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Formulation and Characterization of Colon Targeting Drug Delivery of Etoricoxib

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Abstract

Objective: Design and development of okra gum-based colon-specific tablet formulations for chrono therapeutic delivery of drugs, Eterocoxib for the treatment of diseases.

Materials and methods: The gum was extracted from thoroughly washed, sliced and crushed fruits with a laboratory blender. After extraction, the precipitate of the gum was dried in a hot air oven for about 20 minutes at 50 ^{0}C and then the precipitates were kept in a dessicator for further drying. Etoricoxib, HPMC, E.C. other formulation excipients. The in vitro dissolution test has been performed in 0.1 N HCl for first two hours and the rest in 6.8 pH phosphate buffer using USP apparatus type II (paddle), at 50 rpm for six hours. The spectrum was measured in the solid state as Potassium bromide dispersion. The Press coated tablets were prepared by varying polymer (HPMC): polymer (E.C) ratio i.e., 4:0, 3:1, 2:2, 1:3, 3:1 and 0:4.

Results and conclusion: The drug release from the dosage forms was started after 4hrs lag time. The Press coated tablets obtained by 3:1 ratio(P2F9) shows good lag time, more % drug released immediately after lag time in comparison with those prepared by4:0, 2:2, 3:1, 0:4, hence P2F9. It has been concluded from the above investigation that Press press-coated dosage form of Etoricoxib could delay the release up to 4 hours and further exhibited immediate release of the drug and shows 20 hr action. The results obtained in this research work indicated a promising potential of colon-specific drug delivery of etoricoxib by using okra gum containing HPMC, HPMS EC, as a rate-controlling polymer for the effective treatment of rheumatoid patients.

Keywords: HPMC, E.C, Okra Gum, colon-specific drug delivery.

1. Introduction

Oral drug delivery system is the most commonly used route for drug delivery due to its ease of administration, better patient compliance, and flexibility in design and development of formulation [1-2]. The drug delivery to the colon has attracted a lot of attention of the scientist working on oral drug delivery system which is mainly due to the fact that colon is a site where both local and systemic drug delivery can take place [3-4]. In recent times the colon-specific drug delivery systems are also gaining importance for the systemic delivery of proteins and peptide drugs [5]. Due to negligible activity of brush border membrane peptidase activity and less activity of pancreatic enzymes, the colon is considered to be more suitable for delivery of protein and peptide in comparison to small intestine [6-7]. Besides this low hostile environment, the colonic transit time is long (20-30 h) and the colonic tissue is highly responsive to the action of absorption enhancers [8]. The longer residence time, less peptidase activity, natural absorptive characteristics and high response to absorption enhancers make colon a promising site for the delivery of protein and peptides, oral vaccines, insulin, growth hormone, erythropoietin, interferons and interleukins [9-10].

Colonic delivery can be accomplished by oral or rectal administration. Rectal dosage forms such as suppositories and enemas are not always effective since a high variability in the distribution of these forms is observed and enema solutions can only offer topical treatment to the sigmoid and descending colon [11-13].

Therefore, oral administration is preferred, but for this purpose, many physiological barriers have to be

overcome. Absorption or degradation of the active ingredient in the upper part of the GIT is the major obstacle and must be circumvented for successful colonic drug Delivery [14-16].

