

Formulation and Evaluation of Film-Coated Rifaximin Tablets Using Both Synthetic and Natural Coating Polymers

Devinder Sharma^{1*} and Prashant Beniwal²

¹Research Scholar, School of Pharmaceutical Sciences, Nirwan University Jaipur

²Professor, School of Pharmaceutical Sciences, Nirwan University Jaipur

*Corresponding Author: devindersharma525@gmail.com

Received: 28th Feb, 2026; Revised: 6th March 2026; Accepted: 7th April, 2026; Available Online: 20th April, 2026

ABSTRACT

The present study was conducted to formulate and evaluate film-coated Rifaximin tablets using synthetic polymers (Aquacoat ECD-30 and HPMC) and natural polymers (Gum Arabic and Chitosan). Core tablets were prepared by kneading method and coated by varying process parameters such as spray rate, pan speed, and coating duration. The coated tablets were evaluated for physical appearance and coating defects including surface roughness, edging, chipping, picking/sticking, and colour variation. Among the formulations, SF4, SF8, SF12, SF16, NF3, NF7, NF11, and NF16 showed zero defects with smooth surface texture and uniform coating characteristics. The study concluded that proper optimization of formulation variables and coating conditions plays an important role in producing high-quality, defect-free film-coated tablets suitable for further stability studies and large-scale manufacturing.

How to cite this article: Sharma D, Beniwal P, Formulation and Evaluation of Film-Coated Rifaximin Tablets Using Both Synthetic and Natural Coating Polymers. *Int J Drug Deliv Technol.* 2026;16(5):1064-1068; DOI: 10.25258/ijddt.16.5.100

Source of support: Nil.

Conflict of interest: None

INTRODUCTION

Film coating is a prevalent technique in the production of pharmaceutical tablets. The process entails the deposition of a thin, uniform polymeric coating over tablet surfaces to enhance their aesthetics, stability, and overall patient compliance. In comparison to sugar coating, film coating is more rapid, cost-effective, and yields tablets with negligible augmentation in weight and dimensions.¹ The coating procedure is often conducted with polymers, plasticizer's, colorants, and solvents under regulated circumstances to get a refined and polished surface. The principal aim of film coating is to safeguard the medicine against environmental elements, including moisture, light, and oxygen, which could compromise the stability and efficacy of the formulation. Moreover, film coating conceals undesirable taste and odour of the medication, enhancing the dosage form's palatability and ease of ingestion. It enhances the mechanical strength of tablets and diminishes friability during handling, packaging, and transportation.²

Film coating can be employed to alter the release properties of pharmaceuticals, including delayed release, sustained release, or enteric release formulations. Film coating has become a vital procedure in contemporary pharmaceutical businesses due to its myriad advantages in improving product quality, patient adherence, and therapeutic efficacy.³

METHODS

*Author for Correspondence: devindersharma525@gmail.com

Preparation of core Tablets:

Rifaximin 550 mg sifted through 30# was mixed with required quantities of 11mg croscarmellose sodium sifted through 60# for 3-5 minutes, the blend was granulated by Kneading method or in FBP, using Povidone in isopropyl alcohol as binder, the wet coherent mass was dried in hot air oven at 60°C until the moisture content of granules is NMT 1% and passed through sieve # 20 to get the uniform particle size. The granules were mixed with Croscarmellose sodium, The above granules were lubricated with specified quantity of magnesium stearate for 2-3 minutes. The granules were compressed on 8 station rotary tablet press using 19.5 X 9.5 caplet punches.⁴

Film coating of Tablets: Film coating is a process of applying thin polymer coating on tablets to improve the appearance, stability and patient acceptability. It helps to mask any unpleasant taste and smell, protects the medicine from moisture and light, and makes it easier to swallow. Film coating can also improve mechanical strength and can be used to alter drug release qualities.⁵

Preparation of coating solution:

Film coating of core tablet was done by using synthetic coating polymer ie Aquacoat ECD-30, HPMC and natural polymer i.e. Gum Arabic and chitosan. For each formulation, stated amount of included components were individually weighed, mixed together and the obtained mixture was then transferred into a beaker containing

specified weight of distilled water to form the coating mixture solution.⁶ The mixture solution was then thoroughly blended and homogenized for 45 min (Galaxy Lab stirrer, India) to achieve coating solutions with desired viscosity. The method of preparation of coating solution is described below:

