Available online on 15.12.2025 at http://jddtonline.info

Journal of Drug Delivery and Therapeutics

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Research Article

Comparative study of synthetic and natural superdisintegrants to enhance the disintegration of mouth dissolving tablets

Yogendra Sahu [1], Bharti Sahu [2], Mohan Lal Kori [1]*

1. Vedica College of B. Pharmacy, RKDF University, Gandhi Nagar, Bhopal - 462033, Madhya Pradesh, India.

2. Department of Pharmacy Ram Krishna Dharmarth Foundation University, Gandhi Nagar, Bhopal - 462033, Madhya Pradesh, India.

Article Info:

Article History:

Received 19 Sep 2025
Reviewed 02 Nov 2025
Accepted 23 Nov 2025
Published 15 Dec 2025

Cite this article as:

Sahu Y, Sahu B, Kori ML, Comparative study of synthetic and natural superdisintegrants to enhance the disintegration of mouth dissolving tablets, Journal of Drug Delivery and Therapeutics. 2025; 15(12):88-102
DOI: http://dx.doi.org/10.22270/jddt.v15i12.7496

*For Correspondence:

Mohan Lal Kori, Vedica College of B. Pharmacy, Ram Krishna Dharmarth Foundation University, Near RGPV, Gandhi Nagar, Bhopal - 462033, Madhya Pradesh, India.

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 was to formulate the Mouth dissolving tablets of Aceclofenac using mango pectin powder, Guar Gum and Aloe Vera mucilage. The results obtained from the natural polymer were compared with the synthetic superdisintegrants such as Sodium Starch Glycolate, Crosspovidone and Croscarmellose Sodium. The Mouth dissolving tablets different superdisintegrants with varying concentrations were evaluated for 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, synthetic disintegrants, and natural disintegrants.

INTRODUCTION:

The Mouth dissolving tablets form the desire to provide patient with conventional means of taking their medication. Because of physiological changes associated with, especially, elderly and pediatrics are quite unable to swallow (Dysphasia); rather, this is a common problem of all age groups patients. Some fast-dissolving tablets dosage forms which can be disintegrated, dissolved, or suspended with saliva in the mouth resulting in easy swallowing can provide distinguishable benefits to the pediatric and elderly population, as well as other patients who prefer the convenience of easy swallowing able dosage forms. Mouth dissolving tablets disintegrates quickly when placed on tongue, fast releasing of the drug that dissolves or disperses in the saliva pH 6.8[1]. Recently, pharmaceutical preparations used for elderly patients have been investigated to improve the treatment compliance and quality of life of such patients. Mouth dissolving tablets can fast disintegrate in saliva (pH 6.8). Mouth dissolving tablets is an attractive dosage form and a patient-oriented pharmaceutical preparation[2]. These Mouth dissolving tablets have attracted the interest of many researchers. Many elderly patients have difficulty swallowing tablets, capsules, or powders. To reduce this problem, these tablets are expected to dissolve or disintegrate in the oral cavity without drinking water. The disintegrated mass can slide down smoothly along the oesophagus with the help of saliva, so even people who have swallowing or chewing difficulties can take it with ease. There are two different types of dispersible tablets which have to be distinguished: One dosage form disintegrates instantaneously in the mouth, to be swallowed without the need for drinking water, while the other tablet formulation can readily be dispersed in water, to form dispersion, easy to ingest by the patient[3]. Mouth dissolving tablets are tablets which disintegrate and dissolve rapidly in saliva within seconds even if water is not available. In spite of tremendous development of fast dissolving drug delivery system or technology, oral route remains perfect route for administration of therapeutic reagents because of low cost of therapy,

ease of administration, accurate dose, self medication, pain avoidance, leading to high level of patient compliance[4]. According to European pharmacopoeia, mouth dissolving tablets are those which disintegrate on tongue before swallowing and it should disperse in less than 3 min. Objective of this study was to formulate and evaluate Aceclofenac Mouth dissolving tablets by direct compression method and to increase the drug release profile in short duration of time. Evaluation of formulated tablets was done using various quality parameters like hardness, friability, wetting time, disintegration time, *in-vitro* dissolution study. Finally, stability study of optimized batches was performed[5].

MATERIALS AND METHOD:

Aceclofenac was obtained from Aristo Pharmaceutical Pvt. Ltd. Sodium Starch Glycolate, Croscarmellose Sodium, Microcrystalline cellulose, Magnesium, Mango Pectin Powder (MPP), Guar Gum Powder (GGP), Aloe Vera Mucilage (AVM), Stearate, Calcium carbonate, Crospovidone and Sucralose were purchased from markets.

Identification of Drug: The organoleptic characteristic test of drug sample i.e. Aceclofenac was performed by sensory organs. The parameters such as colour, odour and state were observed and data was shown in Table 10.

Solubility profile of drug samples: Solubility of drug Aceclofenac (Acf) was determined separately in various aqueous media of different pH solution. Solubility profile of Aceclofenac (Acf) was shown in Table 11.

Melting Point: Melting point was established by capillary tube method. 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 12.

Partition coefficient: The partition coefficient of Aceclofenac (Acf) was determined to calculate the hydrophobecity/hydrophilicity of drug sample in 100ml of mixed solvent system. It was determined by mixture of n-octanol: phosphate buffer (pH-7.4) solutions, taken this mixture in 100ml 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 275nm. The amount of drug in n-octanol was obtained by subtracting the quantity of drug in phosphate buffer medium from the quantity of drug taken. The partition coefficient of drug sample was calculated from following equation. The results have shown in Table 13.

$$log\ P\ (n\text{-}oct\ /\ pH\ 7.4) = log\ (C\ oct\ /\ C\ pH\ 7.4)\ equilibrium$$

Authentication of drug sample by U.V. Spectrophotometer: 1ml of standard stock solution of Aceclofenac was taken in 10ml standard volumetric flask diluted to 10ml with distilled water to get the concentration of 10µg/ml. The maximum absorbance of resulting solution was measured against respective blank solution (distilled water) in the UV region of 200-400nm, which shows maximum absorbance at 275nm.