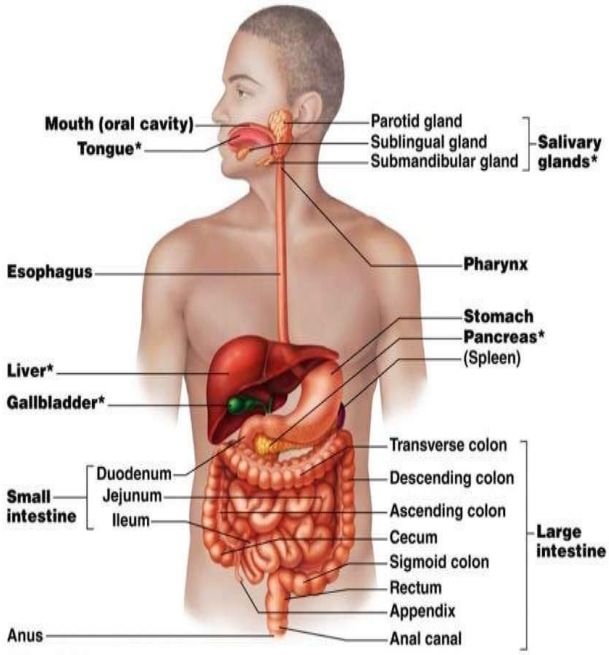

Figure 1. Anatomy of human gastrointestinal tract

2. Materials and methods

2.1 Isolation of Okra Gum

Unripe and tender fruits of Okra were purchased from a local market. A 3kg weight of fruits were thoroughly washed, sliced and crushed with a laboratory blender (Jyoti Pvt Ltd. Vadodara). The obtained paste was macerated in distilled water for 24h in the presence of 0.1% wt/vol sodium metabisulphite (an antioxidant). Expression was done with a clean muslin cloth by placing a little quantity of the paste in the cloth and then expressed so that the gum exuded from it. Precipitation of the extract was done with acetone, by adding a little quantity of the extract in a beaker containing 20mL of acetone and the mixture was stirred using glass rod for about3min. The precipitated gum was transferred into another beaker containing fresh acetone and stirred continuously(30min) until the gum was completely precipitated. The precipitates were dried in hot air oven for about 20 min at 50°C and then precipitates were kept in a desiccator for further drying. Drying continued until constant weight was obtained.

2.2 Phytochemical Examination

Following chemical tests were conducted to evaluate the phytochemical nature of obtained OG (Table 2). These were Ruthenium red test, Molisch test, Ninhydrin test and test for reducing sugars.

Table 1. Chemical tests for phytochemical examination of gum

S. No	Tests	Reagents	Composition	Test for presence of	Positive test
1	Ruthenium red test	Ruthenium red	-	Mucilage	Red color
2.	Molish test	Molish's reagent	A solution of napthol in 95% ethanol	Carbohydrate	Purple ring at the interface between the acid and test layers
3	Ninhydrin test	Ninhydrin reagent	2,2-Dihydroxyindane-1, -dione	Ammonia or primary and secondary amines	Blue to blue violet color
4	Test for reducing sugars	Fehling I Fehling II	7g Of Hydrated Copper (Ii) Sulfate, Dissolved In 100 Ml Of Dist. Water Fehling II 35 g of potassium sodium tartrate and 10 g of sodium hydroxide in 100 ml of dist. water	Reducing Sugar Reducing Sugar	Brick red precipitate.

2.3 Swelling index

One gram sample was placed in 25mL graduated plastic centrifuge tubes and the volume occupied was noted.10mL of distilled water was added and the content was allowed to swell for 1h with the vigorous shaking at the time interval of 10min. Mixture was allowed to stand for 10min followed by centrifugation at 1000rpmfor 10min on a bench centrifuge. The supernatant was carefully decanted and volume of sediment was measured. The swelling index was computed using following equation

S= V2 /V1---------- (1)

Where S= Swelling index

V = Volume occupied by the gum prior to hydration 1

V = Volume occupied by the gum after hydration

Swelling index was determined for three times for the same sample of OG by keeping the conditions constant.

2.4 Loss on drying

The adopted method is specified in the British Pharmacopoeia2007 for acacia. Same procedure was used to determine loss on drying for Og. According to which Petri dish was dried under the condition prescribed for the substance to be examined. One gram of sample was transferred into dried Petri dish which was then dried in an oven at 105°C until the weight of content became constant. The moisture content was determined as the ratio of weight of moisture loss to weight of sample expressed as a percentage. Loss on drying was determined for three times for the same sample of OG by keeping the conditions constant.

2.5 Total Ash and Acid Insoluble Ash Determination

Ash content was estimated by the measurement of residue left after combustion of two grams (W) of gum in a tared crucible in a furnace at temperature not exceeding 450°C to get carbon free residue which was cooled and weighed (W2).

The obtained ash was boiled with 25mL of 2M hydrochloric acid solution for 5min. The content was filtered. After filtration, the insoluble matter was washed with hot water and the resulting product was ignited. After ignition, residues were obtained. The weight of residues (W3) was determined and percent acid insoluble ash was calculated. The total ash and acid insoluble ash were determined for three times for the same sample of OG by keeping the conditions constant.

The percentage of total ash of the sample was calculated by given equation (2):

(W2/W1) x 100----------(2)

The percentage of acid insoluble ash of the sample was calculated by given equation (3):

(W3/W1) x 100----------(3)

2.6 Analytical method for the estimation of etoricoxib

2.6.1 Determination of λ max for Etoricoxib

On the basis of preliminary identification test, it was concluded that the drug complied the preliminary identification. From the scanning of drug, it was concluded that the drug had λ max of 234.5 nm which was nearer to 234 nm as reported.