- A. Aquacoat ECD-30 Coating Solution:** Aquacoat ECD-30 (FMC Corporation, Philadelphia, USA). Aquacoat ECD-30 is an aqueous ethyl cellulose dispersion with a solid content of 29-32%. It contains 24.5-29.5% ethyl cellulose, 0.9-1.7% sodium lauryl sulfate, 1.7-3.3% cetyl alcohol and small quantities of dimethyl polysiloxane. Appropriate quantities of aqueous ethyl cellulose dispersion, plasticizer and HPMC solution were combined and mixed with a glass blade stirrer for 30 min before and after the standing time of 23 h. The pore former HPMC was added as a solution of a maximum concentration of 10% to the aqueous dispersion.⁷
- B. HPMC tablet coating solution:** 25-30% HPMC solution was dispersed in 20-30% PEG 4000, 5-10% Tween 80, 5-10% titanium dioxide, and 0.4-1% acid red 2, with the remaining volume made up of purified water with continuous stirring at 80°C for 2 h and stirred overnight at room temperature. HPMC is the primary film-forming agent, PEG 4000 acts as a plasticizer, Tween 80 is a surfactant, titanium dioxide is an opacifier, and acid red 2 is a colorant.

- C. Gum Arabic Tablet Coating Solution:** Gum arabic (1.5%) solution was prepared according to the method reported by with some slight modifications. Briefly, 1.5 g of gum arabic was dissolved in 100 mL distilled water and continuously stirred at low heat (50°C) for 90 min on a hot plate stirrer. The coating solution was then filtered using cheese cloth to remove any undissolved impurities and allowed to cool to 20°C before addition of glycerol (1%).
- D. Chitosan tablet coating solution:** Chitosan (1%, w/v) was dispersed in an aqueous solution of glacial acetic acid (1%, v/v), at 40°C (v/v) for 12 h, whereas hydroxy propyl methyl cellulose (1%, w/v) was dispersed in distilled water at 80 for 2 h and stirred overnight at room temperature.⁸

Application of coating solution on core tablet:

The uncoated, de-dusted tablets were loaded into the coating pan and the tablets were warmed up to 50°C. The Coating solution was sprayed over the warmed tablets using 1.5mm air nozzle spray gun for efficient coating⁹. Hot air was passed between each application of coats. Tablets bed temperature during coating procedure should not exceed 35°C.

Process variables: based on the three process variables Pan Speed, Duration, Spray rate following formulations designed as shown in table 1 and 2.

Table 1: Formulation code as per Process variable Specification (synthetic polymer)

Coating	Formulation Code	Duration (minute)	Spray rate	Pan speed
Aquacoat ECD-30	SF1	4.00	20.00	8.00
	SF2	2.00	10.00	4.00
	SF3	4.00	10.00	4.00
	SF4	2.00	20.00	8.00
	SF5	2.00	10.00	8.00
	SF6	4.00	10.00	8.00
	SF7	4.00	20.00	4.00
	SF8	2.00	20.00	4.00
HPMC	SF9	4.00	20.00	8.00
	SF10	2.00	10.00	4.00
	SF11	4.00	10.00	4.00
	SF12	2.00	20.00	8.00
	SF13	2.00	10.00	8.00
	SF14	4.00	10.00	8.00
	SF15	4.00	20.00	4.00
	SF16	2.00	20.00	4.00

Table 2: Formulation code as per Process variable Specification (natural polymer)

Natural Coating Polymer	Formulation Code	Duration (minute)	Spray rate	Pan speed
Gum Arabic	NF1	4.00	20.00	8.00
	NF2	2.00	10.00	4.00
	NF3	4.00	10.00	4.00
	NF4	2.00	20.00	8.00
	NF5	2.00	10.00	8.00
	NF6	4.00	10.00	8.00

Chitosan	NF7	4.00	20.00	4.00
	NF8	2.00	20.00	4.00
	NF9	4.00	20.00	8.00
	NF10	2.00	10.00	4.00
	NF11	4.00	10.00	4.00
	NF12	2.00	20.00	8.00
	NF13	2.00	10.00	8.00
	NF14	4.00	10.00	8.00
	NF15	4.00	20.00	4.00
NF16	2.00	20.00	4.00	

Evaluation of Core and coated tablet [169].

