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(RESEARCH ARTICLE)

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Formulation and evaluation of dosage form of fast dissolving oral film of Rofecoxib

Kumar Raja Jayavarapu *, Praveen Kumar Dassari, Malleli Bhavya Sai Kumari and Yalam Saranya

Department of Pharmaceutical Analysis, Mother Teresa Pharmacy College, Sathupally, Telangana – 507303, India.

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Abstract

Rofecoxib is utilized for the treatment of osteoarthritis, rheumatoid joint inflammation, intense torment in grown-ups, and essential dysmenorrhea, just as intense therapy of headache assaults with or without emanations. Rofecoxib is strong. This compound has a place with the stilbenes. These are natural mixes containing a 1,2-diphenylethylene moiety. Stilbenes (C6-C2-C6) are acquired from the normal phenylpropene (C6-C3) skeleton building block. The presentation of at least one hydroxyl gathering to a phenyl ring leads to stilbenoids. Rofecoxib has a half-existence of 17 hours and its mean oral bioavailability at restoratively suggested dosages of 125,25,and 50 mg is roughly 93%. The proteins that rofecoxib target incorporate elastin and prostaglandin G/H synthase Cytochrome P4501A2, Cytochrome P4503A4, Cytochrome P4502C9, Cytochrome P4502C8, and Prostaglandin G/H synthase1 are known to processor of Rofecoxib. Rofecoxib oral thin films were prepared from the evaluation studies RCX2 with 98.14% drug release is considered as the optimized formulation.

Keywords: Rofecoxib; Oral thin films; Fast Dissolving

1. Introduction

Oral administration is the most effective method for accomplishing systemic effects. A solid dosage form constitutes around 60% of all formulations. The oral route of administration is widely used due to its ease, analgesic, and versatility. Dysphagia affects people of all ages, but it is more widespread in older persons. The fear of choking inhibits many pediatric and elderly patients from conveying this solid dosage forms. Dysphagia is connected to clinical illnesses such as stroke, head and neck thyroid treatment, thyroidectomy, AIDS, parkinson's disease and other neurological issues such as cerebral paralysis. The most common concern was tablet size, followed by surface area and flavour. Oral thin films have a variety of approaches to solve the issues linked with the oral route of administration. Oral thin films are one example in which we utilize super disintegrants to disperse the dosage form. These rapid-dissolving drug delivery systems will diffuse on the patient's tongue without water or chewing in minutes or seconds. Late advancements in the innovation have introduced feasible measurement options from oral courses for pediatrics, geriatric, incapacitated, sick or resistant patients. Buccal drug delivery has lately become a chief route of drug administration. Various bio-adhesive mucosal dosage forms have been developed, which include adhesive tablets, gels, ointments, patches, and more recently the use of polymeric films for buccal delivery, also known as mouth dissolving films. Mouth dissolving films, a new drug delivery system for the oral route of drug administration, originated based on the technology of the transdermal patch. The delivery system contains a very thin oral strip, which is simply placed on the patient’s tongue or any oral mucosal tissue, instantly wet by saliva the film rapidly moisturizes and adheres to the site of application. It then rapidly disintegrates and dissolves to release the drug for oral mucosal absorption or with formula modifications, will maintain the quick-dissolving aspects allow for gastrointestinal absorption to be achieved when swallowed. In contrast to other existing, rapid-dissolving dosage forms, which consist of lyophilisates, the rapid films can be produced with a manufacturing process that is competitive with the manufacturing cost of conventional tablets. Pharmaceutical companies and consumers alike have embraced OTFs as a practical and accepted alternative to traditional OTC drug

* Corresponding author: Kumar Raja Jayavarapu

forms such as liquids, tablets, and capsules. OTFs offer fast, accurate dosing in a safe, efficacious for math at is convenient and portable, without the need for water or measuring devices. OTFs are typically the size of postage stamp and disintegration patient's tongue in a matter of seconds for the rapid release of one or more APIs.

Figure 1 Oral thin film

2. Oral medicated strips/films

A strip or film is a dosage form utilizing a water-dissolving polymer, typically a hydrocolloid or bio-adhesive polymer, which enables the dosage form to quickly hydrate, adhere, and dissolve when placed in the oral cavity (e.g., on the tongue, buccal, palatal, gingival, lingual, or sublingual areas) for rapid local or systemic drug delivery.