2.6.2 Preparation of standard calibration curve of Etoricoxib

The standard calibration curve for Etoricoxib was prepared using pH 6.8 phoshate buffer solution

Standard solution:

The 25 mg of Etoricoxib was dissolved in 25 ml pH 6.8 phosphate buffer solution to give a concentration of 1 mg/ ml (1000 µg/ml).

Stock solution:

From standard solution take 5 ml of solution in 50 ml of pH 6.8 phosphate buffer solution to produce the 50 µg/ml concentration and take from the 50µg/ml of the solution aliquots of 1, 2, 3, 4, and 5 ml of stock solution was pipette out in 10ml volumetric flask. The volume was made up to mark with 6.8 buffer solution to produce concentration as 2, 4, 6, 8, and 10 µg/ml of Etoriccoxib respectively.

The absorbance of prepared solution of Etoriccoxib was measured at 234 nm in Shimadzu UV/visible 1700 spectrophotometer against pH 6.8 phosphate buffer solution as blank. The absorbance data for standard calibration curve are given in Table 4 and plotted graphically as shown in the Figure 4. The standard calibration curve yields a straight line, which shows that drug obeys Beer's law in the concentration range of 2 to 10 µg/ml.

Table 2 Composition of different core tablet formulations(F1-F5)

S. No	Ingredients (mg)	F1	F2	F3	F5	F5
1	Etoricoxib	49	49	49	49	49
2	Lactose Monohydrate	149.3	144.8	139.5	149.3	144.8
3	Talc	4.2	4.2	4.2	4.2	4.2
4	Megnesium Stearate	4.2	4.2	4.2	4.2	4.2
5	Pvp	4.2	4.2	4.2	4.2	4.2
6	Ssg	6.2	10.5	15.6	-	-
7	Ccs	-	-	-	6.3	10.6
8	Cp	-	-	-	-	-
9	Total Weight	219	219	219	219	219

Table 3 Composition of different core tablet formulations(F6-F10)

S. No	Ingredients (mg)	F6	F7	F8	F9	F10
1	Etoricoxib	49	49	49	49	49
2	Lactose Monohydrate	139.3	149.8	144.5	139.3	155.8
3	Talc	4.2	4.2	4.2	4.2	4.2
4	Megnesium Stearate	4.2	4.2	4.2	4.2	4.2
5	Pvp	4.2	4.2	4.2	4.2	4.2
6	Ssg	-	-	-	-	-
7	Ccs	15.5	-	-	-	-
8	Cp	-	6.4	10.5	15.5	
9	Total Weight	219	219	219	219	219

2.7 formulation of core tablets by wet compression method

The inner core tablets were prepared using direct compression method. As shown in Table 4, powder mixtures of etoricoxib, PVP, talc, cross-povidone, and lactulose monohydrate ingredients were dry-blended for 20 minutes, followed by the addition of magnesium stearate. The mixtures were then further blended for 10 min., 200mg of the resulting powder blend was manually compressed using KBr hydraulic press at a pressure of 1 ton, with an 8mm punch and die to obtain the core tablet.

2.7.1 Formulation of mixed blend for barrier layer

The various formulation compositions were containing Okra Gum and HPMC. Different compositions were weighed dry blended at about 10 min and used as Press - coating material to prepare press - coated pulsatile tablets respectively by direct compression method.

2.7.2 Preparation of press-coated tablets

The core tablets were press-coated with 400mg of mixed blend/granules as given in Table 6. 200mg of barrier layer material was weighed and transferred into a 13 mm die then the core tablet was placed manually at the center. The remaining 200 mg of the barrier layer material was added into the die and compressed at a pressure of 5tons for 3min using KBr hydraulic press.

2.7.3 Evaluation of rapid release core (RRCT) and press-coated tablets of Etoricoxib

2.7.3.1 Sieve Analysis

The procedure involves the Electromagnetic Sieve shaking of the sample through a series of successively arranged sieves (sieve no 20, 30, 40, 60, 80, and receiver), and weighing of the portion of the sample retained on each sieve and calculate the percentage retained on each sieve.

2.7.3.2 Flow properties

Angle of Repose (θ)

These are the simple and related techniques for measuring the resistance to particle moment. Angle of repose is defined as the maximum angle possible between the surface of a pile of powder and horizontal plane,

$$\tan \theta = h/r$$

$$\theta = \tan^{-1} h/r$$

Where h = height of pile

r = radius of base of pile

θ = angle of repose

Method:

A glass funnel is held in place with a clamp on a ring support over a tile. Approximately 100 g of powder is transferred into the funnel through a mesh size of number 20, keeping the orifice of the funnel blocked by the thumb. When the powder is emptied from the funnel, the angle of the heap to the horizontal plane is measured with a scale. The height of the pile (h) and the radius at the base are measured with a ruler. The angle of repose is thus estimated. Angle of repose limits are mentioned in the Table 4.

