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Development and evaluation of advanced oral drug-delivery systems of etoricoxib with a focus on mouth-dissolving tablets (MDTs)

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Abstract

Mouth dissolving tablets have received ever-increasing demand during the last decade, particularly the Mouth dissolving tablets drug delivery systems formulated with natural polymers have more demand because natural materials are easily available, easy to administer, non-toxic and non-irritant nature etc. The main aim of the present study is to formulate Etoricoxib mouth dissolving tablets. Etoricoxib is a selective COX-II inhibitor which acts by inhibiting the COX-2 enzyme and decreases the incidences of side effects associated with these agents. Conventional tablets of Etoricoxib are not capable of rapid action, which is required for faster drug effect onset and immediate relief from pain. Etoricoxib MDT's are prepared by direct compression method using different synthetic superdisintegrants like Crospovidone, Croscarmellose sodium and Sodium starch glycolate and using natural superdisintegrants mango pectin powder, Guar Gum and Aloe vera mucilage. Powder mixture formulated was assessed for different rheological properties by using standard procedures. The tablets were prepared by direct compression methods and characterized for different parameters such as weight variation, hardness, friability, wetting time, water absorption ratio, drug content, disintegration time and drug release. The mouth dissolving tablets made from natural disintegrants was found superior over a mouth dissolving tablets made from a synthetic polymer.

Keywords: Mouth dissolving tablets, Etoricoxib, synthetic superdisintegrants and natural disintegrants.

INTRODUCTION:

The oral route of administration still continues to be the most preferred route due to its manifold advantages including ease of administration, accurate dosage, versatility, self-medication and most importantly patient compliance. Therefore, oral solid dosage forms are more popular. Among the pharmaceutical dosage forms, the conventional tablets seem to be the most popular, because of ease of transportability and comparatively lower manufacturing cost[1]. The disadvantage of oral conventional dosage forms such as Dysphasia or difficulty in swallowing can be overcome by developing rapidly disintegrating and dissolving tablet dosage forms for oral administration because they dissolve in saliva and does not require water for swallowing[2]. Recent advances in novel drug delivery system to enhance the safety and efficacy of drugs by administration of conventional tablets led to the development of oral disintegrating tablets. Administration is simple, as the tablet is placed in a mouth, and allowed to disperse or dissolve in the saliva, and swallowed[3].

Clinically, nonsteroidal anti-inflammatory drugs (NSAIDs) are the most frequently prescribed by physicians for inflammatory disorders. NSAIDs exert their effect through inhibition of cyclooxygenase-II, the main form of isozyme associated with inflammation. But the simultaneous inhibition of cyclooxygenase-I and the resulting gastric and renal dysfunction limit their frequent use [4]. Etoricoxib is a cyclooxyginase-II (COX-II) selective NSAID used in the treatment of rheumatoid arthritis, osteoarthritis, postoperative dental pain, chronic low back pain, acute gout and primary dismenorrhoea[5]. The COX-I to COX-II selectivity ratio is higher than other COX-II inhibitors such as Rofecoxib, Valdecoxib and Celecoxib[6]. Etoricoxib is practically insoluble in water and peak blood level reaches after 1 h of oral administration[7,8]. The rate and extent of dissolution of the drug from any solid dosage form determines rate and extent of absorption of the drug. In the case of poorly water-soluble drugs, dissolution is the

rate-limiting step in the process of drug absorption that in turns dependent on disintegration. The dissolution rate and bioavailability of poorly soluble drug from solid dosage form depend much on formulation additives and formulation characteristics.

Etoricoxib is an effective and selective cox-2 inhibitor with anti-inflammatory and analgesic properties. The poor water solubility of the drug give rise to difficulties in the formulation of dosage form leading to variable dissolution rate, hence it was selected as a model drug. In the present work an attempt has been made to prepare MDTs of etoricoxib using different superdisintegrants in different concentrations.

MATERIALS AND METHOD:

Etoricoxib was obtained as Gift sample. Sodium Starch Glycolate, Croscarmellose Sodium, Microcrystalline cellulose, Magnesium, Mango Pectin Powder (MPP), Guar Gum Powder (GGP), Aloe Vera Mucilage (AVM), Stearate, Calcium carbonate, Microcrystalline Cellulose, and Sucralose were purchased from markets.

Identification of Drug:

Organoleptic Characteristics: The organoleptic characteristic test of drug sample i.e. Etoricoxib was performed by sensory organs. The parameters such as colour, odour and state were observed and shown in Table 1.

Preliminary Investigation on Solubility of Etoricoxib

The absorption rate of poorly water soluble drugs through the mucosal membrane is governed by the solubility of drug in the saliva i.e. solubility is the rate limiting step in the overall process of absorption of poorly water soluble drugs. So an attempt was made to determine the solubility of Etoricoxib with different solvents at room temperature as described below.

Table 2: The Solubility Profile of Etoricoxib (Etx)

Medium	Solubility
Distilled Water	-
Methanol	+++
Ethanol	++
Hydrochloride Solution	++++
Sodium Hydroxide	+
Acetone	+++
Phosphate buffer pH 6.8	++++
Phosphate buffer pH 7.4	++++

Keys: **+ + + +** Freely soluble **+ + +** Soluble
+ + Sparingly soluble **+** Slightly soluble **-** Insoluble

Melting Point: Melting point was established by capillary tube method in digital melting point apparatus. The powder of drug sample was filled in glass capillary tube with tapping pinch of pure drug sample. The filled in capillary tube is previously sealed from one end with flame. The filled capillary tube was kept stand in melting point apparatus. Temperature at which the drug powder was started to melt was shown in Table 3.

Partition coefficient: The partition coefficient of Etoricoxib (Etx) was determined to calculate the hydrophobecity/hydrophilicity of drug sample in 100 ml of mixed solvent system. It was determined by mixture of n-octanol: phosphate buffer (pH-7.4) solutions, taken this mixture in 100 ml separating funnel added 10mg of drug, shaken for 24 hours in wrist shaker. After that separating funnel was kept to stand for 2 hours in a stand then both layer i.e. n-octanol and phosphate buffer were separated and collected individually. The quantity of drug dissolved in phosphate buffer medium was determined by UV-visible spectrophotometer at 238 nm and data shown in Table 4.

