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ORIGINAL ARTICLE

Process optmization of Aqueous coating of Eudrajit l 100 l on Rabeprazole Sodium tablets

Ashish Srivastava*[1], Sanjay Bhawar[2]
[1]Research Scholar, Department of Pharmaceutical Sciences Bhagwant University, Ajmer, Rajasthan, India.
[2]Research Guide, Department of Pharmaceutical Sciences Bhagwant University, Ajmer, Rajasthan, India.
For Correspondence : sbbhawar@gmail.com

ABSTRACT
Finding the best way to coat rabeprazole sodium tablets with aqueous Eudragit L-100 was the driving force behind this study. This study developed an enteric-coated tablet to protect rabeprazole sodium from acidic environment of stomach, since it is very acid-labile.I choose to encapsulate rabeprazole sodium tablets with an aqueous version of Eudragit L-100 (Ecopol L-100) for this study. Various formulations of rabeprazole core tablets were created by combining lactose with SSG for disintegration and Ca(OH)2 for stabilization. The core tablets were coated with HPMC E-5 (0.5%, 1%, 1.5%, and 2%). After sub-coating, enteric (aqueous) coating was done on the sub-coated tablets. Each sub-coated batch was coated with 5%, 6%, 7%, 8%, 9%, 10%, and 12% of enteric polymer Ecolpol L-100 at optimized process parameters.Laboratory tests were performed on all twelve batches of the enteric-coated tablets to determine their weight variation, hardness, thickness, friability, in-vitro disintegration, and in-vitro dissolution. Formulations F6 and F12 were determined to have the most effective outcomes by comparing the data of all the formulations.
Keywords: *Rabeprazole sodium, proton pump inhibitors, aqueous coating, polymer.*

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INTRODUCTION

As a member of the proton pump inhibitor (PPI) pharmacological class, rabeprazole sodium is an effective treatment. Conditions including Zollinger-Ellison syndrome, peptic ulcer disease, and gastroesophageal reflux disease (GERD) are often treated with this medication because of the extra stomach acid it causes. Rabeprazole sodium alleviates acid reflux, acid regurgitation, and indigestion by decreasing gastric acid production. It aids in the healing process and helps to avoid future damage to the stomach and esophagus caused by acid reflux. Although not everyone experiences them, rabeprazole sodium tablets carry the possible adverse effects of any medicine. Headache, nausea, diarrhea, stomachache, and flatulence are some of the most common adverse effects. Rare yet serious adverse effects include moderate to severe allergic responses, liver issues, and magnesium deficiency. [1]

Rabeprazole sodium is typically administered orally and taken once daily, irrespective of food intake. The specific dosage and duration of treatment may vary depending on the patient's health profile and the condition being addressed. .[2,3]

Rabeprazole sodium offers a notable advantage with its ability to provide prolonged relief from symptoms, particularly in alleviating inflammation and irritation in the digestive system. Although it is an effective medication, there are potential side effects associated with its use, such as headache, nausea, diarrhea, and abdominal pain. [4, 5].

"Core Tablets" with enteric coating are a specific type of tablet design in which the medication is enclosed within a central core that is surrounded by a protective coating. The coating is specifically engineered to endure the very acidic environment found in the stomach. Doing so ensures the drug makes it through the digestive tract undamaged, increasing the likelihood of efficient absorption into the bloodstream. [6].

Typically, the medication is supplied in the form of core tablets that have been coated with an enteric layer. This coating serves multiple purposes, such as shielding the medication from stomach acid,

minimizing potential irritation to the stomach lining, and enhancing absorption in the intestines. The core tablets contain the active ingredient(s), while the enteric coating is commonly composed of cellulose acetate phthalate or methacrylic acid copolymers [7-8].

Aqueous coating of tablets involves applying a thin layer of a water-based coating material onto the surface of tablets to achieve various purposes such as improving appearance, protecting the tablet from moisture, enhancing stability, facilitating swallowing, and masking taste. Some commonly used aqueous polymers for tablet coating include Hydroxy propyl methylcellulose (HPMC), Polyvinyl alcohol (PVA),Ethyl cellulose (EC), Methacrylic acid copolymers (e.g., Eudragit). A pharmaceutical technique known as enteric coating is employed to encase oral medications in a unique polymer that can withstand the acidic conditions found in the stomach. Ensuring that the medication enters the small intestine intact is the primary goal of enteric coating, which serves to prevent its dissolution or degradation in the stomach.