Table 4. Relationship between angle of repose (θ) and powder flow

Angle of repose (θ) degrees	Powder Flow
<25	EXCELLENT
20-30	GOOD
30-40	PASSABLE
>40	VERY POOR

2.7.3.3 Compressibility index

It is the propensity of a powder to be compressed. It is measured by tapped density apparatus for 500, 750 and1250 taps for which the difference should be not more than2 %. Based on the apparent bulk density and tapped density the percentage compressibility of the blend was determined using the following formula

Compressibility Index (%)=

$$\frac{\text{Tapped Density} - \text{Bulk Density}}{\text{Tapped Density}} \times 100$$

Where:

- **Bulk Density** = weight of the powder / bulk volume (before tapping)
- **Tapped Density** = weight of the powder / volume after tapping (after standard tapping procedure

Table 5 Acceptance limits for Consolidation index

Consolidation index	Flow
5-15	Excellent
12-16	Good
18-21	Fair to passable
23-35	Poor
33-38	Very poor
>40	Very very poor

2.7.3.4 Hausner's ratio

It indicates the flow properties of the powder. The ratio of tapped density to the bulk density of the powder is called Hausner ratio

$$\text{Hausner's Ratio} = \frac{\text{Bulk Density}}{\text{Tapped Density}}$$

Where:

- **Bulk Density** = Mass of powder / Bulk volume (before tapping)
- **Tapped Density** = Mass of powder / Volume after tapping (after mechanical tapping)

Table 6. Interpretation of Hausner's Ratio

Hausner's Ratio	Flowability
≤ 1.11	Excellent
1.12 – 1.18	Good
1.19 – 1.25	Fair
1.26 – 1.34	Passable
1.35 – 1.45	Poor
> 1.45	Very Poor

2.7.3.5 Bulk Density

Bulk density of a compound varies substantially with the method of crystallization, milling or formulation. Bulk density is of great importance when considers the size of high dose capsule product or homogenicity of allow dose formulation in which there are large differences in drug and excipient densities Bulk density is determined by graduated cylinder containing a known mass of powder whose initial volume is noted. Cylinder is fixed on the mechanical tapper apparatus. Then the final volume is noted, and this bulk volume. Then bulk density is calculated is using following

$$\text{Bulk Density} = \frac{\text{Mass of the powder}}{\text{Bulk Volume}}$$

Where:

- **Mass of the powder** is usually measured in **grams (g)**
- **Bulk volume** is the volume the powder occupies before tapping, measured in **milliliters (mL) or cubic centimeters (cm^3)**

2.7.3.6 Weight variation

Twenty tablets were randomly selected from each batch weighed individually. The average weight and standard deviation were calculated.

2.7.3.7 Thickness

Three tablets from each batch of formulation were collected and the thicknesses of the tablets were measured with the help of Vernier caliper. The average thickness was calculated.

2.7.3.8 Hardness

Hardness was measured using Monsanto tablet hardness tester. The hardness of five tablets in each batch was measured and the average hardness was calculated in terms of kg/cm.

2.7.3.9 Friability (F)

Friability of the tablet determined using Roche friabilator. Pre weighted sample of tablets were placed in the friabillator and were subjected to the 100 revolutions. Tablets were dusted using a soft muslin cloth and reweighed.

2.7.3.10 Wetting time

Wetting time of dosage form is related to the contact angle. Apiece of tissue paper folded twice was placed in a small Petri dish containing 6 ml of water. Tablet was kept on the paper and the time for complete wetting was measured. The mean ± SD values were calculated accordingly.

2.7.3.11 Drug content

For determination of drug content at least five tablets from each formulation were weighed individually, crushed and diluted to100 ml with sufficient amount of phosphate buffer of pH 6.8 in a volumetric flask. Then aliquot of the filtrate was diluted suitably and analyzed spectrophotometrically at 234 nm against blank. Drug content was calculated using a standard curve.

2.7.3.12 Disintegration time for RRCTs

To test the disintegration time of tablets, one tablet was placed in each tube and the basket rack was positioned in a 1-liter beaker containing phosphate buffer pH 6.8 at 37°C ± 1°C such that the tablet remains 2.5 cm below the surface of the liquid. The time taken for the complete disintegration of the tablets was noted.

