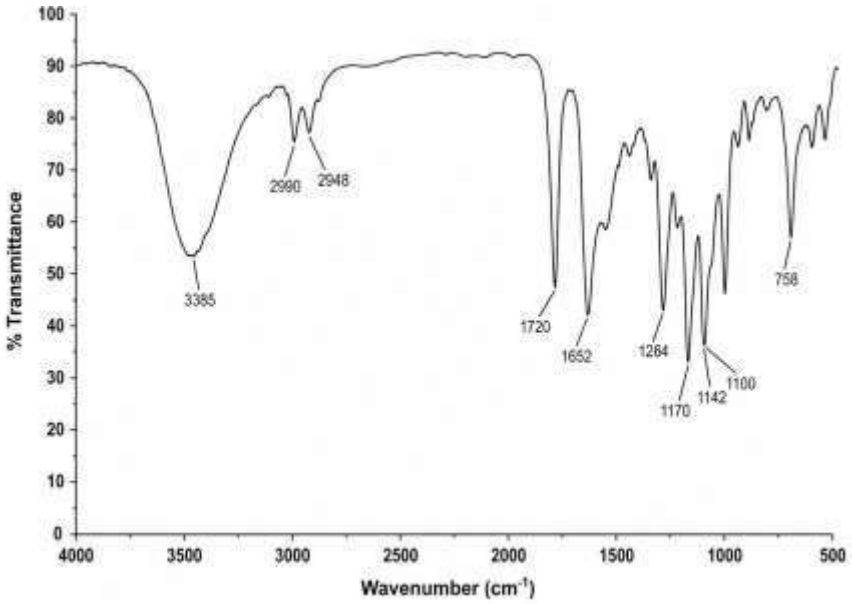

Fig 3: FTIR spectrum of the optimized formulation.

Nanoparticle characteristics

All formulations produced uniform opalescent dispersions without visible aggregation. Increasing Eudragit RL100 generally increased percentage yield and entrapment efficiency while reducing drug loading. F3 provided the most suitable balance among polymer concentration, drug content, entrapment, and redispersibility.

Table 4: Physical appearance of rimegepant-loaded polymeric nanoparticles

Formulation	Appearance	Homogeneity	Sedimentation
F1	Slightly opalescent dispersion	Uniform	No visible aggregation
F2	Opalescent dispersion	Uniform	No visible aggregation
F3	Milky white nanosuspension	Uniform	No visible aggregation
F4	Milky white nanosuspension	Uniform	Slight sedimentation on standing
F5	Dense milky dispersion	Fairly uniform	Slight sedimentation observed
F6	Dense milky dispersion	Less uniform	Mild sedimentation observed

Table 5: pH, percentage yield, drug content, and entrapment efficiency

Formulation	pH	Percentage Yield	Drug Content	Entrapment Efficiency
F1	6.42 ± 0.08	62.48 ± 4.12	91.64 ± 4.86	49.26 ± 3.18
F2	6.39 ± 0.07	68.35 ± 4.87	94.18 ± 5.12	58.74 ± 4.21
F3	6.36 ± 0.09	74.62 ± 5.24	97.36 ± 5.48	68.92 ± 5.36
F4	6.31 ± 0.08	78.15 ± 5.96	96.82 ± 5.31	76.38 ± 5.48
F5	6.28 ± 0.10	81.43 ± 6.35	95.74 ± 5.66	82.17 ± 6.09
F6	6.24 ± 0.11	84.26 ± 6.70	94.28 ± 5.92	85.46 ± 6.42

Table 6: Drug loading and redispersibility

Formulation	Drug Loading (%)	Redispersibility study
F1	24.18 ± 1.69	18 ± 1.3
F2	19.47 ± 1.35	21 ± 1.5
F3	16.72 ± 1.21	26 ± 1.8
F4	14.63 ± 1.09	34 ± 2.6
F5	12.95 ± 0.94	42 ± 3.5

F6	11.64 ± 0.83	56 ± 4.8

In vitro release and optimized formulation

The nanoparticle formulations improved rimegepant dissolution compared with the pure drug. F3 released 85.42% drug within 20 min, compared with 50.72% from pure rimegepant, and was selected as the optimized formulation. Higher polymer concentrations progressively reduced release because of the denser Eudragit matrix.

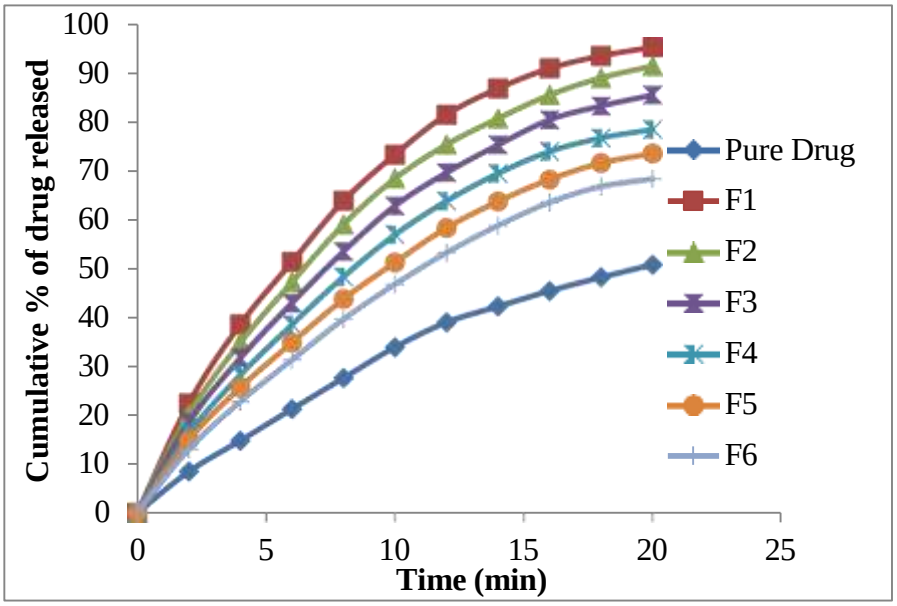

Fig 4: In vitro drug-release profiles of rimegepant and polymeric nanoparticles.

Stability

No significant deterioration in appearance, pH, drug content, or release was reported for the optimized formulation during the accelerated storage period.

CONCLUSION

Rimegepant-loaded Eudragit RL100 nanoparticles were successfully prepared by nanoprecipitation using PVA as stabilizer. Polymer concentration influenced percentage yield, entrapment, drug loading, redispersibility, and dissolution. F3 showed the most balanced formulation performance and released 85.42% rimegepant within 20 min compared with 50.72% from the pure drug. The optimized dispersion remained acceptable during the accelerated stability study.

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