Methacrylic acid copolymers are pH-dependent polymers that can be used for enteric coating of tablets. The coatings keep the medicine from being released until the tablet reaches the intestines, shielding it from the acidic stomach environment. Eudragit is a well-known brand of methacrylic acid copolymers used in pharmaceutical formulations.

MATERIALS AND METHOD

All substances and agents utilized were of the highest analytical grade. The sodium salt of rabeprazole was provided as a complimentary sample by Cadila Healthcare Ltd.

Rabeprazole Sodium powder preparation

Weigh the required amount of Rabeprazole Sodium powder using a calibrated analytical balance. The amount of powder to be weighed depends on the intended use and the desired concentration of the drug. Transfer the weighed Rabeprazole Sodium powder into a clean, dry, and labeled container. Keep the container out of direct sunlight, heat, and moisture and in a cold, dry, dark area.

Preparation of Rabeprazole Sodium Powder

Utilize a calibrated analytical balance to accurately measure the required quantity of Rabeprazole Sodium powder. The amount of powder to be measured depends on the intended purpose and the desired drug concentration. Place the weighed Rabeprazole Sodium powder into a clean, dry, and labeled container.

Preformulation Studies

The objective of preformulation studies is to examinephysicochemical characteristics of drug molecule, which may impact its overall performance, as well as the stability, efficacy, and safety of the formulation.

Organoleptic Properties

A substance's organoleptic features include its perceivable sensory qualities, including flavor, aroma, texture, look, and color. These properties are often used to assess quality of a product and can influence consumer acceptance.

Identification of the Drug Using IR Spectroscopy

It is a proton pump inhibitor used for management of gastrointestinal conditions like acid reflux and ulcers. Identification of Rabeprazole Sodium can be achieved by employing infrared (IR) spectroscopy.

Solubility Evaluation

To determine the solubility characteristics of Rabeprazole Sodium in various solvents and at different temperatures, a solubility investigation can be conducted. This involves adding a precise amount of Rabeprazole Sodium to a predetermined volume of solvent and agitating mixture until drug is completely dissolved.

Construction of a Standard Curve for Rabeprazole Sodium

A series of standard solutions with predetermined concentrations of Rabeprazole Sodium can be prepared to generate a standard curve. These solutions should cover a range of concentrations suitable for the intended analysis. The response of the drug in the standard solutions can be quantified using UV spectroscopy.

Preparation of Stock Solution

A stock solution is a highly concentrated solution of a drug that serves as a reference for preparing solutions with known concentrations for analytical purposes. To prepare a standard stock solution of Rabeprazole Sodium, accurately add 10 mg of the drug to 10 ml of ethanol, resulting in a concentration of 1000 µg/ml. To create Stock II with a concentration of 100 µg/ml, take 1 ml of this stock solution and further dilute it with ethanol as a solvent until the final volume reaches 10 ml.

Construction of a Calibration Curve

From the stock solution (100 µg/ml) of Rabeprazole Sodium, prepare a series of dilutions with concentrations ranging from 2 µg/ml to 14 µg/ml. Measure absorbance of these dilutions at maximum

absorption wavelength. Subsequently, plot the absorbance values against the corresponding concentrations of the dilutions to construct a calibration curve.

Evaluation of granules

Angle of Repose

An approach to evaluating a powder's flow characteristics is the angle of repose. The static angle of repose, a specialized measurement tool included in the funnel method, is used for this purpose. A precise adjustment is made to the height of the funnel such that its tip meets the peak of the powder mixture. The next step is to release the powder mixture onto a surface by letting it run freely through the funnel. The formula is used to determine the angle of repose after measuring the diameter of the powder cone that is produced. [9]

$\tan \theta = h/r$

θ = angle of repose, h = height of powder cone, and r =radius of powder cone.

Bulk Density

Pouring a measured mixture into a graduated cylinder gives the bulk density. Bulk volume is determined by volume that poured mixture occupies. Bulk density is calculated using following formula:[10]

Bulk density = weight of powder blend / untapped volume of packing

Tapped Density

A known mass of the mixture is poured into the graduated cylinder and tapped for a predetermined duration to determine the tapped density. It measures the smallest volume that the mixture occupies in the cylinder following tapping. The following formula is used to compute the tapped density:

Tapped density = weight of blend / tapped volume of packing

Compressibility Index

In order to find the powder blend's compressibility index, one uses Carr's formula:.[11]

Carr's index (%) = {(TD - BD) × 100} / TD

Here, TD = tapped density, and BD = bulk density.