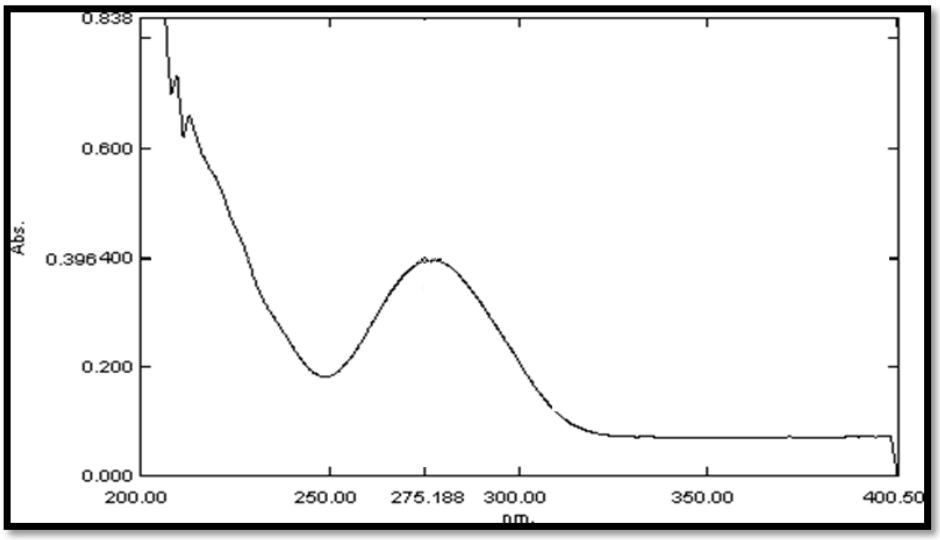


Figure 1: UV Spectra of Aceclofenac

Preparation of standard curve of Aceclofenac

Preparation of calibration curve in Phosphate buffer pH 6.8: A stock solution containing 1000 µg/ml of pure drug was prepared by dissolving 100 mg of Aceclofenac in sufficient Phosphate buffer pH 6.8 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 275 nm.

Table 1: Calibration curve data for aceclofenac in Phosphate buffer pH 6.8

Concentration (µg/ml)	Absorbance
Blank	0
2	0.095
4	0.185
6	0.286
8	0.379
10	0.474
12	0.568
14	0.664
16	0.761
18	0.852
20	0.958

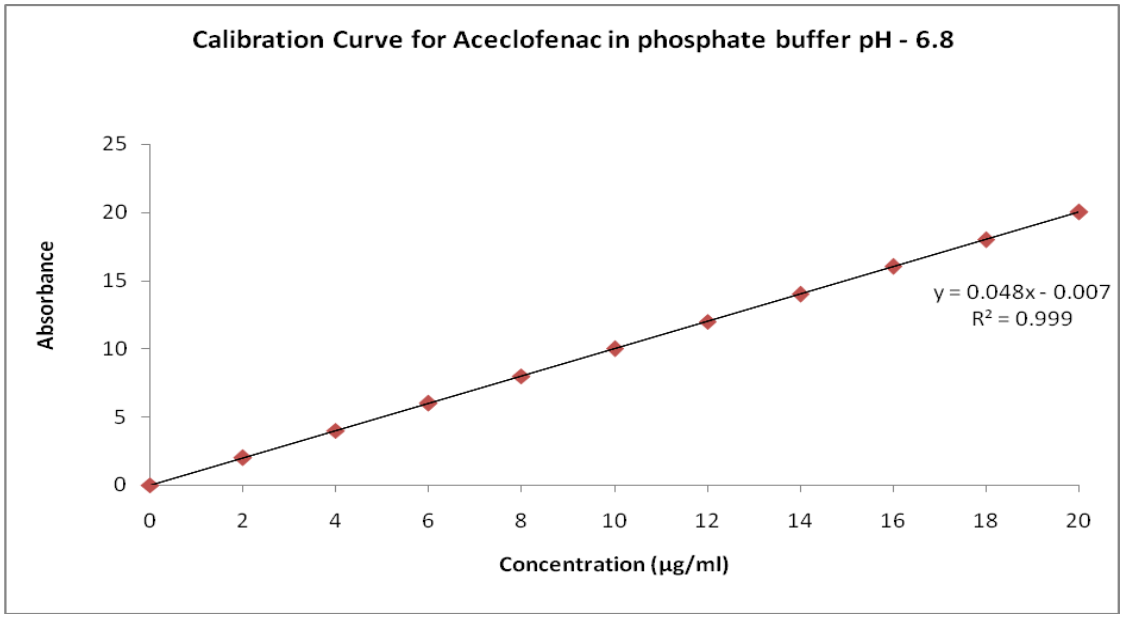


Figure 2: Calibration Curve for Aceclofenac in Phosphate buffer pH 6.8

Preparation of calibration curve in phosphate buffer pH 7.4

Working solution: 100mg of Aceclofenac was dissolved in phosphate buffer 7.4 in a 100ml volumetric flask and filled up to the mark using phosphate buffer 7.4. Serial dilutions of working solution of Aceclofenac (100 ml) were made in to a series of 10ml volumetric flasks and volume was made up to the mark with phosphate buffer 7.4 to get 2-20 µg/ml. The absorbance of the resulting solutions was measured at 275nm against a blank solution (Phosphate buffer, pH-7.4) using visible double beam spectrophotometer. Calibration curve was prepared by plotting concentration versus absorbance. Data have shown in Table 2 and in fig. 3.