Preparation of standard curve of Etoricoxib:

Preparation of calibration curve in 0.1N HCl:

Standard Stock Solution: A stock solution containing 1000 µg/ml of pure drug was prepared by dissolving 100 mg of Etoricoxib in sufficient 0.1N HCl solution to produce 100 ml solution in a volumetric flask. From this solution 2-20 µg/ml of dilutions were made. The prepared concentrations were analyzed in UV-Visible spectroscopy at 238 nm.

Table 5: Calibration Curve of Etoricoxib in 0.1N HCl

S.No.	Concentration (mcg/mL)	Absorbance
1.	2	0.089
2.	4	0.175
3.	6	0.285
4.	8	0.397
5.	10	0.469
6.	12	0.568
7.	14	0.654
8.	16	0.782
9.	18	0.874
10.	20	0.998

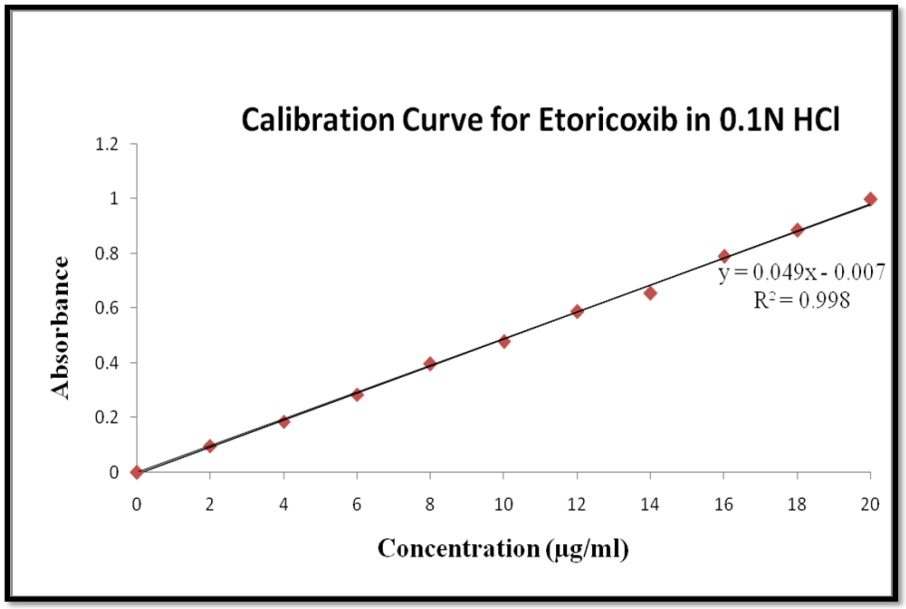

Figure 1: Calibration Curve of Etoricoxib in 0.1N HC1

Preparation of calibration curve in Phosphate buffer pH 6.8:

A calibration curve for Etoricoxib was obtained by measuring the absorbance at the λ_{max} of 238 nm using spectrometer. Calibration curve was prepared by plotting concentration vs absorbance and data shown in Table 4.14 and in fig. 4.8.

Table 6: Calibration Curve of Etoricoxib in Phosphate buffer (pH - 6.8)

S.No.	Concentration (µg/mL)	Absorbance
1	2	0.091
2	4	0.221
3	6	0.314
4	8	0.432
5	10	0.512
6	12	0.62
7	14	0.718
8	16	0.845
9	18	0.925
10	20	1.101

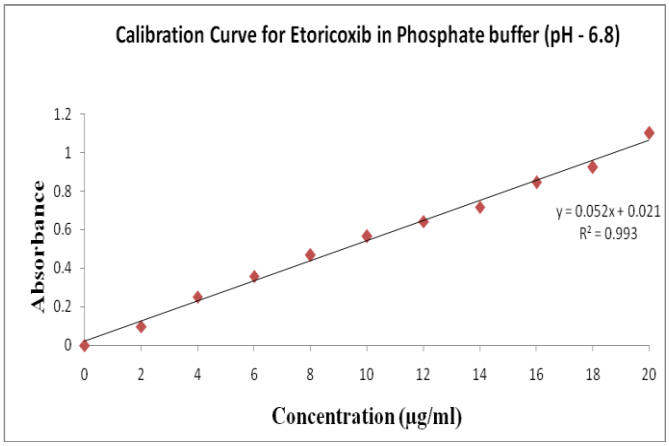

Figure 2: Calibration Curve of Etoricoxib in Phosphate Buffer (pH = 6.8)

Development of Formulation: Direct compression is the most preferred method for Mouth dissolving tablets formulation because it is simple, economical, moisture-free, and suitable for heat-sensitive and moisture-sensitive drugs. The technique requires free-flowing, non-hygroscopic powder blends and offers benefits such as minimal processing steps, low contamination risk, and improved dissolution characteristics[9]. Considering these advantages, the method was selected for the formulation of both synthetic and natural superdisintegrant-based MDTs in this study.

A 3^3 factorial design was adopted to optimize the concentration of three superdisintegrants Crospovidone, Sodium Starch Glycolate, and Croscarmellose Sodium (CP, SSG, CCS) in synthetic superdisintegrants based formulations and Mango Pectin Powder (MPP), Guar Gum Powder (GGP) and Aloe Vera Mucilage (AVM) in natural superdisintegrants based formulations. The factorial design enabled systematic evaluation of main effects, interactions, and polynomial (non-linear) relationships among formulation variables. Twenty-seven formulations each were prepared for synthetic (SC_1Etx) and natural (SC_2Etx) superdisintegrant systems respectively.

All formulations were subjected to a comprehensive set of pre-compression parameters such as angle of repose, bulk density, tapped density, Carr's index and Hausner's ratio to assess flow properties, and post-compression

parameters such as weight variation, hardness, thickness and friability to ensure compliance with pharmacopoeial standards. The presents study detailed evaluation and interpretation of these results to identify the most suitable combination of superdisintegrants capable of producing high-quality MDTs.