Hausner's Ratio:

One numerical measure of a material's flowability is Hausner's ratio, which is applicable to both powders and granules. The following formula is used to compute it: tapped density/bulk density.[11]

Hausner's ratio = tapped density / bulk density.

Preparation of core tablets

Formulation process for the core tablet containing Rabeprazole involves the following steps:

1. The following ingredients were combined in a dry condition using a planetary mixer: rabeprazole (20 mg), lactose (85 mg), starch (3 mg), sodium starch glycolate (10 mg), calcium hydroxide (4 mg), syloid 244 FP (2.5 mg), and syloid 63 FP (2.5 mg). The ingredients were first passed through a #40 sieve to achieve consistent particle size.
2. The planetary mixer was used to incorporate talc and magnesium stearate into the previously mixed granular material.
3. Isopropyl alcohol (IPA) was used to create a PVP K-30 binder solution.
4. The granular material was pre-mixed in the planetary mixer with the binder solution, and the mixture was combined for 5 minutes at an impeller speed of 65 rpm. A moist mass was formed as a consequence of this.
5. To get granules, the moist mixture was run through a granulator with a #20 sieve.
6. The next step was to dry the granules in a hot air oven at around 30°C for around 45 minutes, or until the loss on drying (LOD) was less than 2%.
7. To the dried granules in the planetary mixer, magnesium stearate was added after drying.
8. A 6mm circular biconcave punch was used on a tablet punching machine to compress the final blend into core tablets. Twenty milligrams of Rabeprazole (around one hundred thirty-five to one hundred forty milligrams) was the target weight for each pill.

By following these steps, the core tablets containing Rabeprazole were successfully prepared.

Tablet coating

Seal-coating of core tablet

The purpose of seal coating is to create a barrier between core tablet and enteric coating material. It effectively prevents any interaction between the acid-sensitive rabeprazole sodium and the acidic enteric coating material. Additionally, seal coating serves as a moisture barrier for the core tablet.

To prepare the seal coating, HPMC E-5 was utilized. A mixture of IPA (Isopropyl alcohol) and DCM (Dichloromethane) was combined in a beaker, following a ratio of 60:40. The mixture was then placed on a magnetic stirrer with continuous stirring. Accurately weighed HPMC E-5 was added to the solvents while stirring continuously until a homogeneous suspension was achieved.

Enteric-coating

Because of its susceptibility to breakdown in the stomach's acidic pH, the seal-coated tablet was enteric coated to avoid the release of rabeprazole sodium while in the stomach. This enteric coating process involved the use of a methacrylate polymer called Ecopol L-100. By applying the enteric coating with Ecopol L-100, the tablet's contents are protected until they reach the intended site of absorption in the gastrointestinal tract.

Preparation of enteric coating formulation (aqueous dispersion)

Excipient dispersion

To prepare the enteric coating formulation, the following steps were followed:

1. Accurately weigh Ecopol L-100 (9.9% w/w) as specified in Table 1 and slowly add it to 2/3rd part of water.
2. Stir the mixture for 5 minutes until the polymer is completely dispersed.
3. After 5 minutes, precisely measure 1N NH3 (5.6% w/w) as mentioned in Table 1 and add it to the dispersion.
4. Stir the dispersion for 60 minutes.
5. Accurately weigh triethyl citrate (4.9% w/w) as mentioned in Table 1 and add it to the same dispersion.

By following these steps, the enteric coating formulation with Ecopol L-100 was prepared. The dispersion was initially formed by mixing Ecopol L-100 with water, then NH3 was added, and finally, triethyl citrate was incorporated into the same dispersion. Stirring was performed for the designated durations to ensure proper dispersion and homogeneity of the enteric coating formulation

Spray suspension

In the remaining 1/3rd of the diluent mixture, talc and lake were added. The mixture was then stirred for 10 minutes using a homogenizer. This step ensured proper mixing and homogeneity of talc and lake within the diluent mixture, completing the preparation of the enteric coating formulation.