Physical appearance and coating defects: The physical appearance and surface morphology of the coated-tablets were examined visually. Samples of ten tablets were collected randomly from each trial for the characterization of film quality and observed results for each sample were recorded.¹⁰ Coated tablets obtained by each trial have to be free of any visual defects and uniform in colour. A qualitative method was used to study the film quality by measuring the resistance of the coated tablet to the abrasion by gently rubbed it on a white paper.¹¹ The coated tablets were considered to pass the test if no colour or coating residues have been transferred to the paper. Any changes with the film or colour were carefully observed and noted.¹² Colour uniformity test was conducted according to the method introduced by. Samples from each

trial were randomly collected and examined visually on the day light over a white background to identify any colour differences. The observed results for each sample were recorded. Coated tablets were considered to be accepted when no colour difference can be observed, which give an indication of equal distribution of the coating material over the tablets bed.¹³

RESULTS

Physical appearance and coating defects: Evaluating the physical appearance of tablet coatings involves assessing several characteristics to ensure quality and functionality. These include the smoothness, uniformity, and adhesion of the coating, as well as the absence of defects like Surface roughness, Edging, Chipping, Picking / sticking, Colour variation (table 3 and 4).

Table 3: Coating Defect Observations (Synthetic Polymer) :

Formulation Code	Surface roughness	Edging	Chipping	Picking / sticking	Colour variation
SF1	+	+	-	-	+
SF2	++	-	+	+	-
SF3	-	+	++	-	-
SF4	-	-	-	-	-
SF5	+	-	-	++	-
SF6	-	+	+	+	+
SF7	++	+	-	+	-
SF8	-	-	-	-	-
SF9	+	+	+	-	+
SF10	-	++	-	+	+
SF11	-	-	+	+	++
SF12	-	-	-	-	-
SF13	+	+	-	++	-
SF14	+	-	+	-	-
SF15	++	-	-	+	++
SF16	-	-	-	-	-

Formulations SF4, SF8, SF12, and SF16 showed no visible defects in any of the evaluated parameters. These formulations exhibited smooth surface texture, uniform colour distribution, proper edge formation, and absence of sticking or chipping. The results suggest that these

formulations possessed optimum coating characteristics and acceptable mechanical integrity. Proper balance of polymer concentration, plasticizer level, drying conditions, and coating process parameters might have contributed to the superior quality of these batches.

Table 4: Coating Defect Observations (Natural Polymer) :

Formulation Code	Surface roughness	Edging	Chipping	Picking / sticking	Colour variation
NF1	+	+	+	-	++
NF2	-	-	+	+	-
NF3	-	-	-	-	-

NF4	++	-	-	-	+
NF5	+	-	+	++	-
NF6	-	+	+	+	+
NF7	-	-	-	-	-
NF8	-	++	-	+	+
NF9	+	+	+	-	+
NF10	-	++	-	+	+
NF11	-	-	-	-	-
NF12	-	+	+	+	-
NF13	+	+	-	++	-
NF14	+	-	+	-	-
NF15	+	-	+	+	++
NF16	-	-	-	-	-

(-) none, (+) moderate, (++) extreme

Among all formulations, NF3, NF7, NF11, and NF16 exhibited excellent coating characteristics with no observable defects in any of the evaluation parameters. These formulations showed smooth tablet surfaces, proper edge formation, absence of chipping and sticking, and uniform colour distribution. The absence of coating

defects suggests that these formulations possessed optimum coating composition and suitable processing conditions, leading to better film formation and overall coating quality.

Selected formulations which were of zero defects are shown in table 5.