Different Formulations with their respective Compositions as per 3^3 factorial designs:-

[A] Optimization of concentration of synthetic superdisintegrants such as Crospovidone, Sodium Starch Glycolate and Croscarmellose Sodium (CP: SSG: CCS). All the formulations were represented as SC_1Etx for synthetic superdisintegrants and 27 formulations were prepared and blend was evaluated before compression, then tablets was prepared by direct compression and further evaluated for different parameters.

Table 7: Factorial design layout for optimization of synthetic superdisintegrants (SC_1Etx)

S. No.	Code	Coded Value	Amount of CP in mg	Amount of SSG in mg	Amount of CCS in mg
1	X_1	-1	9	9	9
2	X_2	0	12	12	12
3	X_3	1	15	15	15

Table 8: Composition of SC_1Etx for preparing mouth dissolving tablets (in mg) of Etoricoxib

Formulation Code	Etx	CP	CCS	SSG	Sucra-lose	$CaCO_3$	Flavour	Colloidal Silicon Dioxide	Mg. Ste.	MCC	Total Weight
F1SC_1Etx	120	15	15	15	8	20	8	8	6	q.s.	350
F2SC_1Etx	120	15	15	12	8	20	8	8	6	q.s.	350
F3SC_1Etx	120	15	15	9	8	20	8	8	6	q.s.	350
F4SC_1Etx	120	15	12	15	8	20	8	8	6	q.s.	350
F5SC_1Etx	120	15	12	12	8	20	8	8	6	q.s.	350
F6SC_1Etx	120	15	12	9	8	20	8	8	6	q.s.	350
F7SC_1Etx	120	15	9	15	8	20	8	8	6	q.s.	350
F8SC_1Etx	120	15	9	12	8	20	8	8	6	q.s.	350
F9SC_1Etx	120	15	9	9	8	20	8	8	6	q.s.	350
F10SC_1Etx	120	12	15	15	8	20	8	8	6	q.s.	350
F11SC_1Etx	120	12	15	12	8	20	8	8	6	q.s.	350
F12SC_1Etx	120	12	15	9	8	20	8	8	6	q.s.	350
F13SC_1Etx	120	12	12	15	8	20	8	8	6	q.s.	350
F14SC_1Etx	120	12	12	12	8	20	8	8	6	q.s.	350
F15SC_1Etx	120	12	12	9	8	20	8	8	6	q.s.	350
F16SC_1Etx	120	12	9	15	8	20	8	8	6	q.s.	350
F17SC_1Etx	120	12	9	12	8	20	8	8	6	q.s.	350
F18SC_1Etx	120	12	9	9	8	20	8	8	6	q.s.	350
F19SC_1Etx	120	9	15	15	8	20	8	8	6	q.s.	350
F20SC_1Etx	120	9	15	12	8	20	8	8	6	q.s.	350
F21SC_1Etx	120	9	15	9	8	20	8	8	6	q.s.	350
F22SC_1Etx	120	9	12	15	8	20	8	8	6	q.s.	350
F23SC_1Etx	120	9	12	12	8	20	8	8	6	q.s.	350
F24SC_1Etx	120	9	12	9	8	20	8	8	6	q.s.	350
F25SC_1Etx	120	9	9	15	8	20	8	8	6	q.s.	350
F26SC_1Etx	120	9	9	12	8	20	8	8	6	q.s.	350
F27SC_1Etx	120	9	9	9	8	20	8	8	6	q.s.	350

Values are expressed in miligram (mg)

[B] Optimization of concentration of Natural Superdisintegrants Mango Pectin Powder, Gaur Gum Powder and Aloe Vera Mucilage (MPP: GGP: AVM) respectively.

Different Formulations with their respective Compositions for Natural Superdisintegrants as per 3^3 factorial design, Various variables were selected as Independent variables for Natural Superdisintegrant such as Mango Pectin Powder (MPP), Guar Gum Powder (GGP), Aloe Vera Mucilage (AVM) and Dependent variables were Weight Variation (Y_1), Hardness (Y_2), Thickness (Y_3), Friability (Y_4).

Table 9: Factorial design layout for optimization of natural superdisintegrants (SC_2Etx)

S. No.	Code	Coded Value	Amount of MPP in mg	Amount of GGP in mg	Amount of AVM in mg
1	Xa	-1	9	9	9
2	Xb	0	12	12	12
3	Xc	1	15	15	15

Table 10: Composition of SC_2Etx for preparing mouth dissolving tablets (in mg) of Etoricoxib

Formulation Code	Etx	MPP	GPP	AVM	Sucra-lose	$CaCO_3$	Flavour	Colloidal Silicon Dioxide	Mg. Ste.	MCC	Total
F1SC_2Etx	120	15	15	15	8	20	8	8	6	q.s.	350
F2SC_2Etx	120	15	15	12	8	20	8	8	6	q.s.	350
F3SC_2Etx	120	15	15	9	8	20	8	8	6	q.s.	350
F4SC_2Etx	120	15	12	15	8	20	8	8	6	q.s.	350
F5SC_2Etx	120	15	12	12	8	20	8	8	6	q.s.	350
F6SC_2Etx	120	15	12	9	8	20	8	8	6	q.s.	350
F7SC_2Etx	120	15	9	15	8	20	8	8	6	q.s.	350
F8SC_2Etx	120	15	9	12	8	20	8	8	6	q.s.	350
F9SC_2Etx	120	15	9	9	8	20	8	8	6	q.s.	350
F10SC_2Etx	120	12	15	15	8	20	8	8	6	q.s.	350
F11SC_2Etx	120	12	15	12	8	20	8	8	6	q.s.	350
F12SC_2Etx	120	12	15	9	8	20	8	8	6	q.s.	350
F13SC_2Etx	120	12	12	15	8	20	8	8	6	q.s.	350
F14SC_2Etx	120	12	12	12	8	20	8	8	6	q.s.	350
F15SC_2Etx	120	12	12	9	8	20	8	8	6	q.s.	350
F16SC_2Etx	120	12	9	15	8	20	8	8	6	q.s.	350
F17SC_2Etx	120	12	9	12	8	20	8	8	6	q.s.	350
F18SC_2Etx	120	12	9	9	8	20	8	8	6	q.s.	350
F19SC_2Etx	120	9	15	15	8	20	8	8	6	q.s.	350
F20SC_2Etx	120	9	15	12	8	20	8	8	6	q.s.	350
F21SC_2Etx	120	9	15	9	8	20	8	8	6	q.s.	350
F22SC_2Etx	120	9	12	15	8	20	8	8	6	q.s.	350
F23SC_2Etx	120	9	12	12	8	20	8	8	6	q.s.	350
F24SC_2Etx	120	9	12	9	8	20	8	8	6	q.s.	350
F25SC_2Etx	120	9	9	15	8	20	8	8	6	q.s.	350
F26SC_2Etx	120	9	9	12	8	20	8	8	6	q.s.	350
F27SC_2Etx	120	9	9	9	8	20	8	8	6	q.s.	350

Values are expressed in milligram (mg)

Evaluation of pre-compression characteristics of powder blend: Powder mixture formulated was assessed for different rheological properties by using standard procedures. The evaluation was done thrice time (n=3) and mean data were shown in table 13 and 14.