2.8 In-vitro release studies for RRCTs

Tablet was introduced into the basket of the LABINDIA TS 8000USP dissolution test apparatus and the apparatus was set in motion at 50 rpm for time period of 1hrs, 5 ml of sample was With drawn for every 5min intervals and replaced by pH 6.8phosphate buffer solutions. Samples withdrawn were analyzed by UV spectrophotometer for presence of drug using buffer solution as blank.

2.9 *In-vitro* Dissolution methods for press-coated tablets

In vitro Dissolution studies of Pulsesatile delivery systems was performed with the conventional paddle method of press coated tablets were performed at 37 ± 0.5 °C using 0.1%hcl for 2 hours, followed by 6.8 buffer in

USP II paddle method at 50 rpm. 5 ml of filtered aliquot was manually withdrawn at pre-determined time intervals and replaced with 5 ml of fresh 6.8 buffer solution maintained at the same temperature. The samples were analyzed at 234nm using a UV spectrophotometer. The lag time and percentage release were determined of each formulation.

2.10 Stability Studies

The stability study of the formulations was carried out according to ICH guidelines at 40 ± 2 °C/75 ± 5 % RH for one month by storing the samples in stability chamber.

2.11 Compatibility Studies

FT-IR Spectra: The Infra-red studies were performed by the instrument Shimadzu Corporation Japan. In this, enough samples are placed on the crystal area, and the pressure arm should be positioned over the sample area. Force is applied to the sample, pushing it onto the diamond surface. Later the sample is analyzed. The same procedure is repeated for analysis of pure drug, excipients and mixture.

3. Result and Discussion

Table 7. Chemical tests for phytochemical examination of okra gum powder

Test	Observations	Inference
Ruthenium red test	Red color	mucilage
Moilish test	Purple ring at the interface between the acid test layers	carbohydrate
Ninhydrin test	No blue and No violet color	Absence of amino acid
Test for reducing sugar		
Benedict's reagent	Blue to green yellow orange red brown	Reducing sugars
Fehling I	Brick red precipitate	Reducing sugars
Fehling I	Brick red precipitate	Reducing sugars

Table 8. Physicochemical characterization

Parameters	Normal limits	Okra gum
Solubility		Slightly soluble in water. Practically insoluble in ethanol, acetone and chloroform
Swelling index	pH1.2 pH 7.4 pH 6.8 Distilled water	2.25 ± 0.2 2.38±0.3 2.15±0.2
Loss on drying		0.89 ±0.01%
Total ash		1.8±0.03%
Acid insoluble ash		0.6 ±0.03%
Angle of repose		32±0.11°
pH		6.8±0.54
Bulk density		0.72±0.021 g/cm3
Tapped density		0.84±0.031 g/cm3
Compressibility index		14.3 ±0.014%
Hausner's ratio		1.16 ±0.014

3.1 Standard calibration curve of Etoricoxib

The standard calibration curve for Etoricoxib was prepared using pH 6.8 phoshate buffer solution. The absorbance of prepared solution of Etoricoxib was measured at 234 nm in Shimadzu UV/visible 1700 spectrophotometer against pH 6.8 phosphate buffer solution as blank. The drug showing linearity up to 10 µg/ml.