Table 1 **. Optimized enteric coating formula**

S.N	Coating materials	Amount (w/w)
1	Ecopol L-100	9.9
2	Triethyl citrate	4.9
3	Talc	4.4
4	1N NH3	5.6
5	Lake	0.5
6	Water	74.4

The excipient suspension was poured slowly into the Ecopol L-100 solution while continuously stirring. This step ensured the gradual and uniform incorporation of the excipients into the solution. Afterward, the resulting mixture was passed through 0.5 mm sieve to achieve smooth and consistent texture for the spray suspension. This sieving process helps remove any larger particles or impurities, ensuring a fine and homogeneous spray suspension for the subsequent coating process.

Coating process

EUDRAGIT polymethacrylates are compatible with a wide range of coating equipment found in the pharmaceutical sector. Tablet coating is best accomplished with coating pans that include spraying mechanisms and a large capacity for drying air.

The general process for tablet coating using EUDRAGIT polymethacrylates involves the following steps:

1. Place the tablets in a moving bed within the coating pan.
2. Spray the coating mixture onto the tablets using a spray gun. The coating mixture typically contains the EUDRAGIT polymethacrylates and other necessary components.
3. Simultaneously apply hot air to the tablets to facilitate the removal of the solvent present in the coating mixture.
4. During the coating process, several parameters need to be optimized to achieve the desired coating quality. These parameters include the inlet temperature (temperature of the hot air entering the coating pan), bed temperature (temperature of the tablets in the moving bed), pan RPM (rotation speed of the coating pan), atomizing air pressure (pressure used to atomize the coating mixture), pump RPM (speed of the pump delivering the coating mixture), and the distance between the spray gun and the bed of tablets.

Optimizing these parameters helps ensure uniform and efficient coating of the tablets with the EUDRAGIT polymethacrylates.

Optimized coating parameters

Table 2 (a) and table 3 (b) indicate the optimal sets of parameters for the two stages of coating—seal coating and enteric coating—used in the formulation of enteric coated tablets of rabeprazole sodium, respectively, utilizing the R & D pan coater.

Table 2.(a) Optimized coating parameters for seal coating

COATING PARAMETER	VALUE
Inlet temperature	40°C
Pan Rpm	25
Bed temperature	38°C
Atomizing air pressure	1 bar
Pump Rpm	1
Gun to bed distance.	4 cm

Table 3 (b) Optimized coating parameters for enteric (aqueous) coating

S.N	COATING PARAMETER	VALUE
1	Inlet temperature	50°C
2	Bed temperature	45°C
3	Pan Rpm	25
4	Atomizing air pressure	1 bar
5	Pump Rpm	1
6	Gun to bed distance.	4 bar

Evaluation of developed tablets [9-15]

The following tests and measurements were conducted to evaluate the quality and characteristics of the enteric-coated tablets of rabeprazole sodium:

Thickness: Verniercalipers were used to measure the dimensions of the tablets. The average thickness was determined by randomly selecting ten tablets from the batch and measuring them.

Weight Variation: An electronic balance was used to measure the individual weights of twenty randomly selected tablets. We calculated the average weight and then compared the weight of each tablet to it to see how much variation there was.

Hardness:A Monsanto hardness tester was used to measure the tablets' hardness. The hardness tester had ten tablets chosen at random from the batch, and each one was set between the anvils. We measured the hardness of the pill as the force needed to smash it.

Friability: Twenty tablets were chosen at random and their weights recorded. After that, the pills were spun at 25 revolutions per minute for five minutes in a friabilator. Following the rotation, the tablets were brushed with a dusting brush, weighed again, and the friability, a measure of weight loss, was computed.

pH stability studies To ensure the stability of Rabeprazole sodium, which is prone to degradation in acidic conditions, a pH stability study was conducted. In buffers with different pH levels, Rabeprazole sodium was dissolved to provide stock solutions with a concentration of 1 mg/ml. These stock solutions were stored in a refrigerator. Samples were collected and analyzed at specific time intervals of 2, 4, 16, 24, and 72 hours after appropriate dilution.

Thermal Stability Study In order to assess the thermal stability of Rabeprazole sodium during the coating process, both aqueous solvents such as water and organic solvents including IPA and DCM were used at temperatures ranging from 40-50 degrees Celsius. The investigation involved heating Rabeprazole sodium stock solutions to 40°C and 50°C after dissolving them in water, IPA, and DCM to a concentration of 1 mg/ml. After the proper dilution, samples were taken at4,16, and 72 hour intervals for analysis.