Table 5: Physical appearance of selected formulations

S.No.	Formulation Code	Physical appearance
1	SF4	Zero defects
2	SF8	Zero defects
3	SF12	Zero defects
4	SF16	Zero defects
5	NF3	Zero defects
6	NF7	Zero defects
7	NF11	Zero defects
8	NF16	Zero defects
9	Core Tablet	Zero defects

Overall, the study demonstrated that the optimized formulations produced tablets with excellent physical appearance and defect-free coating characteristics. The results confirmed that proper optimization of formulation variables and coating process parameters plays a significant role in achieving high-quality pharmaceutical coated tablets. These formulations can be considered suitable for further evaluation studies such as stability testing and large-scale manufacturing.

CONCLUSION

This study effectively developed and assessed film-coated Rifaximin tablets utilising synthetic polymers (Aquacoat ECD-30 and HPMC) and natural polymers (Gum Arabic and Chitosan). The formulated preparations were assessed for physical appearance and coating imperfections, including surface roughness, edge, chipping, picking/sticking, and colour change. The evaluation results demonstrated that coating quality was significantly affected by formulation composition and process variables such as spray rate, coating duration, and pan speed. Among the synthetic polymer formulations, SF4, SF8, SF12, and SF16 exhibited superior coating properties with no discernible flaws. Likewise, within the natural polymer formulations, NF3, NF7, NF11, and NF16 exhibited a smooth surface texture, homogeneous colour distribution,

and flawless coating characteristics. The research validated that optimized coating parameters are crucial for producing high-quality pharmaceutical film-coated tablets with enhanced aesthetics, stability, and patient acceptability. Both synthetic and natural polymers were determined to be useful for film coating applications. The optimised formulations are thus deemed appropriate for subsequent evaluation studies, stability assessments, and scaling for industrial production.

REFERENCES

1. Aulton ME, Taylor K. *Aulton's Pharmaceutics: The Design and Manufacture of Medicines*. 5th ed. Elsevier; 2018.
2. Lachman L, Lieberman HA, Kanig JL. *The Theory and Practice of Industrial Pharmacy*. 3rd ed. Lea & Febiger; 1986.
3. Felton LA. Mechanisms of polymeric film formation. *International Journal of Pharmaceutics*. 2013;457(2):423-427.
4. Cahyadi, C., Tan, B. X., Chan, L. W., & Heng, P. W. S. (2012). A study on in-line tablet coating—The influence of compaction and coating on tablet

- dimensional changes. *AAPS PharmSciTech*, 13, 785-792
5. Banker GS, Rhodes CT. *Modern Pharmaceutics*. 4th ed. Marcel Dekker Inc.; 2002.
 6. Remington JP. *Remington: The Science and Practice of Pharmacy*. 22nd ed. Pharmaceutical Press; 2013.
 7. FMC Corporation. *Aquacoat ECD Technical Bulletin*. FMC Biopolymer; 2010.
 8. Porter SC. Coating of pharmaceutical dosage forms. In: *Encyclopedia of Pharmaceutical Technology*. 3rd ed. Informa Healthcare; 2007.
 9. Parmar KD, Bhatt NM, Pathak N, Chauhan Vijay V, Patel LD, Kela AN, Nathani HS. An Overview: Aqueous Film Coating Technology on tablets. *Int J Pharm. and chem. science* 2012; 1(3): 06-07.
 10. Felton LA. Film coating of oral solid dosage forms. *AAPS PharmSciTech*. 2013;14(2):123-128.
 11. Koli M, Nogai L, Bhandari M, Mishra R, Pathak R, Sharma H. Formulation and evaluation of berberine hydrochloride film coated tablet. *J. Pharm. Negat. Results*. 2023 Apr 1;14(2):3439-49.
 12. Shammout H, Hopp B, Smausz T, Bohus J, Jójárt-Laczkovich O, Cseh M, Kopniczky J, Tari B, Saker R, Kristó K, Sovány T. Laser-Based QR Code Marking on Double Film-Coated Tablets: Balancing Marking Efficiency and Tablet Integrity—A Step Toward Safer Medicines. *Pharmaceutics*. 2026 Jan 6;18(1):73.
 13. Riski R, Adnyana IK, Nugraha YP, Rachmawati H. Optimization of Effervescent Tablet Stability Containing *Physalis angulata* L. Fruit Extract via Fluid Bed Coating of Sodium Bicarbonate and Box-Behnken Design. *Journal of Drug Delivery Science and Technology*. 2026 Jan 17:108032.