Table 9 Linearity values for Etoricoxib

S. No	Concentration (µg/ml)	Absorbance (nm)
1.	0	0
2.	2	0.1406
3.	4	0.2846
4.	6	0.4346
5.	8	0.6323
6.	10	0.8131

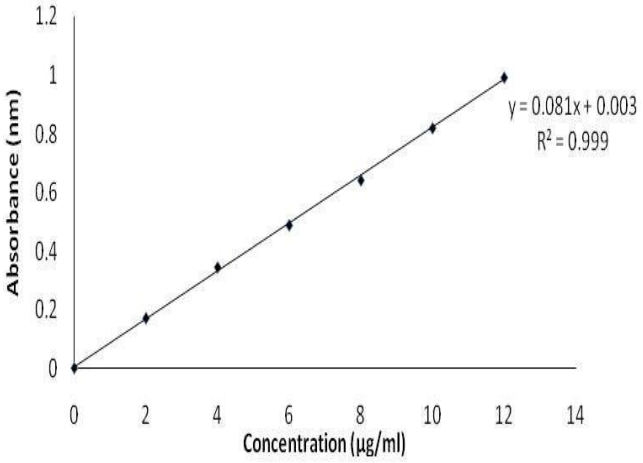

Figure 2. Standard plot of Etoricoxib in pH 6.8 phosphate buffer

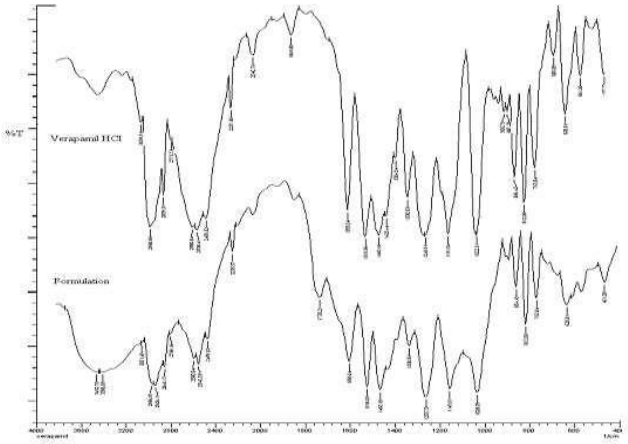

Figure 3. FT – IR spectra of pure Etoricoxib

Table 10. Pre-compressional parameters of power blend (F1 to F6)

Parameters	Formulation Code					
	F1	F2	F3	F4	F5	F6
Angle of repose	24.22 ±1.25	25.15±1.31	27.22 ±1.59	28.39 ± 1.52	29.74±1.67	28.56 ± 0.492
Bulk density (g/ml)	0.238 ±0.008	0.242 ±0.009	0.028±0.009	28.39 ± 1.52	0.237 ±0.006	0.2150 + 0.005
Tapped density (g/ml)	0.263±0.010	0.277 ±0.018	0.259 ±0.014	0.267±0.012	0.265 ± 0.011	0.2484 ± 0.018
Compressibility	9.54 ±0.71	12.63±1.78	11.71 ± 1.56	11.20 ±1.23	10.56 ±0.78	13.46 ±0.45
Housner's ratio	1.21±0.01	1.19±0.01	1.23±0.02	1.22±0.01	1.17±0.02	1.18±0.01

% Compressibility ranges from 9.2 ± 0.04 to 26.58 ± 0.03 and Hausner's Ratio 1.10 ± 0.04 to 1.36 ± 0.04 respectively. All the formulations showed good and Fair flow properties.

Table 11. Pre-compressional parameters of power blend (F7 toF10)

Parameters	Formulation Code			
	F7	F8	F9	F10
Angle of repose	21.20 ±0.261	22.44 ±0.380	26.76 ±0.311	26.42 ±0.144
Bulk density (g/ml)	0.46±0.02	0.45±0.02	0.49±0.00	0.44±0.01
Tapped density (g/ml)	0.43±0.02	0.43±0.04	0.43±0.01	0.41±0.01
Compressibility	16.04 ± 0.78	12.00 ± 0.70	314.29 ± 1.24	16.83 ±0.64
Housner's ratio	1.23±0.01	1.22±0.01	1.18±0.01	1.21±0.01

3.2 Post Compressional Parameters

3.2.1 Hardness:

Table No shows hardness of all tablet formulations. hardness of all formulations was in between 3.5 to 5.5 kg/cm2

3.2.2 Percent Friability:

Table shows the friability values of all tablet formulations. The results indicated that the % friability of formulation was between 0.7% and 0.1% which is considered to be acceptable for withstanding normal shipping and handling.

3.2.3 Thickness:

Table shows the thickness of all tablet formulations. The results indicated that the thickness of all formulations was between 3 – 3.7 mm. Thickness of all the tablets are almost same.

3.2.4 Weight variation test:

Table shows the % weight variation of all table formulations. The results indicated that average %weight variation of all tablets formulations was around 7%.

3.2.5 Disintegration Time:

All the formulations showed disintegration time in the range of 2 min 40sec to 3 min 40 sec.