Flow property: Angle of Repose - The frictional forces in a loose powder can be measured by the angle of repose, θ. This is the maximum angle possible between the surface of a pile of powder and horizontal plane when only gravity acts upon it, will tend to form a conical mount. The tangent of the angle of repose is equal to the coefficient of friction between the particles. Angle of repose is used to measure the flow property of drug powder which is important in formulation point of view.

Method: In this process the fennel was placed above graph paper at distance of 6 cm. The powder is carefully poured through the funnel until the apex of the conical pile just touches the tip of the funnel. The radius of the base (r) of the conical pile was measured. The angle of repose was calculated by applying following formula:

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

Where,

h=height of heap of granular bed,

r = radius of heap of granular bed.

Table 11: Flow property with Angle of Repose

Flow Property	Angle of Repose (Degrees)
Excellent	25-30
Good	31-35
Fair - Aid not needed	36-40
Passable - may hang up	41-45
Poor- must agitate, vibrate	46-55

Bulk Density: The bulk density and tapped density are evaluated to determine the rate of filling of blend to die. The bulk density was measured by 50:0.5 ml measuring cylinder. The pre-compression blends were weighted and filled in a measuring cylinder, and after that the complete volume was noted. Bulk density refers to describe about packing of particles or granules for dosage form. It is defined as the mass of a powder divided by bulk volume. The following formula was used to determine the bulk density.

Method- An accurately weighed, 50 gm sample of powder is carefully added into a 100ml measuring cylinder. The initial volume is noted.

Bulk Density = Weight of the powder / Volume of the powder

Tapped density: Tapped density was determined by the mixtures were filled in a measuring cylinder. After that the measuring cylinder was tapped 100 times. Measure the weight of the total powders. The tapped density was calculated by applying following formula:

Tapped Density = Weight of the powder / Tapped Volume of the powder

Hausner's ratio: Hausner's ratio was calculated by using following formula and it was expressed in percentage

$$H=D_t/D_b$$

Where

D_t - denoted the tapped density of the powder

D_b - denoted the bulk density of the powder, Values less than 1.25 indicates good flow and greater than 1.25 indicates poor flow.

Compressibility Index: Compressibility index can be a measure of the potential strength that a powder could built up in its arch in a hopper and also the ease with which such an arch could be broken. It is used to characterize the nature of powder and granules. It is indirectly related to the relative flow rate, cohesiveness and particle size.

Compressibility Index (%) = (Tapped density-Bulk density) x100/Tapped density

Table 12: Compressibility Index and flow property relationship

Carr's Index	Flow Character	Hausner's Ratio
5-15	Excellent	1.00-1.11
12-16	Good	1.12-1.18
18-21	Fair	1.19-1.25
23-35	Passable	1.26-1.34
33-38	Poor	1.35-1.45
5-15	Very Poor	1.46-1.59
>40	Extremely poor flow	>1.60

COMPRESSION OF POWDERS INTO TABLETS

Before compression of powder into tablets, the Lubricant (talc) and glidant (magnesium stearate) were mixed to the prepared powders. By the help of tablet compression machine the powder were compressed into tablets using 10mm diameter, flat faced punches.

EVALUATION OF POST COMPRESSION PARAMETERS:

After formulation of tablets it required to check the suitability of dosage form for proper therapeutic response. The various parameters are used for evaluation of compression to tablets. The thickness, friability, hardness, weight variation and dissolution test were evaluated for prepared tablets using standard procedures. The following post compression

parameters were tested for prepared mouth dissolving tablets and result data shown in table No. 15 and 16

Weight variation test

In this process the 20 tablets were weighed separately. The average weight of one tablet was calculated by taking average mean. As per I.P. it has mentioned that not more than 2 tablets produce distinctive weight. As per I.P. not more than 2 of the distinctive weights from the mean weight, and none should be aberrant by longer than twice that percentage given in the monographs.

Hardness test

The Monsanto hardness tester was used to determine the hardness of formulated tablets. The hardness was calculated in respect to kg/cm^2. Thrice readings were measured and average was noted.

Thickness test

By the help vernier-caliper, we measure the thickness of the tablets in terms of micrometer. The averages of three readings were noted and the results of mean were recorded (n = 3)

Friability test

The Roche friabilator was used to measure the abrasion rate of formulated tablets. Measure the weight of 20 tablets and kept in the friabilator chamber. The friabilator was rotated at speed of 25 rpm for 4 min. After completion of rotation of friabilator tablets were weighted and by the help of formula the percentage weight loss was calculated.

$$\%\text{Friability} = \frac{\text{Initial weight of tablets} - \text{Final weight of tablets}}{\text{Initial weight of tablets}} \text{ X } 100$$

Evaluation of Optimized Formulations: Among 27 formulations of synthetic and natural superdisintegrants respectively on the basis of fundamental post-compression characteristics such as weight variation, hardness, thickness, and friability were determined to ensure compliance with pharmacopoeial standards. Selected 3-3 formulations from synthetic and natural superdisintegrants respectively for parameters including Drug content uniformity, wetting time, water absorption ratio, *in-vitro* disintegration time, and dissolution studies were conducted to evaluate how efficiently the tablets disperse and release the drug in the oral cavity. Drug content uniformity was assessed to confirm that each tablet delivers the required dose of the active ingredient, ensuring therapeutic efficacy.