Table 2: Calibration curve for Aceclofenac in Phosphate Buffer Solution (pH- 7.4)

Concentration (µg/ml)	Absorbance
Blank	0
2	0.082
4	0.164
6	0.239
8	0.324
10	0.408
12	0.479
14	0.564
16	0.639
18	0.724
20	0.798

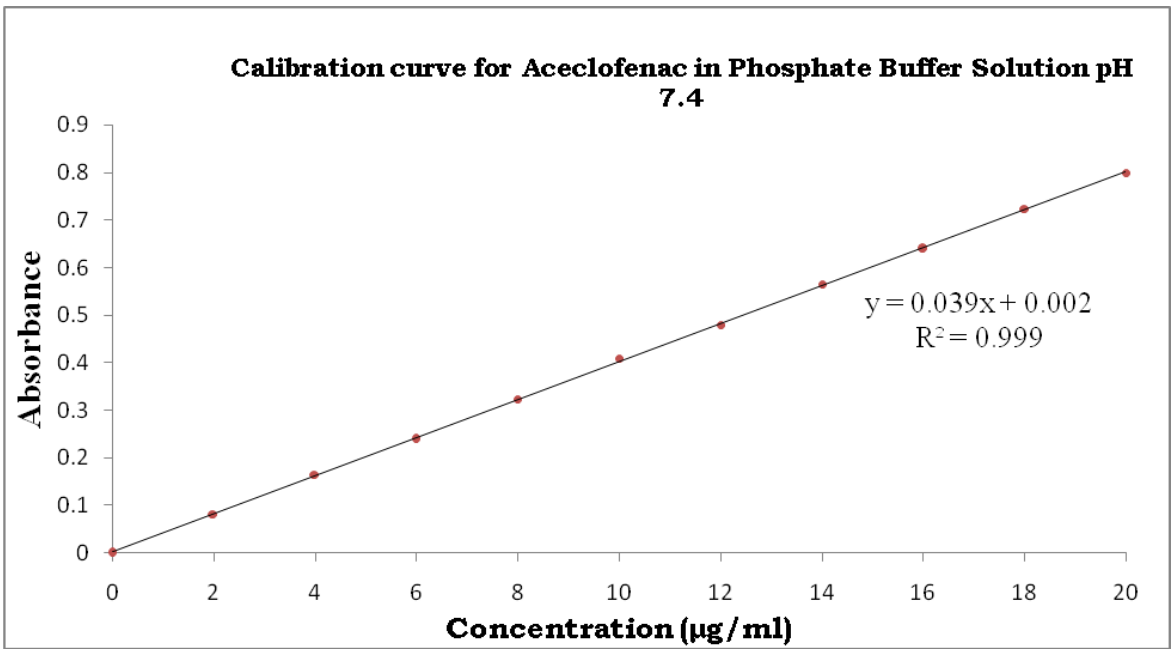


Figure 3: Calibration curve for Aceclofenac in Phosphate Buffer Solution (pH- 7.4)

Development of Formulations: 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. 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_1Acf) and natural (SC_2Acf) 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) and drug sample i.e. Aceclofenac [SC_1Acf]

Table 3: Factorial design layout for optimization of synthetic superdisintegrants (SC_1Acf)

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

27 formulations of mouth dissolving tablet (average weight 350mg) were prepared using three variables Crospovidone, Sodium Starch Glycolate and Croscarmellose Sodium (CP: SSG: CCS) with other excipients named as Micro crystalline cellulose, Sucralose, $CaCO_3$, Flavour Mango, Colloidal Silicon Dioxide, Mg Stearate.

Table 4: Formulations of SC_1Acf for preparing mouth dissolving tablets of Aceclofenac

Formulation Code	Acf	CP	CCS	SSG
F1SC_1Acf	100	15	15	15
F2SC_1Acf	100	15	15	12
F3SC_1Acf	100	15	15	9
F4SC_1Acf	100	15	12	15
F5SC_1Acf	100	15	12	12
F6SC_1Acf	100	15	12	9
F7SC_1Acf	100	15	9	15
F8SC_1Acf	100	15	9	12
F9SC_1Acf	100	15	9	9
F10SC_1Acf	100	12	15	15
F11SC_1Acf	100	12	15	12
F12SC_1Acf	100	12	15	9
F13SC_1Acf	100	12	12	15
F14SC_1Acf	100	12	12	12
F15SC_1Acf	100	12	12	9
F16SC_1Acf	100	12	9	15
F17SC_1Acf	100	12	9	12
F18SC_1Acf	100	12	9	9
F19SC_1Acf	100	9	15	15
F20SC_1Acf	100	9	15	12
F21SC_1Acf	100	9	15	9
F22SC_1Acf	100	9	12	15
F23SC_1Acf	100	9	12	12
F24SC_1Acf	100	9	12	9
F25SC_1Acf	100	9	9	15
F26SC_1Acf	100	9	9	12
F27SC_1Acf	100	9	9	9

[B] Optimization of concentration of Natural Superdisintegrants Mango Pectin Powder, Gaur Gum Powder and Aloe Vera Mucilage (MPP: GGP: AVM) respectively [SC_2Acf]

Table 5: Factorial design layout for optimization of Natural Superdisintegrants (SC_2Acf)

S. No.	Code	Coded Value	Amount of MPP in mg	Amount of GGP in mg	Amount of AVM in mg
1	X_1	-1	9	9	9
2	X_2	0	12	12	12
3	X_3	1	15	15	15

27 formulations of mouth dissolving tablet (average weight 350mg) were prepared using three variables Mango Pectin Powder, Gaur Gum Powder and Aloe Vera Mucilage (MPP: GGP: AVM) with other excipients named as Micro crystalline cellulose, Sucralose, $CaCO_3$, Flavour Mango, Colloidal Silicon Dioxide, Mg Stearate.