Drug-Excipient Interaction Study: To examine potential interactions between Rabeprazole sodium and various excipients, the two components were mixed in a 1:1 weight-to-weight ratio. In triplicate, 10 mg of both Rabeprazole sodium and each excipient (including lactose, calcium hydroxide, syloid 63 FP, syloid 244 FP, magnesium stearate, starch, sodium starch glycolate, and PVP k-30) were weighed into vials. The mixtures were thoroughly blended, and the vials were sealed with caps. The prepared samples were then open to temperature of 25°C for 10 days in a humidity cum photostability chamber.

Percentage Drug Content:A tablet was broken up with a pestle and mortar and then dissolved in fifty milliliters of isopropyl alcohol (IPA) to get the percentage of drug content. The absorbance of the diluted

sample was measured at 282 nm after it was produced to an appropriate concentration. By referring to a calibration curve, the percentage drug content was calculated.

Disintegration Time: We used the USP tablet disintegration instrument to find out how long it took for the tablets to dissolve. At first, the tablets were kept in 0.1 N HCl at a temperature of 37±2°C for two hours, and the duration it took for them to dissolve was recorded. To find the overall disintegration time of the pills, they were then moved to a phosphate buffer with a pH of 7.4 and watched for another hour.

In-vitro drug release studies

A USP class 2 dissolution device was used for the in vitro dissolution studies. This process was carried out as follows:

1. One, in the dissolving container, 900 milliliters of 0.1 N hydrochloric acid (HCl) was added to a tablet.
2. The temperature was kept at 37±0.5°C and the paddle speed was adjusted to 50 rpm.
3. after two hours in the acidic solution, the tablet was allowed to disintegrate.
4. Samples were removed from the dissolving media at precise intervals (e.g., 5 ml samples at predefined time points).
5. After that, a 282 nm UV spectrophotometer was used to examine the samples.
6. Following the 2-hour dissolve time in the 0.1 N HCl, 900 ml of a phosphate buffer solution with a pH of 7.4 was added to the dissolution medium.
7. The dissolution test was continued for an additional 45 minutes at the same temperature and paddle speed.
8. Further samples (5 ml each) were taken out at 15, 30, 45, and 60 minutes, and the same volume of dissolution medium was replaced.
9. samples collected during the dissolution test in the pH 7.4 phosphate buffer were also analyzed using a UV spectrophotometer at 282 nm.

By analyzing the samples taken at different time intervals, the dissolution profile of the tablet in both the acidic and neutral environments can be determined. This information helps assess the release characteristics and dissolution behavior of the tablet formulation.

RESULT AND DISCUSSION

Identification of Drug

The powder's visual appearance yielded satisfactory outcomes. The patches that were prepared exhibited flexibility, uniformity, opacity, non-stickiness, and a smooth texture.

Table 4 Physical properties of Drug

S. No.	Parameters	Remarks
1.	Colour	White To Slightly Yellowish
2.	Odour	Characteristic
3.	Taste	Slightly bitter

Solubility Study :(Solubility of Rabeprazole Sodium in Surfactant)

Before beginning formulation development, a solubility study on the drug is conducted to determine the best excipients that can solubilize and deliver drug to site of action.

Table 5 Solubility Study

S. No.	Surfactant	Wavelength(nm)	Solubility
1.	Lactose	237 nm	Insoluble
2.	Microcrystalline cellulose	237nm	Insoluble
3.	Sodium starch glycolate	237 nm	Slightly soluble
4.	Crospovidone	237 nm	Insoluble
5.	Calcium hydroxide	237 nm	Slightly soluble
6.	Magnesium stearate	237 nm	Insoluble

Calibration of pure drug

The table below presents the absorbance values for Rabeprazole Sodium at different concentrations, as determined using UV-Vis spectroscopy at a wavelength of 283 nm in 0.1 M HCl:

Table 6 Absorbance values for Rabeprazole Sodium

Concentration µg/ml	Absorbance
5.0	0.054
10.0	0.108
15.0	0.162
20.0	0.217
25.0	0.271
30.0	0.326
35.0	0.379