Uniformity of Content: The drug content was calculated by triturating the ten tablets in a mortar with pestle after calculating their average weight to get fine powder. Taken powder equivalent average weight of single tablet and was dissolved in 100 ml pH 6.8 phosphate buffer solutions and filtered. Measure the absorbance of diluted sample of optimized formulations of synthetic superdisintegrants and natural superdisintegrants respectively, using UV-Visible Spectrophotometer. The drug content was calculated by using standard calibration curve.

Wetting time: The wetting time was calculated by placing the tablets in Petridish. The petridish was consisting of 6 ml of purified water along with tissue paper folded two times. The time required for complete wetting of tablets was measured.

$$\text{Wetting Time} = T_t - T_0$$

Where

T_t = Time after tablet wetted

T_0=Time of tablet Placed

Water absorption ratio: The procedure used in wetting time was applied for the determination of water absorption ratio. Water absorption ratio R was calculated using equation.

$$\text{Water absorption ratio(R)} = \frac{\{Wa - Wb\}}{Wb} \text{ x } 100$$

Where

Wa = the weight after absorption

Wb= is the weight before absorption.

***In-vitro* disintegration time:** Rate of disintegration imparts chief role for mouth dissolving tablets. The disintegrating agents are used to enhance the disintegration of mouth dissolving tablets. The disintegrants promotes the moisture penetration into the tablets.

Following are the factors which affect the rate of disintegration of mouth dissolving tablets

- Quantity of disintegrants available in mouth dissolving tablets.
- Nature of diluents, polymer, excipients present in mouth dissolving tablets.
- Combination of various types of disintegrants.
- Nature of blending of disintegrants for tablets.

Dissolution studies: Dissolution rate was studied by using USP type-II apparatus (USPXXIII Dissolution Test Apparatus at 50 rpm) using 900 ml of pH 6.8 phosphate buffer as dissolution medium. Temperature of the dissolution medium was maintained at 37±2°C, aliquot of dissolution medium was withdrawn at every min interval and filtered. The absorbance of filtered solution was measured by UV spectrophotometric method and concentration of the drug was determined from standard calibration curve. The formulation which shows best drug release was shown in table 16.

Stability Studies: A solid dosage form, apart from other requirements, should be stable with regard to its properties especially its dissolution characteristics in the case of poorly soluble drug. The stability of selected Etoricoxib formulations developed in the present investigation was evaluated as per ICH guidelines.

The stability studies carried out for optimized formulations of synthetic and natural superdisintegrants for etoricoxib for 6 months according to ICH guidelines. The tablets were packed in screw capped HDPE bottles and were stored at 40°C and 75% RH for 6 months. After storage for 6 months, the products were tested for hardness, friability, drug content, disintegration time and dissolution rate as per the methods and result shown in table 17.

Among all the evaluated batches, the optimized natural superdisintegrant formulations (F21SC_2Etx, F22SC_2Etx, and F23SC_2Etx) showed the most desirable characteristics, including disintegration within 45-53 seconds and drug release exceeding 98% within 2 minutes. Stability studies conducted under accelerated conditions for six months confirmed that these optimized formulations retained their physical attributes, drug content, and dissolution efficiency, thereby establishing their strength and storage stability.

RESULT AND DISCUSSION:

Table 13: Organoleptic Properties of Etoricoxib

S. No.	Organoleptic Properties	Reported	Observed
1	Colour	Off white	Off white
2	Odour	Odourless	Odourless
3	State (Microscopic examination)	Crystalline powder	Crystalline in nature

Table 14: Melting Point of Etoricoxib (Etx)

S. No	Drug samples	Temperature (°C)	
1	Etoricoxib (Etx)	Reported	Observed
		134-138°C	137±1°C

Table 15: Partition Coefficient of Etoricoxib

S. No	Drug Samples	Partition coefficient
1	**Etoricoxib (Etx)**	1.86

Table 16: Pre-compression Evaluation of SC_1Etx mouth dissolving tablets (in mg) of Etoricoxib

Formulation Code	Angle of repose*	Apparent Bulk Density* (g/cm^3)	Tapped Bulk Density* (g/cm^3)	Compressibility Index* (%)	Hausner's Ratio*
F1SC_1Etx	37.50	0.563	0.665	15.338	1.181
F2SC_1Etx	37.25	0.548	0.651	15.822	1.188
F3SC_1Etx	36.34	0.563	0.668	15.719	1.187
F4SC_1Etx	38.21	0.565	0.663	14.781	1.173
F5SC_1Etx	37.28	0.563	0.673	16.345	1.195
F6SC_1Etx	38.10	0.564	0.684	17.544	1.213
F7SC_1Etx	37.14	0.567	0.664	14.608	1.171
F8SC_1Etx	37.04	0.572	0.679	15.758	1.187
F9SC_1Etx	38.04	0.564	0.673	16.196	1.193
F10SC_1Etx	37.45	0.568	0.68	16.471	1.197
F11SC_1Etx	35.50	0.578	0.677	14.623	1.171

F12SC$_1$Etx	36.89	0.583	0.672	13.244	1.153
F13SC$_1$Etx	37.12	0.572	0.678	15.634	1.185
F14SC$_1$Etx	38.01	0.578	0.68	15.000	1.176
F15SC$_1$Etx	34.82	0.574	0.659	12.898	1.148
F16SC$_1$Etx	37.23	0.572	0.664	13.855	1.161
F17SC$_1$Etx	36.98	0.576	0.667	13.643	1.158
F18SC$_1$Etx	37.56	0.578	0.674	14.243	1.166
F19SC$_1$Etx	37.85	0.572	0.664	13.855	1.161
F20SC$_1$Etx	38.14	0.562	0.666	15.616	1.185
F21SC$_1$Etx	37.54	0.563	0.647	12.983	1.149
F22SC$_1$Etx	38.32	0.569	0.658	13.526	1.156
F23SC$_1$Etx	37.85	0.568	0.669	15.097	1.178
F24SC$_1$Etx	37.64	0.578	0.687	15.866	1.189
F25SC$_1$Etx	37.68	0.581	0.68	14.559	1.170
F26SC$_1$Etx	37.36	0.564	0.669	15.695	1.186
F27SC$_1$Etx	38.17	0.541	0.642	15.732	1.187