Table 6: Formulations of SC_2Acf for preparing mouth dissolving tablets of Aceclofenac

Formulation Code	Acf	MPP	GPP	AVM
F1SC_2Acf	100	15	15	15
F2SC_2Acf	100	15	15	12
F3SC_2Acf	100	15	15	9
F4SC_2Acf	100	15	12	15
F5SC_2Acf	100	15	12	12
F6SC_2Acf	100	15	12	9
F7SC_2Acf	100	15	9	15
F8SC_2Acf	100	15	9	12
F9SC_2Acf	100	15	9	9
F10SC_2Acf	100	12	15	15
F11SC_2Acf	100	12	15	12
F12SC_2Acf	100	12	15	9
F13SC_2Acf	100	12	12	15
F14SC_2Acf	100	12	12	12
F15SC_2Acf	100	12	12	9
F16SC_2Acf	100	12	9	15
F17SC_2Acf	100	12	9	12
F18SC_2Acf	100	12	9	9
F19SC_2Acf	100	9	15	15
F20SC_2Acf	100	9	15	12
F21SC_2Acf	100	9	15	9
F22SC_2Acf	100	9	12	15
F23SC_2Acf	100	9	12	12
F24SC_2Acf	100	9	12	9
F25SC_2Acf	100	9	9	15
F26SC_2Acf	100	9	9	12
F27SC_2Acf	100	9	9	9

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

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 6cm. 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 7: 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 100 ml 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 8: 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 and weight variation were evaluated for prepared tablets using standard procedures. The following post compression parameters were tested for prepared mouth dissolving tablets and results shown in Table 15.

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 digital 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 milimeter. 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.

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

Evaluation of Optimized Formulations: Fundamental post-compression characteristics such as weight variation, hardness, thickness, and friability were determined to ensure compliance with pharmacopoeial standards. Drug content uniformity was assessed to confirm that each tablet delivers the required dose of the active ingredient, ensuring therapeutic efficacy. Functional performance parameters including 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.

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 100ml 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.

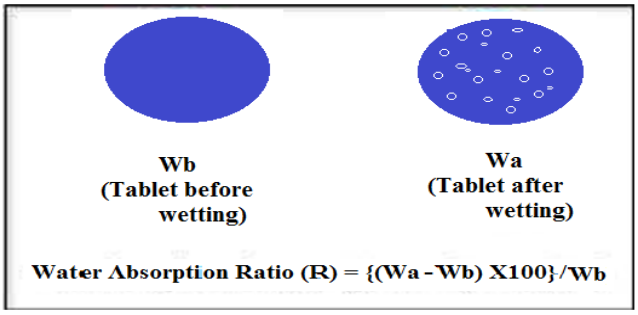
$$\text{Wetting Time} = T_t - T_0$$

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.



***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 50rpm) 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 compared with the marketed product.

Table 9: 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	F15SC$_1$Acf	97.88	98.12	100	100	100	100	100	100	100	100
2	F16SC$_1$Acf	98.49	98.89	100	100	100	100	100	100	100	100
3	F17SC$_1$Acf	98.60	98.87	100	100	100	100	100	100	100	100
7	F19SC$_2$Acf	98.58	98.89	100	100	100	100	100	100	100	100
8	F20SC$_2$Acf	98.61	98.99	100	100	100	100	100	100	100	100
9	F21SC$_2$Acf	97.48	98.68	100	100	100	100	100	100	100	100

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 Aceclofenac 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 aceclofenac 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, drug content, disintegration time and dissolution rate.

RESULT AND DISCUSSION:

The present study was carried out in order to develop mouth dissolving tablets of Aceclofenac using synthetic and natural superdisintegrants.

Table 10: Organoleptic characteristic of drug sample (Aceclofenac)

S. No.	Parameters	Reported	Observed
1	Colour	White powder	White powder
2	Odour	Odourless	Odourless
3	State	Crystalline powder	Slightly Crystalline powder

Table 11: The Solubility Profile of Aceclofenac (Acf) (IP 2007)

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

Firstly Aceclofenac complied with pharmacopoeial identity tests, partition coefficient of 0.319, is less lipophilic and demonstrates moderate solubility, requiring formulation techniques for enhanced bioavailability and Calibration curves in all mediums displayed excellent linearity, validating the UV spectrophotometric method for quantitative analysis.

Table 12: Melting Point of Aceclofenac (Acf) (IP 2007)

S. N.	Drug samples	Temperature (°C)	
		Reported	Observed
1	Aceclofenac (Acf)	149-150	149±1

Table 13: Partition Coefficient of Drug Sample (Aceclofenac)

S. No	Drug Sample	Partition coefficient
1	Aceclofenac (Acf)	0.319

In the pre-compression studies, the angle of repose for Aceclofenac formulations ranged from 28.65° to 32.89° for SC_1Acf and 29.64° to 32.45° for SC_2Acf, indicating excellent to good flow properties. Bulk density, tapped density, Carr's Index, and Hausner's ratio further supported the suitability of the blends for tablet compression. For Aceclofenac formulations, Carr's Index ranged between 15.61-22.90% in SC_1Acf and 13.55-18.34% in SC_2Acf, while the Hausner's ratio ranged from 1.158-1.229 and 1.157-1.225, respectively. Aceclofenac mouth-dissolving tablets (MDTs), prepared by the direct compression method, and complied with acceptable pharmaceutical quality standards.