2.1. Future challenges for Oral thin films

Fast-dissolving intraoral products encounter numerous challenges as they develop and incorporate new technologies.

- Most Of the drugs need taste masking.
- A novel manufacturing process is a challenge, due to new equipment, technology and process.
- Limited Drug Loading due to technology limitation, taste masking and tablet size.
- Need More Clinical Trials to study more clinical/medical benefits.
- Older Patient Benefits By change in taste, flavours and dissolves too fast.
- Cost Of the product is a major challenge

A drug can be administered via many different routes to produce a systemic pharmacological effect. The most significant method of drug administration is via peroral route in which the drug is consumed and enters the systemic circulation primarily through the membrane of the small intestine. The oral route is the primary method for administering drugs to achieve systemic effects. The parenteral route is occasionally used for self–administration of medication. It is probable that at least 90 % of all drugs used to produce systemic effects are administered by the oral route

2.2. Characteristics of an ideal orally soluble film drug delivery system

- Do not require water to swallow and should dissolve or disintegrate in the mouth within a few seconds.
- Compatible with taste masking and other excipients.
- They possess pleasant mouth feel.
- Leave minimal Residue in mouth after oral administration.
- Theycanwithstandtherigorsofthemanufacturingprocessandpost-manufacturing handling.
- Resistant to Environmental Conditions such as temperature and humidity.
- Theyareadaptableandamenabletotheexistingprocessingandpackagingmachinery.
- Processing and packaging of strips/films can be done at low costs and prices

2.3. Advantages of Oral Films

- The oral film administered sublingually and buccally delivers the drug with high potential to improve the onset of action, lower the dose, and enhance the efficacy and safety profile of the medicament.
- All single unit dosage forms, soft gels and liquid formulations primarily enter the bloodstream via the gastrointestinal tract, which subjects the drug to degradation from stomach acid, bile, digestive enzymes and other first pass effects. As a result, such formulations often require higher doses and typically have a delayed

onset of action. Current oral film drug delivery systems resolve these problems by providing faster onset of action with reduced dosage requirements.

- Oral film is more stable, durable and quicker dissolving than other conventional dosage forms.
- Oral film enables improved dosing accuracy relative to liquid formulations since every strip is manufactured to contain a precise amount of the drug.
- Oral film ensures more accurate administration of drugs.
- Oral films can enhance compliance due to their intuitive dosage form and ease of administration. These properties are particularly beneficial for pediatric, geriatric, and neurodegenerative disease patients, where ensuring proper and complete dosing can be challenging.
- The ability of oral films to dissolve rapidly without needing water provides an alternative for patients with dysphagia and those suffering from nausea, such as chemotherapy patients.
- Oral film drug delivery has the potential to develop sensitive drug targets that might not be feasible with tablet or liquid formulations.
    - From a commercial standpoint, oral film drug delivery technology offers pharmaceutical companies an opportunity to extend the revenue lifecycles of drugs whose patents are expiring and becoming susceptible to generic competition.
    - j) Sublingual Film delivers a convenient, quick-dissolving therapeutic dose containing a wioralan abuse-deterrent film matrix that cannot be crushed or injected by patients, and rapidly absorbs under the tongue to ensure compliance.

2.4. Disadvantages of oral film

Oral disintegrating films have limitations in terms of the amount of drug that can be incorporated in each unit dose. Lyophilized dosage forms typically require drug doses under 400 mg for insoluble drugs and under 60 mg for soluble drugs. Additionally, due to the delicate nature of ODTs, special packaging is necessary, potentially increasing costs. To avoid these minute problems associated with oral disintegrating Film - Oral Soluble Film came to existence from early 1970s since then a tremendous research work was carried out in this current field to deliver active ingredients through the oral cavity, using soluble film technology.

2.5. Choice of drug candidate

An ideal drug candidate for orally soluble chewable films should possess the following characteristics.

- No bitter taste or if it is then it should be masked.
- Good stability in water and saliva.
- Dose should below as possible.
- Unsuitable drug candidate for orally soluble chewable films should include
- Short half-life and frequent dosing.
- Required controlled or sustained release.