Table 12. Friability values of all tablet formulations

Physical parameter	F1	F2	F3	F4	F5	F6	F7	F8	F9	F 10
Weight variation(%)	6.2	6.6	7.7	6.3	7.1	7.9	6.9	7.0	7.4	6.7
Hardness (Kg/cm^2)	3.6	4.2	5.2	4	4.5	5	3.4	3.9	4.5	5.5
Thickness (mm)	3.3	3	2.9	3	3.2	3.7	3.1	3.0	3.5	3.7
Friability%	0.8	1	0.9	0.7	0.9	0.9	0.8	0.8	0.9	1
Disintegration time	3min	2min52s	3mis	3min	3min10se	3min20s	2min40s	2min40s	2min30s	3min40s

Table 13. Post compressional parameters of Press coated tablets

Physical parameters	P1F9	P2F9	P3F9	P4F9	P5F9
Weight variation (%)	4.5	4.6	4.0	3.9	4.4
Hardness (Kg/cm^2)	7.2	6.8	7.0	6.9	7.1
Thickness (mm)	5.0	4.8	4.5	4.7	4.8
Friability %	0.8	0.9	0.9	0.7	0.9

From the above results it is evident that the post compressional parameters are in acceptable limits.

3.3 In-vitro Release Studies

All the formulations were studied for 60 minutes, with time interval of 5 minutes. During this study among the 10 formulations F9 formulation showing fastest release (97%) within 30 min. Based on the drug release F9 selected was optimized and further formulated for press coating.

Table 14. Dissolution studies of different formulations

Dissolution time (min.)	F1	F2	F3	F4	F5	F6	F7	F8	*F9*	F10
5	26	31	31	29	29	25	31	32	***41***	31
10	25	48	43	35	37	39	43	54	***63***	29
15	43	49	53	47	49	47	56	66	***78***	34
20	52	55	62	59	62	63	68	78	***91***	39
30	63	76	70	66	72	74	79	84	***99***	46
45	78	89	83	78	84	83	83	93	-	50
60	89	92	93	86	91	96	102	98	-	63