Table 13: Pre-compression Evaluation of SC_1Acf mouth dissolving tablets (in mg) of Aceclofenac

Formulation Code	Mean Angle of repose	Mean Apparent Bulk Density (g/cm³)	Mean Tapped Bulk Density (g/cm³)	Compressibility Index (%)	Hausner's Ratio
F1SC_1Acf	32.48	0.534	0.636	16.038	1.191
F2SC_1Acf	32.46	0.532	0.635	16.220	1.194
F3SC_1Acf	31.25	0.528	0.633	16.588	1.199
F4SC_1Acf	30.13	0.544	0.642	15.265	1.180
F5SC_1Acf	31.45	0.556	0.666	16.517	1.198
F6SC_1Acf	30.98	0.524	0.644	18.634	1.229
F7SC_1Acf	31.12	0.528	0.625	15.520	1.184
F8SC_1Acf	29.36	0.532	0.639	16.745	1.201
F9SC_1Acf	28.65	0.526	0.635	17.165	1.207
F10SC_1Acf	32.65	0.542	0.654	17.125	1.207
F11SC_1Acf	31.89	0.534	0.633	15.640	1.185
F12SC_1Acf	31.98	0.524	0.613	14.519	1.170
F13SC_1Acf	32.87	0.536	0.642	16.511	1.198
F14SC_1Acf	29.54	0.542	0.644	15.839	1.188
F15SC_1Acf	30.48	0.538	0.623	13.644	1.158
F16SC_1Acf	32.89	0.542	0.634	14.511	1.170
F17SC_1Acf	30.57	0.544	0.635	14.331	1.167
F18SC_1Acf	28.98	0.528	0.624	15.385	1.182
F19SC_1Acf	29.15	0.536	0.628	14.650	1.172
F20SC_1Acf	28.85	0.542	0.646	16.099	1.192
F21SC_1Acf	29.69	0.538	0.622	13.505	1.156
F22SC_1Acf	30.27	0.526	0.615	14.472	1.169
F23SC_1Acf	31.68	0.538	0.639	15.806	1.188
F24SC_1Acf	31.21	0.542	0.651	16.743	1.201
F25SC_1Acf	30.95	0.528	0.627	15.789	1.188
F26SC_1Acf	30.84	0.542	0.647	16.229	1.194
F27SC_1Acf	30.72	0.536	0.637	15.856	1.188

n=3

Table 14: Pre-compression Evaluation of SC_2Acf for mouth dissolving tablets (in mg) of Aceclofenac

Formulation Code	Mean Angle of repose	Mean Apparent Bulk Density(g/cm³)	Mean Tapped Bulk Density (g/cm³)	Compressibility Index (%)	Hausner's Ratio
F1SC_2Acf	31.89	0.532	0.634	16.088	1.192
F2SC_2Acf	32.26	0.534	0.637	16.170	1.193
F3SC_2Acf	32.25	0.518	0.623	16.854	1.203
F4SC_2Acf	31.13	0.524	0.622	15.756	1.187
F5SC_2Acf	32.45	0.536	0.646	17.028	1.205
F6SC_2Acf	31.98	0.534	0.654	18.349	1.225
F7SC_2Acf	31.12	0.538	0.635	15.276	1.180
F8SC_2Acf	30.36	0.532	0.639	16.745	1.201
F9SC_2Acf	30.65	0.536	0.645	16.899	1.203
F10SC_2Acf	31.65	0.532	0.644	17.391	1.211
F11SC_2Acf	32.19	0.524	0.623	15.891	1.189
F12SC_2Acf	31.18	0.544	0.633	14.060	1.164
F13SC_2Acf	31.87	0.546	0.652	16.258	1.194
F14SC_2Acf	29.64	0.532	0.634	16.088	1.192
F15SC_2Acf	31.48	0.536	0.621	13.688	1.159
F16SC_2Acf	32.26	0.552	0.644	14.286	1.167
F17SC_2Acf	31.57	0.542	0.633	14.376	1.168
F18SC_2Acf	30.98	0.538	0.634	15.142	1.178
F19SC_2Acf	30.45	0.534	0.626	14.696	1.172
F20SC_2Acf	30.85	0.534	0.638	16.301	1.195
F21SC_2Acf	31.59	0.536	0.62	13.548	1.157
F22SC_2Acf	31.57	0.536	0.625	14.240	1.166
F23SC_2Acf	32.38	0.534	0.635	15.906	1.189
F24SC_2Acf	32.28	0.532	0.641	17.005	1.205
F25SC_2Acf	31.68	0.524	0.623	15.891	1.189
F26SC_2Acf	31.62	0.536	0.641	16.381	1.196
F27SC_2Acf	31.52	0.534	0.635	15.906	1.189

n=3

Post-compression parameters revealed equally consistent outcomes. Weight variation for Aceclofenac tablets remained between 349.1-353.0 mg, all within IP/USP permissible limits. This uniformity reflects excellent flow of the powder into the die cavity and accurate control during compression. Mouth dissolving tablets hardness showed a systematic increasing trend with higher concentrations of superdisintegrants. In Aceclofenac formulations, SC_1Acf batches showed hardness values between 1.04-4.88 kg/cm², while natural superdisintegrant batches (SC_2Acf) ranged from 2.86-3.19 kg/cm². Uniformity in tablet thickness was also observed. Aceclofenac formulations exhibited thickness values between 2.82-3.23 mm, indicating consistent powder packing and uniform compression force throughout all batches.