With the above mentioned information earlier studies were carried out to deliver lidocaine, as local anaesthetics, for dental applications from polymer films. However, recently several thin- film or strip intra-oral dosage form technologies have been developed as a means to quickly release an active ingredient upon administration of the film on the tongue. Thin-film and strip intraoral dosage forms have been developed by several companies including LTS Lohman Therapy-System A G, Zengen Inc., and Lavipharm Laboratories introducing Quick-Dis™ and Slow-Dis™ technology Using a unique solution-coating process, the formulation is applied and regulated to a precise thickness on a moving bed, then dried in multi-zone ovens with controlled temperature precision. Generally these films dissolve rapidly (within seconds), to release the drug, whose release can be altered depending upon their thickness, and selection of the polymer matrix

2.6. Manufacture Process Of Films

The oral films can be manufactured using one or a combination of the following processes:

- Solvent casting
- Hot-melt extrusion
- Solid Dispersion extrusion
- Rolling method.
- Semi Solid Casting

3. Material and methods

Rofecoxib was received as a gift sample from NATCO LABS Pvt. Ltd., Hyderabad. Chitosan was obtained from Signet Chemical Corporation, Mumbai, India., Carrageenan gum from SD fine chemicals, Mumbai, India. while Sodium CMC was purchased from Merck Specialties Pvt Ltd, Mumbai, India. Citric Acid and aspartame was supplied by Merck, Mumbai. All other chemicals and compounds utilized were of analytical grade.

3.1. Pre formulation studies

The first step in the systematic development of dosage forms is the preformulation study, which examines the molecular and physical characteristics of the drug, both independently and when combined with excipients. This assessment aims to gather data that aids formulators in creating dosage forms that are safe, bioavailable, and capable of mass production 7.

3.2. Excipient - Drug Compatibility Research

Fourier Transform Infrared (FTIR) Spectroscopy was performed using an FT-IR spectrophotometer (Bruker alpha, Germany) to investigate potential interactions between the drug and polymers. The ingredients were compressed into pellets using a hydraulic press (less than 5 kPa), and the resulting discs were placed in the sample holder for spectrum recording.

3.3. Analytical Method Development

A 10mcg/ml standard solution of Rofecoxib was scanned on a double beam spectrophotometer against respective media blanks. An absorption maximum (λ max) of 270 nm was obtained for all solutions and was selected to prepare a standard curve.

3.4. Preparation of standard curve for Rofecoxib

Standard curves for Rofecoxib were obtained in a water, 6.8 pH saline phosphate buffer. Aliquots of 0.1, 0.2, 0.3, 0.4, 0.5 and 0.6 ml of Rofecoxib standard solution of 100 mcg/ml (stock solution-II) was taken and diluted to obtain concentrations from 0.1to 0.6 mcg/ml with appropriate media. The absorbance of solutions was determined at 270 nm against respective media as blank. The experiment was repeated six times for each buffer and a calibration curve was determined from the mean value.

3.5. Selection of drug and other ingredients

- Rofecoxib was selected as a model drug based on its Physico-chemical and biological properties and based on its suitability.
- Locust Bean Gum, Sodium CMC, Xanthan Gum were selected as polymers.
- Propylene glycol was selected as a permeation enhancer and plasticizer.

3.6. Dose calculation

OD films are generally of stamp size but the range acceptable is around 5-20 sq cm. Each patch with 4 cm^2 was chosen as optimum size based on dose, ease of handling and administration. Calculation of the total amount of drug required per petri plate is given below.

Dose of Rofecoxib per each film :12.5mg
Area of the film designed : 4 cm^2
Area of the petri plate : 31.4 cm^2
Amount of polymer solution per plate : 15 ml The amount of drug required for the total plate is around :100mg.

Hence per each plate approximately 8 films of 4 cm^2 were obtained

3.7. Formulation

Development of Oral thin films: Oral thin films were prepared by solvent casting method. Solvent casting method: Locust bean gum, Sodium CMC, Xanthan gum was weighed in required ratios and they were then dissolved in water (Cold water) as solvent. Rofecoxib, Propylene glycol was added to the above dispersion under continuous stirring. Sweeteners such as aspartame were added to the solution, along with citric acid, and the uniformly dispersed mixture was poured

into the petri dish. The rate of evaporation of solvent was controlled by inverting cut funnels over the thin films. After 24 h, the dried thin film was taken out and stored in a desiccator.