*Value shown in tables is mean of three determinations

Table 17: Pre-compression Evaluation of SC$_2$Etx mouth dissolving tablets (in mg) of Etoricoxib

Formulation Code	Angle of repose*	Apparent Bulk Density* (g/cm^3)	Tapped Bulk Density* (g/cm^3)	Compressibility Index* (%)	Hausner's Ratio*
F1SC$_2$Etx	36.21	0.553	0.655	15.573	1.184
F2SC$_2$Etx	35.56	0.528	0.631	16.323	1.195
F3 SC$_2$Etx	35.34	0.536	0.641	16.381	1.196
F4SC$_2$Etx	37.89	0.556	0.654	14.985	1.176
F5SC$_2$Etx	36.98	0.563	0.673	16.345	1.195
F6SC$_2$Etx	38.39	0.546	0.666	18.018	1.220
F7SC$_2$Etx	36.72	0.576	0.673	14.413	1.168
F8SC$_2$Etx	37.12	0.578	0.685	15.620	1.185
F9SC$_2$Etx	37.84	0.572	0.681	16.006	1.191
F10SC$_2$Etx	36.75	0.574	0.686	16.327	1.195
F11SC$_2$Etx	36.32	0.587	0.686	14.431	1.169
F12SC$_2$Etx	36.28	0.558	0.647	13.756	1.159
F13SC$_2$Etx	36.34	0.548	0.654	16.208	1.193
F14SC$_2$Etx	37.22	0.569	0.671	15.201	1.179
F15SC$_2$Etx	34.22	0.582	0.667	12.744	1.146
F16SC$_2$Etx	36.58	0.562	0.654	14.067	1.164
F17SC$_2$Etx	36.98	0.568	0.659	13.809	1.160
F18SC$_2$Etx	36.86	0.558	0.654	14.679	1.172

F19SC$_2$Etx	37.76	0.574	0.666	13.814	1.160
F20SC$_2$Etx	37.52	0.562	0.666	15.616	1.185
F21SC$_2$Etx	37.25	0.568	0.652	12.883	1.148
F22SC$_2$Etx	37.44	0.572	0.661	13.464	1.156
F23SC$_2$Etx	36.92	0.562	0.663	15.234	1.180
F24SC$_2$Etx	36.82	0.572	0.681	16.006	1.191
F25SC$_2$Etx	36.68	0.582	0.681	14.537	1.170
F26SC$_2$Etx	37.32	0.582	0.687	15.284	1.180
F27SC$_2$Etx	37.25	0.552	0.653	15.467	1.183

*Value shown in tables is mean of three determinations

EVALUATION OF POST COMPRESSION PARAMETERS:

Table 18: Evaluation parameters of SC$_1$Etx for preparing mouth dissolving tablets of Etoricoxib

Formulation Code	Weight Variation (mg)	Hardness (Kg/cm^2)	Thickness (mm)	Friability (%)
F1SC$_1$Etx	351.35±3.15	1.06±0.5	3.08±0.1	1.35±0.1
F2SC$_1$Etx	351.25±2.71	1.16±0.4	3.01±0.5	1.27±0.6
F3SC$_1$Etx	350.15±4.45	2.02±0.3	3.06±0.4	0.91±0.8
F4SC$_1$Etx	351.85±3.27	1.14±0.4	2.97±0.6	1.27±0.2
F5SC$_1$Etx	351.05±2.93	1.28±0.3	2.96±0.5	1.14±0.3
F6SC$_1$Etx	351.45±2.70	2.22±0.5	3.08±0.1	0.89±0.5
F7SC$_1$Etx	352.40±3.24	1.39±0.3	3.09±0.9	1.05±0.8
F8SC$_1$Etx	353.55±3.25	1.42±0.5	3.10±0.5	1.03±0.4
F9SC$_1$Etx	352.45±2.98	4.26±0.3	3.07±0.4	0.25±0.2
F10SC$_1$Etx	352.15±3.57	3.02±0.2	3.05±0.6	0.57±0.4
F11SC$_1$Etx	352.45±3.07	2.56±0.4	3.07±0.8	0.76±0.3
F12SC$_1$Etx	352.25±2.55	3.43±0.3	3.03±0.4	0.51±0.6
F13SC$_1$Etx	353.65±2.93	3.90±0.1	2.91±0.5	0.48±0.8
F14SC$_1$Etx	352.35±3.28	2.86±0.2	2.82±0.4	0.67±0.7
F15SC$_1$Etx	353.55±2.70	2.67±0.1	3.05±0.3	0.75±0.5
F16SC$_1$Etx	353.05±2.59	2.51±0.2	2.85±0.5	0.78±0.5
F17SC$_1$Etx	352.05±2.95	2.38±0.3	2.97±0.7	0.81±0.2
F18SC$_1$Etx	352.45±3.33	2.02±0.4	3.02±0.2	0.90±0.8
F19SC$_1$Etx	351.90±3.51	3.99±0.1	2.95±0.6	0.46±0.8
F20SC$_1$Etx	351.90±3.35	4.04±0.3	2.96±0.4	0.45±0.7
F21SC$_1$Etx	352.25±3.29	4.14±0.3	2.96±0.8	0.42±0.2
F22SC$_1$Etx	352.05±2.67	4.21±0.1	3.12±0.6	0.40±0.4
F23SC$_1$Etx	352.90±3.24	4.33±0.4	3.10±0.9	0.39±0.1
F24SC$_1$Etx	353.80±3.09	4.55±0.6	3.05±0.6	0.37±0.6
F25SC$_1$Etx	352.20±2.57	4.64±0.1	3.19±0.8	0.34±0.4
F26SC$_1$Etx	352.75±3.14	4.77±0.7	3.15±0.4	0.32±0.2
F27SC$_1$Etx	352.35±2.74	4.85±0.2	3.20±0.6	0.31±0.4

Table 19: Evaluation parameters of SC_2Etx for preparing mouth dissolving tablets of Etoricoxib