Friability testing revealed that most formulations exhibited values below the acceptable limit of 1%. SC_1Acf batches showed friability ranging from 0.48-1.36%, Natural superdisintegrant batches performed notably better, with SC_2Acf showing 0.31-0.57%. This

indicates that the inclusion of natural superdisintegrants such as mango pectin, guar gum, and aloe vera mucilage imparted superior mechanical resistance compared to synthetic ones.

Table 15: Evaluation parameters of SC_1Acf for preparing mouth dissolving tablets of Aceclofenac

Formulation Code	Weight Variation (mg)	Hardness (Kg/cm^2)	Thickness (mm)	Friability (%)
F1SC_1Acf	349.11±1.18	1.04±0.3	3.05±0.8	1.36±0.08
F2SC_1Acf	350.20±1.59	1.15±0.3	3.05±0.9	1.26±0.01
F3SC_1Acf	349.56±1.38	1.98±0.5	3.09±0.5	0.96±0.06
F4SC_1Acf	349.89±1.94	1.16±0.1	2.87±0.6	1.22±0.07
F5SC_1Acf	349.66±1.47	1.18±0.3	3.03±0.4	1.12±0.04
F6SC_1Acf	350.15±2.23	2.01±0.3	3.06±0.4	0.98±0.05
F7SC_1Acf	350.05±2.06	1.26±0.3	3.07±0.4	1.08±0.08
F8SC_1Acf	350.60±2.52	1.32±0.2	2.85±0.5	1.02±0.07
F9SC_1Acf	349.89±1.94	2.16±0.5	3.08±0.1	0.88±0.02
F10SC_1Acf	350.20±2.14	1.19±0.1	3.19±0.8	1.16±0.06
F11SC_1Acf	350.20±2.53	1.30±0.4	3.10±0.9	1.06±0.02
F12SC_1Acf	351.05±2.73	2.05±0.7	3.15±0.4	0.89±0.08
F13SC_1Acf	350.15±2.08	1.56±0.4	3.02±0.2	0.92±0.02
F14SC_1Acf	350.25±2.23	1.45±0.4	3.01±0.5	0.96±0.05
F15SC_1Acf	350.65±2.26	2.20±0.1	3.07±0.8	0.88±0.02
F16SC_1Acf	351.80±2.12	3.51±0.4	3.01±0.5	0.62±0.03
F17SC_1Acf	351.00±2.36	2.05±0.3	2.96±0.4	0.89±0.04
F18SC_1Acf	351.25±2.36	2.30±0.3	2.97±0.7	0.85±0.05
F19SC_1Acf	350.40±2.14	2.45±0.1	3.05±0.3	0.82±0.08
F20SC_1Acf	351.10±2.08	3.15±0.2	3.05±0.6	0.66±0.06
F21SC_1Acf	351.65±2.08	3.87±0.2	2.82±0.4	0.72±0.04
F22SC_1Acf	351.75±2.36	3.20±0.6	3.05±0.6	0.65±0.02
F23SC_1Acf	350.70±2.70	4.30±0.2	3.20±0.6	0.52±0.01
F24SC_1Acf	353.00±2.51	4.46±0.5	3.08±0.1	0.48±0.04
F25SC_1Acf	352.10±2.51	4.52±0.1	3.12±0.6	0.42±0.08
F26SC_1Acf	351.95±2.89	4.68±0.3	2.96±0.5	0.38±0.03
F27SC_1Acf	352.65±3.03	4.88±0.4	2.97±0.6	0.34±0.04

Table 16: Evaluation parameters of SC_2Acf for preparing mouth dissolving tablets of Aceclofenac

Formulation Code	Weight Variation (mg)	Hardness (Kg/cm^2)	Thickness (mm)	Friability (%)
F1SC_2Acf	352.75±2.79	1.22±0.5	3.05±0.2	1.20±0.5
F2SC_2Acf	352.05±2.78	1.30±0.4	3.02±0.3	1.17±0.5
F3SC_2Acf	352.95±3.09	2.05±0.3	3.04±0.2	0.98±0.1
F4SC_2Acf	353.05±2.98	1.27±0.4	2.89±0.5	1.16±0.2
F5SC_2Acf	352.40±2.87	1.34±0.3	2.92±0.3	1.14±0.6
F6SC_2Acf	352.80±2.91	2.22±0.5	3.07±0.1	0.96±0.2
F7SC_2Acf	353.05±2.91	1.45±0.3	3.03±0.5	1.12±0.4
F8SC_2Acf	353.55±2.72	1.38±0.3	3.06±0.2	1.09±0.2
F9SC_2Acf	354.70±3.01	2.32±0.3	3.06±0.2	0.93±0.3
F10SC_2Acf	350.10±2.36	1.38±0.2	3.03±0.4	1.07±0.4
F11SC_2Acf	353.35±2.54	2.02±0.4	3.05±0.7	1.04±0.3
F12SC_2Acf	352.55±2.39	2.35±0.3	3.04±0.2	0.92±0.6
F13SC_2Acf	353.25±2.44	2.38±0.1	2.97±0.2	0.86±0.3
F14SC_2Acf	353.20±2.59	2.61±0.2	2.89±0.3	0.38±0.6
F15SC_2Acf	352.25±3.42	2.88±0.1	3.03±0.4	0.37±0.3
F16SC_2Acf	352.95±2.37	3.57±0.2	2.86±0.2	0.58±0.5
F17SC_2Acf	353.05±2.69	3.18±0.3	3.01±0.5	0.72±0.4
F18SC_2Acf	353.75±2.51	3.21±0.4	3.03±0.2	0.68±0.2
F19SC_2Acf	352.75±2.59	3.30±0.1	2.88±0.7	0.65±0.5
F20SC_2Acf	353.05±2.65	3.78±0.3	3.03±0.4	0.52±0.6
F21SC_2Acf	353.10±2.59	3.08±0.3	2.91±0.6	0.74±0.1
F22SC_2Acf	353.35±2.50	3.36±0.1	3.11±0.4	0.63±0.4
F23SC_2Acf	353.25±2.45	4.03±0.4	3.08±0.6	0.42±0.2
F24SC_2Acf	353.05±2.76	4.06±0.6	3.04±0.3	0.34±0.2
F25SC_2Acf	353.20±2.35	4.19±0.1	3.08±0.4	0.31±0.6
F26SC_2Acf	353.30±2.58	4.17±0.7	3.12±0.2	0.26±0.5
F27SC_2Acf	352.80±2.38	4.25±0.2	3.16±0.1	0.23±0.3