Table 1 Formulations of Rofecoxib oral thin film

S.NO	Ingredients (mg)	RB1	RB2	RB3	RB4	RB5	RB6
1	Drug	100	100	100	100	100	100
2	Chitosan	50	100	-	-	-	-
3	Carrageenan gum	-	-	50	100	-	-
4	Sodium CMC	-	-	-	-	50	100
5	Propylene glycol (ml)	2	2	2	2	2	2
6	Citric Acid	5	5	5	5	5	5
7	Aspartase	3	3	3	3	3	3
8	Water(ml)	20ml	20ml	20ml	20ml	20ml	20ml

3.8. Evaluation

3.8.1. Assessment of oral thin film using the solvent casting method:

Fast disintegrating oral films are estimated for the following parameters:

- Thickness of the film.
- Disintegration time.
- Dissolution time.
- Folding endurance.
- pH.
- Percentage of moisture uptake.
- Tensile strength of the Film.
- Swelling property.
- Transparency.

3.8.2. Organoleptic Evaluation

For psychophysical evaluation of the product, special controlled human taste panels are used. In-vitro methods of utilizing taste sensors, specially designed apparatus and drug release by modified pharmacophobia methods are being used for this purpose. These in-vitro taste assessment apparatuses and methodologies are ideal for efficiently screening the taste of oral Pharmaceutical formulations in high-throughput settings.

3.8.3. Thickness measurement

The film thickness is assessed using a dial gauge tester. Thickness at different points is measured from which the average thickness of the fast dissolving oral films was determined.

3.8.4. Disintegration Time

This refers to the time at which the film starts to degrade upon contact with water. It can be determined by keeping a film of desired size in a Petri dish containing water and noting the time it takes to break down

Petri dish Methods: 2ml of distilled water was placed in a Petri dish and one film was added on the surface of the water and the time measured until the oral film was dissolved completely.

3.8.5. Dissolution time

It is defined as the time at which not less than 80% of the tested film is dissolved in aqueous media. It can be done by both in vitro and in vivo methods. In vitro dissolution time can be determined by keeping the desired piece of film in Petri Dish containing water and noting the time required to dissolve at least 80% of the film. Invivo dissolving time of

film is studied by selecting groups of volunteers of different ages. The films of desired size should be kept in the oral cavity still they completely dissolve without any residue left in mouth and invivo dissolving time of film is noted

3.9. Measurement of folding endurance

To conduct the endurance study, the film strip is folded repeatedly at the same location until it fractures. The number of folds at that spot before the film breaks determines its folding endurance.

3.9.1. pH

pH measurement is carried out by keeping the film in contact with distilled water, and after 1 hour, the pH of the solution or dispersion is measured.

3.9.2. pH value

The pH value was determined by dissolving one oral film in 2 ml of distilled water and measuring the pH of the resulting solution using pH paper. Variations were expected due to the inclusion of various polymers and the active pharmaceutical ingredient (API).

3.9.3. Assay

The assay was performed to check the drug loading onto each film. This test was performed by dissolving a 6 cm26.8 phosphate buffer with stirring. The resultant solution was filtered using a Whatman filter paper, and the filtrate was diluted to100ml with the same buffer in a volumetric flask. Then 1ml of the filtrate was further diluted to10 ml with buffer. This solution was analyzed using a spectrophotometer at 270 nm.

3.9.4. Content uniformity

The content uniformity test was used to ensure that every film contains the intended amount of drug substance with little variation among films area of film in 50 ml of a patch. Three pieces, each 6 cm and 2 cm), were cut from the whole patch, and assayed for drug content. Same method was repeated for all the nine batches.

3.9.5. In Vitro Dissolution

The in vitro drug release study of the film was conducted using a USP 23 type 2 rotating paddle dissolution test apparatus.250ml of phosphate buffer (pH 6.8) was used, and maintained at 37±5°C while the basket was setup at 50 rpm. A film sample of 4 cm^2 was fixed onto the specially designed SS disk with the help of cyano acrylate adhesive. The disk was placed at the bottom of the dissolution vessel, ensuring that the patch remained on the upper side of the disk.