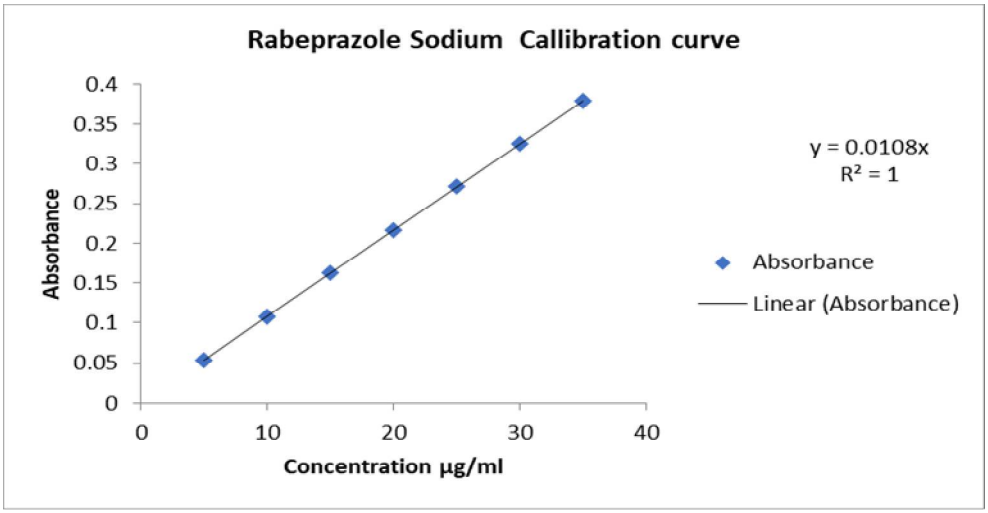

Fig 1 Rabeprazole Sodium Calibration curve

Evaluation parameter of granules of rabeprazole sodium

Evaluation parameter of granules of rabeprazole sodium is shown in table-

PARAMETER	VALUES
Angle of repose	28.37° (goodflow)
Bulk density	0.50gm/ml
Hausner's ratio	1.30(passable flow)
Tapped density	0.63 gm/ ml
Compressibility index	24.12 (passable flow)

Evaluation of tablet

Thickness, Hardness and Weight variations of uncoated and coated tablet

Weight variations, Thickness, Hardness of uncoated and coated rabeprazole sodium tablets was determined which is shown in the table

Table 7 Physical parameter for uncoated Rabeprazole sodium tablets

Formulation	Mean thickness (mm)	Mean hardness (kg/cm²)	Mean diameter (mm)	Weigh variation (%)
F1	4.01	3	6	132 ±5
F2	4.03	3	6	133±5
F3	4.01	2.5	6	126±5
F4	4.02	2.5	6	130±5
F5	4.01	3	6	132±5
F6	4.03	3	6	132±5
F7	4.02	2.5	6	132±5
F8	4.03	2.5	6	130±5
F9	4.01	3	6	130±5
F10	4.01	3	6	130±5
F11	4.01	2.5	6	132±5
F12	4.01	3	6	130±5

(Average of 20 tablets ± maximum deviation of any of tablet from average value)

Table 8 Physical parameter for enteric coated Rabeprazole sodium tablets

Formulation	Mean thickness (mm)	Mean hardness (kg/cm²)	Mean diameter (mm)	Weight variation (%)
F1	4.18	3	6.2	140±5
F2	4.19	3	6.2	141±5
F3	4.18	2.5	6.2	133±5
F4	4.20	2.5	6.2	141±5
F5	4.17	3	6.2	145±5
F6	4.18	3	6.2	142±5
F7	4.14	2.5	6.2	141±5
F8	4.20	2.5	6.2	139±5
F9	4.19	3	6.2	136±5
F10	4.16	3	6.2	143±5
F11	4.15	2.5	6.2	148±5
F12	4.17	3	6.2	140±5

(Average of 20 tablets ± maximum deviation of any of tablet from average value)

Formulation	*Average weight variation (uncoated tablets)*	*Average weight variation (coated tablets)*	*Percent coating*
F1	*132±5*	*140±5*	*6*
F2	*133±5*	*141±5*	*6*
F3	*126±5*	*133±5*	*6*
F4	*130±5*	*141±5*	*9*
F5	*132±5*	*145±5*	*10*
F6	*132±5*	*142±5*	*8*
F7	*132±5*	*141±5*	*7*
F8	*130±5*	*139±5*	*7*
F9	*130±5*	*136±5*	*5*
F10	*130±5*	*143±5*	*10*
F11	*132±5*	*148±5*	*12*
F12	*130±5*	*140±5*	*8*

Friability

Friability of the uncoated and coated rabeprazole sodium tablets was found to < 1% w/w.