The evaluation of the optimized formulations of Aceclofenac MDTs was carried out to confirm their pharmaceutical suitability and functional efficiency. The results obtained from physical, mechanical, and functional performance parameters collectively demonstrate that all optimized formulations fulfilled the required standards for mouth-dissolving tablets.

Stability studies: The stability studies carried out at accelerated ICH conditions (40°C ± 2°C, 75% ± 5% RH for 6 months) for the optimized formulations of Aceclofenac using both synthetic and natural superdisintegrants, demonstrated only minor, acceptable variations in hardness, drug content, disintegration, and dissolution that all formulations remained stable under ICH-recommended accelerated and long-term storage conditions. Effect of storage time on hardness of the formulations containing synthetic superdisintegrants (SC_1Acf) increased high rate as compare to formulation containing natural superdisintegrants (SC_2Acf). data shown in Table 17.

Drug content remained stable reduced slowly, disintegration times changed minimally and drug release continued to exceed 97-99% within 2 minutes even after 6 months. Both synthetic and natural superdisintegrants based formulations maintained their stability, confirming their suitability for long-term

storage. These variations remained well within acceptable limits, confirming that the formulations retained their physical integrity and therapeutic performance, but natural superdisintegrants containing formulations were more stable as compare to synthetic once. Data shown in table 18.

Table 17: Hardness of optimized formulations for Stability Study

S.No.	Formulation Code	Hardness (Kg/cm²)		
		After One month	After three month	After six month
1	F15SC$_1$Acf	3.54±0.4	3.60±0.2	3.64±0.3
2	F16SC$_1$Acf	3.20±0.4	3.35±0.3	3.54±0.3
3	F17SC$_1$Acf	4.06±0.3	4.15±0.2	4.30±0.4
7	F19SC$_2$Acf	3.02±0.1	3.24±0.3	3.30±0.1
8	F20SC$_2$Acf	3.15±0.3	3.25±0.1	3.39±0.3
9	F21SC$_2$Acf	3.08±0.3	3.18±0.3	3.29±0.3

n=3, values are express mean±SD

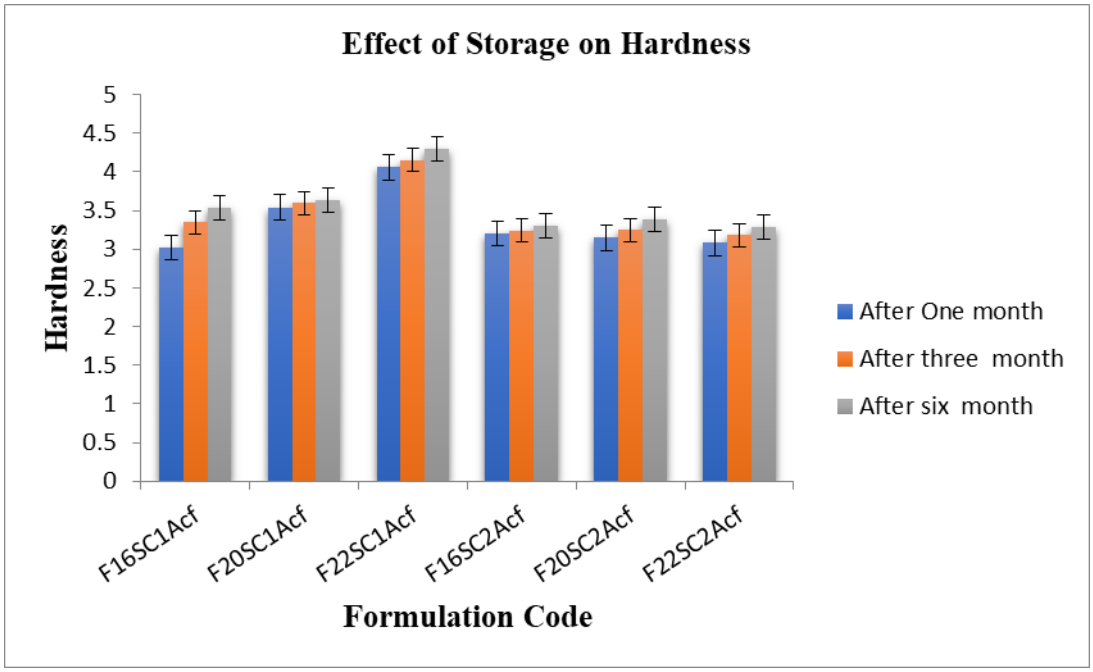


Figure 4: Bar graph showing Effect of Storage Time on Hardness

Table 18: Drug Content of optimized formulations for Stability Study

S.No.	Formulation Code	Drug Content		
		After One month	After three month	After six month
1	F15SC$_1$Acf	97.88	97.60	96.82
2	F16SC$_1$Acf	98.49	98.13	97.65
3	F17SC$_1$Acf	98.60	98.35	97.68
7	F19SC$_2$Acf	98.85	98.52	98.11
8	F20SC$_2$Acf	98.61	98.12	97.74
9	F21SC$_2$Acf	97.48	97.01	96.68