Five milliliters of samples were taken at an interval of 60 sec., and the same amount was replaced with a fresh buffer. The withdrawn samples were filtered through Whatman filter paper and then 1ml of the filtered sample was further diluted to10 ml of the same medium and analyzed using a spectrophotometer at a wavelength of 270 nm. The cumulative percentage release for various formulations was calculated, and the relationship between time and percentage release was plotted. The results of the in-vitro dissolution studies for all formulations

3.9.6. Moisture uptake

The test is done by keeping previously weighed films in desiccators at a particular temperature and relative humidity. After three days, the film is taken out and reweighed to determine the percentage of moisture uptake. Percentage of moisture uptake can be calculated as follows.

Percentage of moisture uptake = Final weight–Initial weight ×100.

3.9.7. Moisture content

Previously weighed films are stored in desiccators for 24 hours. The final weight is noted when there is no further change in the weight of individual film. Percentage of moisture content can be

Calculated As follows,

$$\text{Percentage of moisture content} = \frac{\text{nitial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

3.9.8. Tensile strength

The tensile strength, defined as the maximum stress at which the strip specimen breaks, is measured using a tensile testing machine such as the Instron or Monsanto tester. It is calculated by dividing the applied load at rupture by the cross-sectional area of the strip, as shown in the equation below.

$$\text{Tensile strength} = \text{LoadFailure} \times 100$$

3.10. Drug excipients interaction studies:

FT-IR spectrum interpretation: IR spectral analysis was conducted using FT-IR via the KBr disc method. The sample and KBr were ground and compressed to form discs.

4. Results

4.1. Standard Calibration curve of Rofecoxib:

Table 2 Concentration and absorbance obtained for calibration curve of Rofecoxib (pH6.8)

S. No	Concentration (µg/ml)	Absorbance* (at 270 nm)
1	0.1	0.142
2	0.2	0.248
3	0.3	0.382
4	0.4	0.493
5	0.5	0.621
6	0.6	0.741

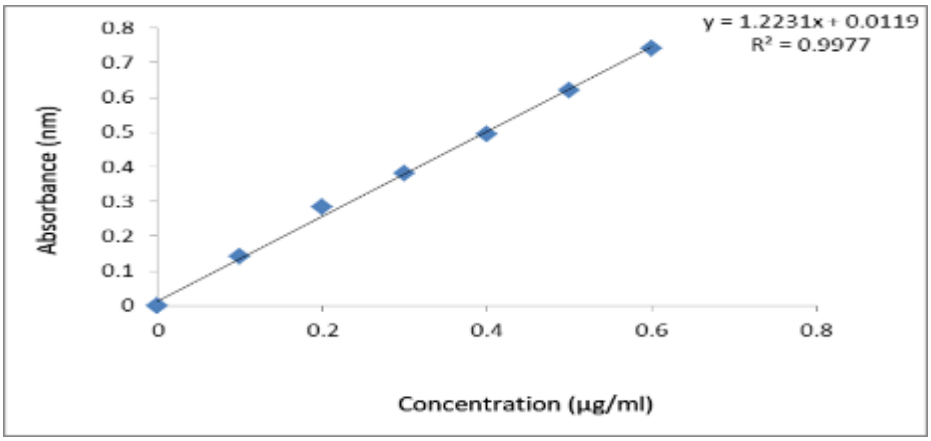

Figure 2 Standard graph of Rofecoxib In pH 6.8 Phosphate buffer

4.2. Evaluation of Rofecoxib oral thin films

4.2.1. Physical appearance

All the Oral thin films were visually inspected for colour, clarity, flexibility.

Flatness: All the Oral thin films were found to be flat without any foams.

Table 3 Evaluation of oral thin films by physical methods

Formulation	Thickness (mm)	Folding endurance	Drug content (%)	Moisture uptake (%)	Moisture content (%)	Weight variation
RB1	0.351	231	97.32	3.11	3.13	171.32
RB2	0.348	242	98.21	2.83	2.98	223.19
RB3	0.349	251	98.41	3.10	2.91	170.21
RB4	0.352	243	97.36	2.98	3.05	221.15
RB5	0.351	243	98.81	3.18	3.03	173.61
RB6	0.353	241	97.12	3.12	3.12	221.13

The prepared Rofecoxib Oral thin films were evaluated by physical methods such as Physical appearance, Weight variation, Thickness, Folding endurance, Drug content, Moisture uptake and Moisture content and all the results were found to be within the Pharmacopeial limits.