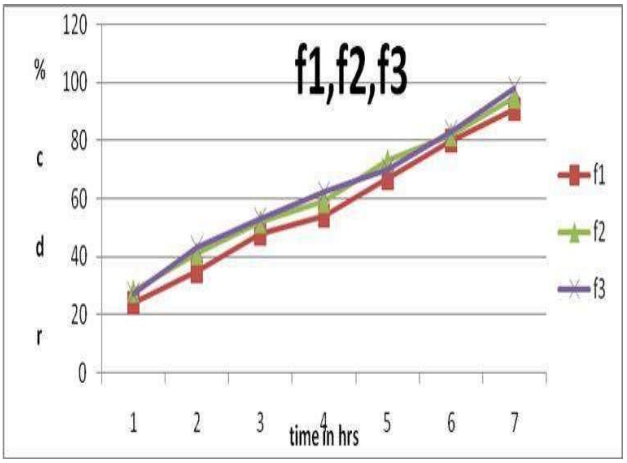

Figure 4. Dissolution study graph of f1, f2, f3

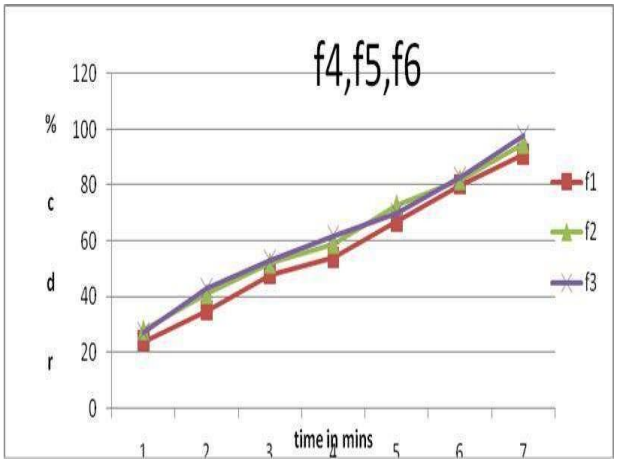

Figure 5. Formulations Dissolution study graph f4, f5, f6

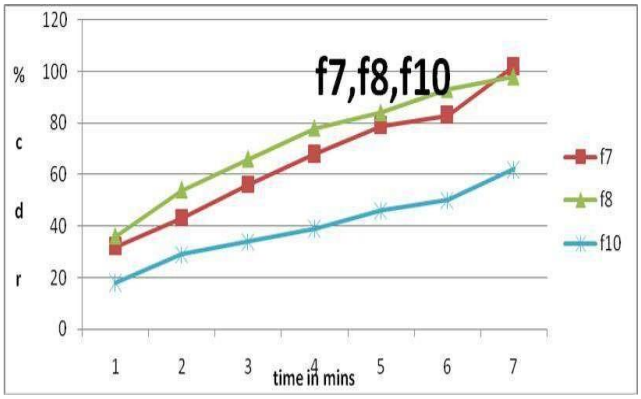

Figure 6. Formulations Dissolution study graph f7, f8, f10

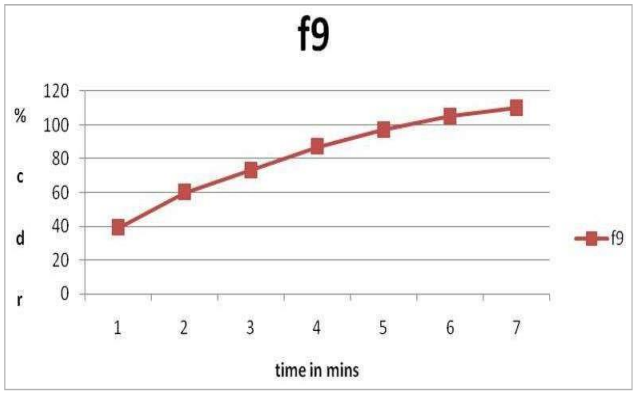

Figure 7. Formulations dissolution study graph of f9

Table 15. Dissolution study of press-coated tablets

Time to hrs.	Press coat Formulation code				
	P1F9(%)	P2F9	P3F9	P4F9	P5F9
1	6	**6**	3	3.8	2
2	11	**8.2**	9	7.7	5
3	14	**10.6**	21	31.1	10
4	18	**13.7**	39	39.6	14
5	23	**34.6**	60	52.3	20
6	36	**48.8**	79	71.6	32
7	48	**88.3**	87	89.4	47
8	75	**99**	92	95.2	59

Based on the drug release within the required time period F9 was optimizedand further formulated for press coating

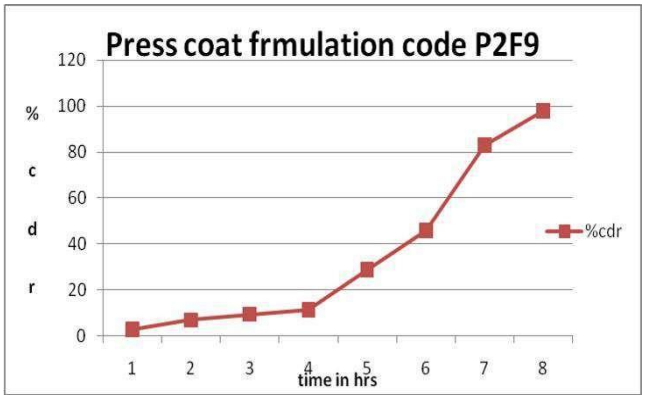

Figure 8. Dissolution study of press-coated tablets

From the above core formulations F9 was selected for press coat by using different polymers (HPMC and E.C) in different ratios (4:0, 3:1, 2:2, 1:3, 0:4) among which 3parts of HPMC and 1 part of E.C was optimized based on the lag time (11% within 4 hours) and percent of drug release and also further evaluated.

3.4 Stability Studies

Stability studies of the formulation F9 of press coated were carrried out to determine the effect of formulation additives on the stability of the drug and also to determine the physical stability of the formulation. The stability studies were carried out at 25 C/60%RH, 30 ºC/65% RH and 40 ^{O} ºC/75% RH for 90 days. There was no significant change in the physical property and percent of drug release during 10 hours during the stability period.

Table 16. Stability studies of the formulation

S.NO	Sampling interval	% of drug release at		
		25°C/60%RH	30°C /65% RH	40°C /75% RH
1	O day	93	92.7	92.2
2	15 days	94.5	94.45	94.40
3	45 days	96.96	96.85	96.82
4	90 days	96.5	96.42	96.38

4. Summary and Conclusion

The dosage forms can be classified based on drug release, such as immediate release and controlled release dosage forms. Among these, controlled release dosage forms are gaining importance due to numerous advantages they offer. There are various routes of drug delivery, like oral and parenteral routes. The oral route has many benefits, including improved patient compliance and dose accuracy. The lag time can be precisely controlled by using press-coated tablets. An extensive literature survey has been conducted to optimize methods, mechanisms, and benefits of controlled release drugs. Pre-formulation studies, such as solubility and melting point of the drug, were performed to assess the drug's suitability for controlled release. The authenticity of the drug was confirmed through FTIR studies, which were compared to reference spectra. Interaction studies using FTIR indicated that there is no interaction between Etoricoxib, HPMC, E.C, and other formulation excipients. Various pre-compression parameters, including angle of repose, bulk density, Hausner's ratio, compressibility index, porosity, and drug content, were evaluated, all showing satisfactory results.

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