Formulation Code	Weight Variation (mg)	Hardness (Kg/cm^2)	Thickness (mm)	Friability (%)
F1SC_2Etx	351.45±2.33	1.20±0.5	3.01±0.2	1.28±0.8
F2SC_2Etx	351.15±2.98	1.28±0.4	3.03±0.3	1.26±0.2
F3SC_2Etx	351.15±3.62	2.02±0.3	3.10±0.5	0.97±0.3
F4SC_2Etx	350.00±2.56	1.46±0.4	3.01±0.4	1.19±0.5
F5SC_2Etx	352.30±3.03	1.58±0.3	3.02±0.5	1.11±0.8
F6SC_2Etx	352.65±2.64	2.17±0.5	3.03±0.1	0.95±0.4
F7SC_2Etx	352.85±2.96	1.57±0.3	3.02±0.7	1.11±0.6
F8SC_2Etx	353.05±2.61	1.66±0.5	3.04±0.4	1.09±0.1
F9SC_2Etx	353.15±2.43	2.29±0.3	3.05±0.3	0.91±0.2
F10SC_2Etx	352.25±3.39	1.93±0.2	3.03±0.5	1.07±0.4
F11SC_2Etx	352.35±3.66	2.05±0.4	3.05±0.6	0.97±0.3
F12SC_2Etx	352.45±3.61	2.23±0.3	3.02±0.3	0.92±0.6
F13SC_2Etx	352.35±2.78	2.45±0.1	3.04±0.3	0.89±0.8
F14SC_2Etx	353.78±2.66	2.52±0.2	2.97±0.4	0.87±0.7
F15SC_2Etx	352.70±2.81	2.78±0.1	3.04±0.2	0.82±0.5
F16SC_2Etx	351.90±3.04	3.07±0.2	3.01±0.3	0.75±0.5
F17SC_2Etx	352.10±2.67	3.18±0.3	2.97±0.2	0.71±0.2
F18SC_2Etx	351.80±2.65	3.26±0.4	3.03±0.4	0.68±0.8
F19SC_2Etx	352.30±2.85	3.39±0.1	2.98±0.7	0.65±0.7
F20SC_2Etx	353.05±3.03	3.56±0.3	2.94±0.2	0.29±0.8
F21SC_2Etx	352.15±3.13	4.03±0.3	3.06±0.5	0.55±0.2
F22SC_2Etx	352.05±3.59	3.84±0.1	3.02±0.5	0.24±0.4
F23SC_2Etx	354.25±3.75	4.09±0.4	3.11±0.7	0.49±0.1
F24SC_2Etx	353.05±2.70	3.70±0.6	3.04±0.5	0.27±0.6
F25SC_2Etx	352.60±3.39	4.13±0.1	3.18±0.6	0.43±0.4
F26SC_2Etx	352.95±3.47	4.18±0.7	3.12±0.3	0.36±0.2
F27SC_2Etx	352.75±3.43	4.24±0.2	3.15±0.4	0.32±0.4

Evaluation of Optimized Formulations:

Table 20: Evaluation parameters of SC_1Etx for preparing mouth dissolving tablets of Etoricoxib

Formulations code / Parameters	F11SC_1Etx	F12SC_1Etx	F13SC_1Etx	F21SC_2Etx	F22SC_2Etx	F23SC_2Etx
Drug Content (%)	98.59	97.96	98.38	97.64	98.04	98.17
Wetting Time	10.33±2.52	09.67±2.52	10.33±2.08	11.33±1.53	09.34±2.52	11.33±3.79
Water Absorption Ratio	44.67±2.52	46.33±2.08	46.67±2.52	42.33±1.53	43.33±2.80	42.33±2.31
Disintegration time	51.5	51.5	51.5	51.5	51.5	51.5