4.2.2. Tensile strength (RB2)

The patches (10 samples of each) were dried at 60^0C for 24 hrs. Then they were placed in an isometric transducer and the force required for their rapture was calculated by an oscillograph.

The tensile strength of the patch was found to be 1.45 gm/cm^2

Table 4 *In-Vitro* Drug Release

Time (Min)	RB1	RB2	RB3	RB4	RB5	RB6
5	15.23	31.13	27.35	18.53	16.23	21.32
10	33.15	33.15	32.11	26.15	37.08	28.12
15	41.29	41.29	51.23	44.31	42.35	53.64
20	54.16	54.16	65.44	59.91	51.64	71.91
25	72.51	72.51	71.31	67.25	71.08	80.15
30	91.28	91.28	80.21	82.61	84.13	86.28

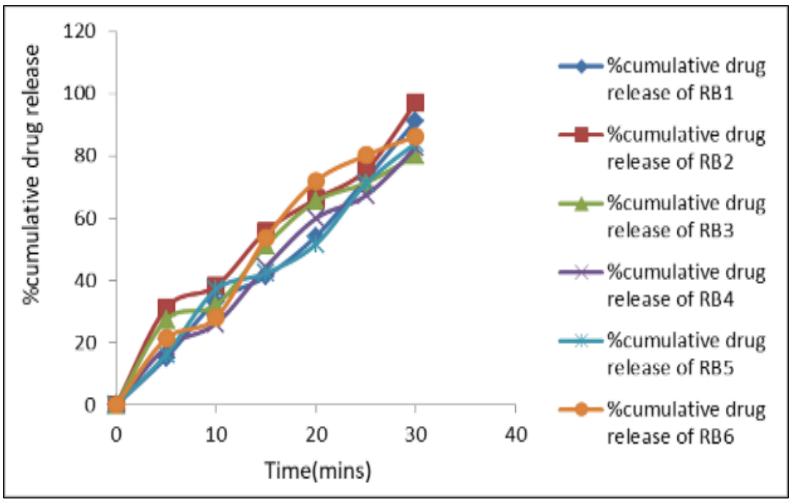

Figure 3 Dissolution graph of all formulations (RB1-RB6)