Percentage Drug Content

Percentage drug content was calculated by calibration curve and calibration equation for coated tablets. It was found to be 98.2%.

Disintegration test

The disintegration time of rabeprazole sodium, as determined by six tablets using a USP disintegration device at 37.5°C, is displayed in the table.

Table 9: Disintegration time of different enteric coated batches

Formulation	*Time (min) in acidic media*	*Time (min) in buffer*	*Result*
F1	*3*	-	*Fail*
F2	*3*	-	*Fail*
F3	*3*	-	*Fail*
F4	*5*	-	*Fail*
F5	*15*	-	*Fail*
F6	-	*6*	*Pass*
F7	*30*	-	*Fail*
F8	*30*	-	*Fail*
F9	*2*	-	*Fail*
F10	*15*	-	*Fail*
F11	*30*	-	*Fail*
F12	-	*5*	*Pass*

Dissolution test

A USP type 2 dissolution apparatus was used to determine the dissolution study of an enteric coated tablet containing rabeprazole sodium. The table displays the computed cumulative percentage of medication release.

Table 10: Percentage of drug release of different batches

Formulations	In acid 2 hours Mean		In buffer					
		SD	15 min mean	SD	30 min mean	SD	45 min mean	SD
F1	0.186	0.009	95.38	0.723	96.502	0.909	98.355	0.771
F2	2.432	0.190	95.63	0.958	97.364	0.850	98.416	0.547

n=6 (values are reported ± SD)

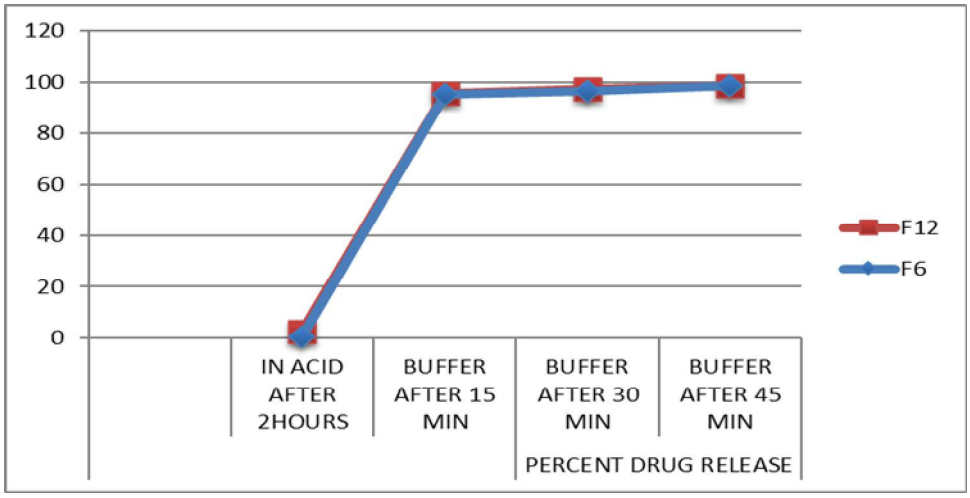

Fig. Percent drug release of F6& F12 formulation

n=6 (values are reported ± SD)

CONCLUSION

The objective of this project was to enhance the aqueous coating of Eudragit L 100 on rabeprazole sodium tablets. The study demonstrated that rabeprazole sodium is an unstable drug, prone to degradation in acidic conditions. Consequently, the inclusion of a stabilizing agent is imperative for formulating its dosage form. Several formulations of enteric-coated tablets containing rabeprazole sodium were prepared, employing different percentages of sub-coating and enteric coating, and subsequently evaluated. evaluation of all 12 formulations (F1 to F12) revealed that formulations F6 and F7 met the dissolution study criteria. These two formulations are recommended for further shelf life studies, and the stable formulation resulting from those studies can be pursued for subsequent bioequivalence assessment.

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Conflict of interest

The authors declare that they have no Conflict of interests.

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