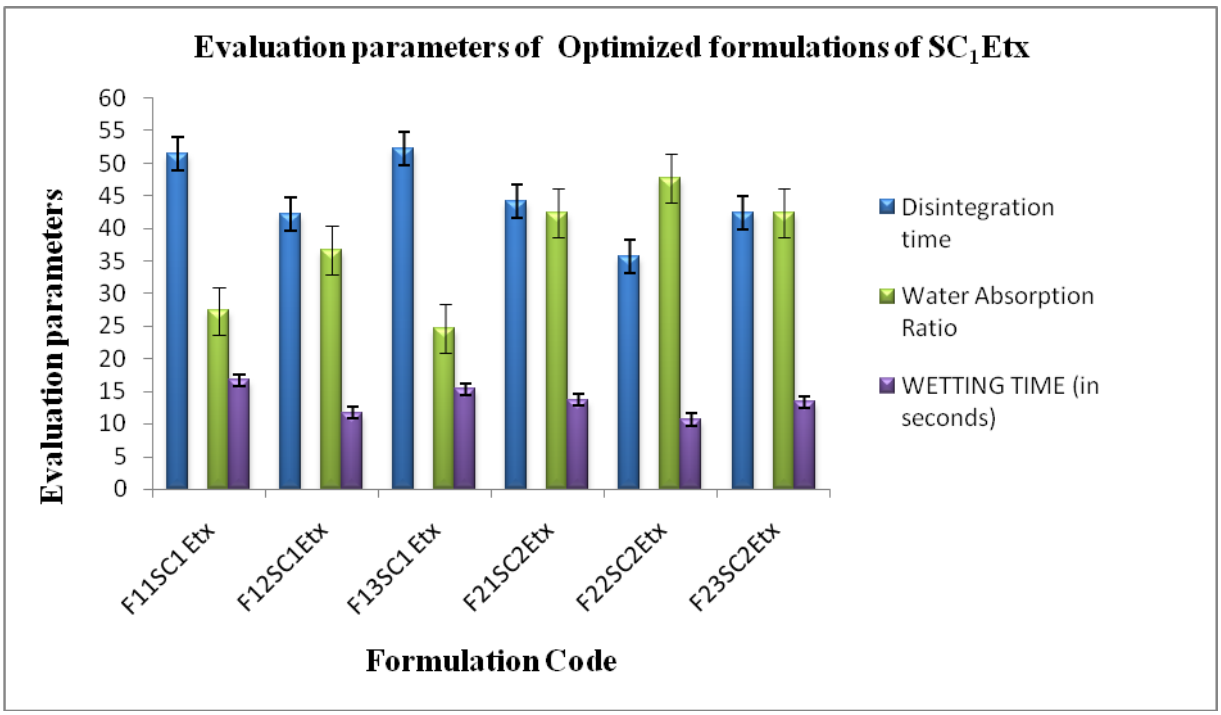

Table 21: Evaluation of Dissolution Studies of optimized Formulations

S. No.	Formulation code	Dissolution time (in min)									
		Percent Drug Content									
		1	2	3	4	5	6	7	8	9	10
1.	F11SC$_1$Etx	99.59	99.85	100	100	100	100	100	100	100	100
2.	F12SC$_1$Etx	97.96	98.52	100	100	100	100	100	100	100	100
3.	F13SC$_1$Etx	98.38	98.58	100	100	100	100	100	100	100	100
4.	F21SC$_2$Etx	97.64	98.86	100	100	100	100	100	100	100	100
5.	F22SC$_2$Etx	98.04	99.56	100	100	100	100	100	100	100	100
6.	F23SC$_2$Etx	98.17	98.98	100	100	100	100	100	100	100	100

Table 22: Different parameters of optimized formulations for Stability Study

Parameters	Duration	F11SC$_1$Etx	F12SC$_1$Etx	F13SC$_1$Etx	F21SC$_2$Etx	F22SC$_2$Etx	F23SC$_2$Etx
Hardness (Kg/cm^2)	After One month	2.98±0.4	3.15±0.3	3.10±0.1	3.28±0.2	3.11±0.4	3.16±0.3
	After three month	3.25±0.4	3.45±0.2	3.25±0.2	3.35±0.3	3.24±0.3	3.28±0.4
	After six month	3.45±0.4	3.55±0.1	3.29±0.3	3.38±0.3	3.35±0.2	3.36±0.3
Drug Content	After One month	99.59	97.96	98.38	97.64	98.04	98.17
	After three month	98.86	97.54	98.12	97.11	97.86	97.89
	After six month	98.14	97.21	97.36	96.84	97.23	97.23
Disintegration time (sec)	After One month	65.6	53.4	54.2	43.6	55.2	54.1
	After three month	64.9	52.6	53.7	44.2	55.6	54.7
	After six month	64.1	51.7	53.1	44.9	57.2	55.8
% Drug Release (within 2 min)	After One month	99.85	98.52	98.58	98.86	99.56	98.98
	After three month	99.78	98.45	98.48	98.75	99.45	98.75
	After six month	98.11	97.34	97.78	97.45	98.57	97.42

Etoricoxib, with a partition coefficient of 1.86, shows higher lipophilicity and pH-dependent solubility, supporting its suitability for oral formulations without major enhancement. Calibration curves in mediums displayed excellent linearity, validating the UV spectrophotometric method for quantitative analysis.

In the pre-compression studies, Etoricoxib formulations showed angle of repose values between 34.22° and 38.39° for SC_1Etx and 34.82° to 38.10° for SC_2Etx, placing them within the fair flow category. These results confirm that the powder blends possessed adequate flowability for successful die filling during direct compression.

Bulk density, tapped density, Carr's Index, and Hausner's ratio further supported the suitability of the blends for tablet compression. For Etoricoxib formulations displayed Carr's Index values of 12.89-17.54% in SC_1Etx and 12.74-18.01% in SC_2Etx with corresponding Hausner's ratios between 1.149-1.213 and 1.147-1.220. All these values fall within pharmaceutically acceptable limits, indicating good compressibility and minimal interparticle friction essential for producing uniform and high-quality tablets.

Post-compression parameters revealed equally consistent outcomes. Weight variation for Etoricoxib tablets showed values between 350.0-354.2 mg, all within permissible limits. This uniformity reflects excellent flow of the powder into the die cavity and accurate control during compression.

A comprehensive scientific evaluation of the optimized formulations done for Drug content uniformity, wetting time, water absorption ratio, *in-vitro* disintegration time, and dissolution studies to ensuring that the selected batches meet the required standards for mouth dissolving tablets in terms of safety, efficacy and quality. Drug content uniformity was assessed to confirm that each tablet delivers the required dose of the active ingredient, ensuring therapeutic efficacy.

Dissolution studies further validated the performance of the optimized formulations. All optimized batches of Etoricoxib achieved 100% drug release within 3 minutes, indicating extremely rapid dissolution in pH 6.8 phosphate buffer. Initial dissolution values were also high, with drug release at the first minute ranging from 97.48% to 99.59%, demonstrating immediate availability of the drug upon tablet administration.

The stability studies carried out for the optimized formulations of Etoricoxib, using both synthetic and natural superdisintegrants, demonstrated that all formulations remained stable under ICH-recommended accelerated and long-term storage conditions. Throughout the 6-month study period, only minor, non-significant variations were observed in critical quality attributes, including hardness, drug content, disintegration time, and dissolution rate. These variations remained well within acceptable limits, confirming that the formulations retained their physical integrity and therapeutic performance.

Overall, the results clearly indicate that the developed solid oral dosage forms possess satisfactory stability, ensuring consistent drug release and product quality during storage.

CONCLUSION:

The present investigation successfully demonstrated that both synthetic and natural superdisintegrants can be effectively employed to formulate Etoricoxib mouth dissolving tablets (MDTs) using the direct compression technique. Comprehensive pre-compression and post-compression evaluations confirmed that all powder blends exhibited desirable micromeritic properties, ensuring uniform die filling and smooth compression behaviour. Synthetic superdisintegrants such as crospovidone, sodium starch glycolate, and croscarmellose sodium produced MDTs with acceptable hardness, friability, disintegration time, and drug release. However, the formulations prepared using natural superdisintegrants mango pectin powder, guar gum powder, and aloe vera mucilage demonstrated comparatively superior performance in terms of mechanical integrity, rapid wetting, enhanced water absorption, shorter disintegration time, and faster dissolution profiles.

Overall, the study concludes that natural superdisintegrants can serve as efficient, biocompatible, and cost-effective alternatives to synthetic agents in the development of Aceclofenac MDTs. Their excellent performance in enhancing tablet breakdown and drug release highlights their potential for broader application in patient-friendly dosage forms, especially for geriatric and pediatric populations where rapid onset of action and ease of administration are clinically desirable.

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