Table 5 Disintegration time

S. No	DISINTEGRATION TIME (Sec)
RB1	48
RB2	49
RB3	44
RB4	45
RB5	44

Figure 4 FTIR spectrum of pure drug

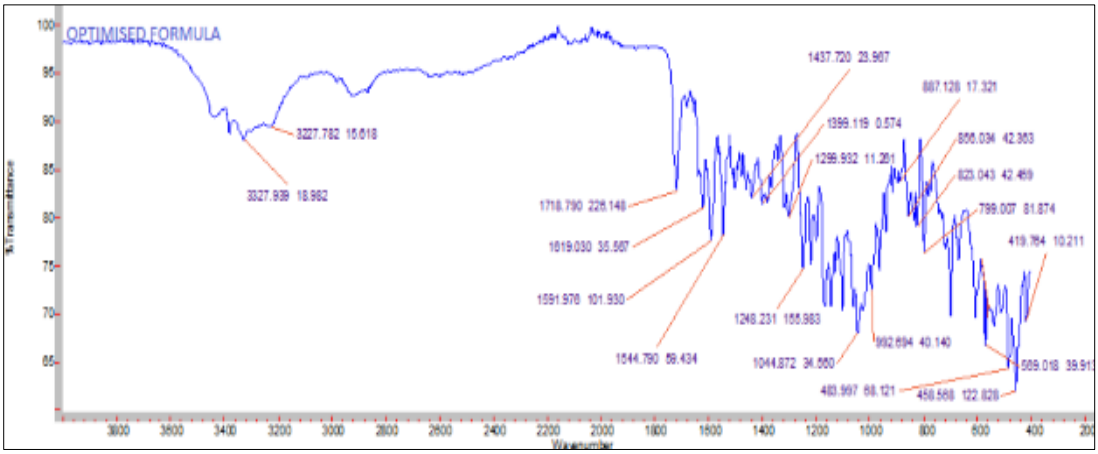

Figure 5 FTIR spectrum of optimized formulation

4.2.3. Optimization of dependent variables

- Response 1 (in vitro disintegration time): The formulations indicated a range of 35 to 62 sec. The equation from the best suited model to coordinate the answer y and variables (HPMC and SSG) was R1 = +15.50000+0.140000HPMC-0.600000SSG. The equation of the model F value of 238.50 and p value is < 0.05, implying that the model is significant. The predicted r2 0.9979 compared with adjusted r2 0.9937 demonstrated a nicely fit response of factors. R1 Three-Dimensional (3D) response surface plot showed an increase in factors HPMC and Sodium starch glycolate. There is a development in the disintegration time Figures 6 and 7.

- Response 2 (Folding Endurance): In the range 290 to 350, the folding endurance values of formulations (F1-F4) were found. R2 = -+109.00000+0.240000HPMC+2.40000SSG was derived from the most appropriate mathematical model for R2 and the independent variables. The model F value 234.00 and P value is < 0.05, implying that the model is significant. And, the r2 0.9970 predicted is in fair competition with the r2 0.9936 adjusted. Variables HPMC and SSG have significantly influenced the folding endurance. Enhanced HPMC and Sodium starch glycolate factors dramatically enhanced folding endurance, according to the R2 three-dimensional response plot Figures 8 and 9.
- Response 3 (Thickness): Based on 22 factorial designs, Various combinations of parameters (HPMC and SSG) they influenced the thickness response (R3). R3= +0.297500+0.000700HPMC-0 .003500SSG. The independent variables fit the proper equation derived from the best response R3. The F value 245.00, p<0.05 implying that the model is significant. And, the 0.9980 r2 predicted was comparable to the 0.9939 r2 adjusted. It was discovered that the factors sodium starch glycolate and HPMC had a significant impact on thickness. R3's 3D response surface plot exhibits a significant rise in the thickness with increased levels of variables HPMC and Sodium starch glycolate Figure 11.

4.3. Checkpoint study and design optimization

By imposing restrictions on the response, such as R1 = 48.5 sec, R2 = 319.9, and R3 = 0.43 mm, the optimized formulation (F5) was discovered using an overlay plot Figure 12. DoE was used to suggest the levels of components from plots which showed a desirability of 0.9428 and the best values of the selected variables, estimated at 0.61 percent for HPMC and 0.67 percent for SSG. The checkpoints were studied for the optimized formulation (F5) using thickness (mm), folding endurance, and disintegration time (sec).

5. Discussion

In present study oral thin films of Rofecoxib were developed to have a faster onset of action. The oral thin films were developed by using polymers Chitosan, Sodium CMC, Carrageenan gum. Oral thin films were prepared by employing a solvent casting method. Propylene glycol was selected as a permeation enhancer and plasticizer. Drug excipient compatibility studies were performed by using FTIR, and it was observed that there were no interactions. Formulations were prepared with the varying concentrations polymers ranging from RB1-RB6, and all the formulations were evaluated for various physical parameters Physical appearance, Weight variation, Thickness, Folding endurance, Tensile strength, Drug content, Moisture uptake, Moisture content and all the results were found to be within the pharmacopeial limits, in-vitro drug release studies by using dialysis membrane. Among all the 6 RB2 formulations which contain Chitosan 100 mg and shown 97.18 % cumulative drug release within 30 min.

6. Conclusion

Solvent casting approach was functionally used to prepare oral thin films that were stocked with Rofecoxib. According to the FT-IR spectrum, the polymer and formulation did not change the functional bands of Rofecoxib. A neutral surface pH of optimized formulation of F5 with smooth surface that was sufficiently elegant to be seen. The dose uniformity test's acceptance value requirement had been met by the optimizedF5 formulation, which also showed excellent stability and a dissolution profile. Based on the findings, it can be said that the optimized formulation F5 offers a quick release of the drug from the site of administration into the systemic circulation, thereby enhancing the bioavailability of rivaroxaban.

Compliance with ethical standards

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Disclosure of conflict of interest

The authors declare that there is no conflict of interest.

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