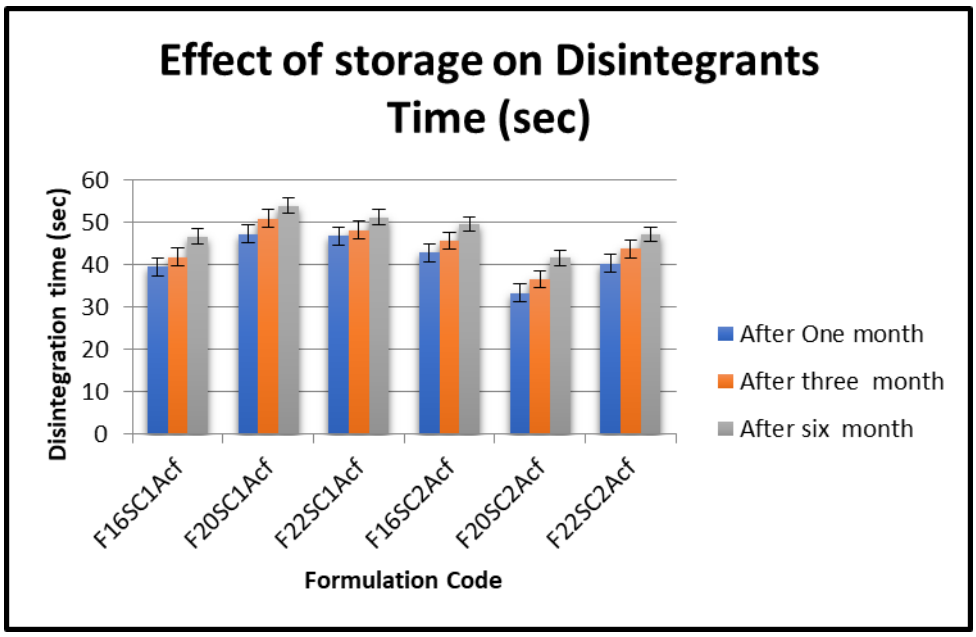


Figure 5: Bar graph showing Effect of Storage Time on Disintegration time

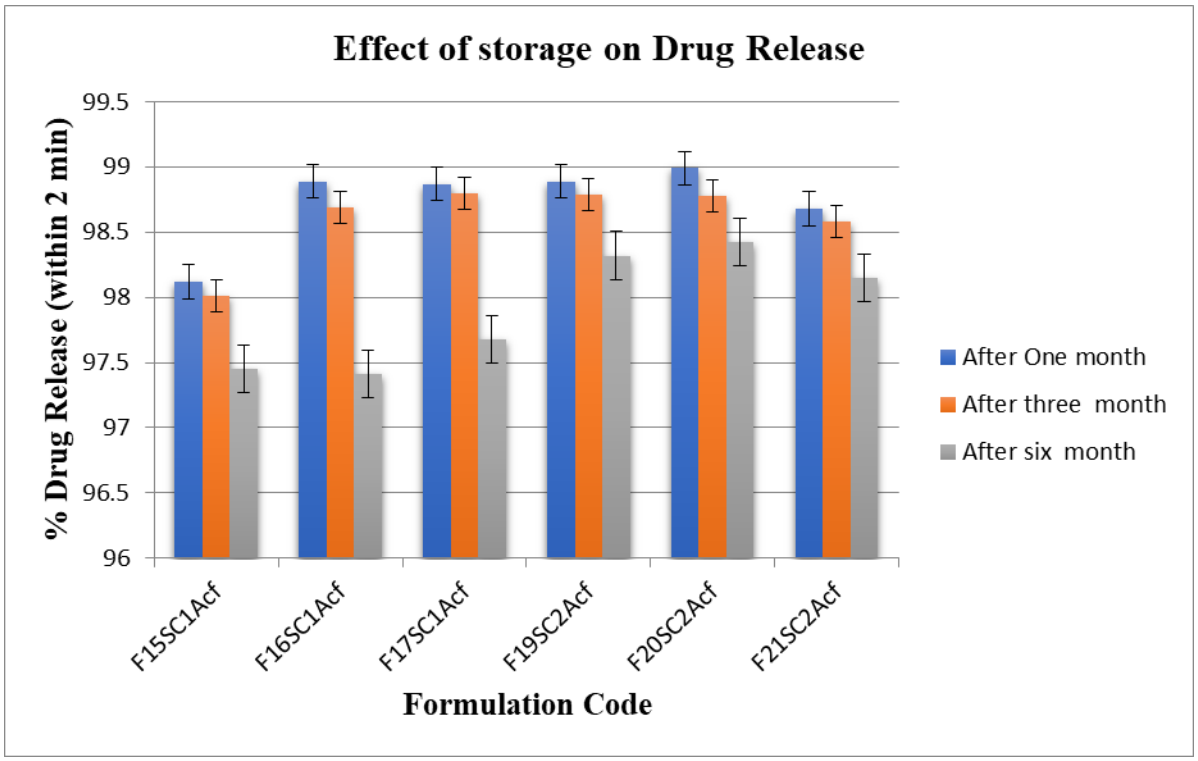


Figure 6: Bar graph showing Effect of Storage Time on Drug Release

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 Aceclofenac 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.

Among all the evaluated batches, the optimized natural superdisintegrant formulations ($F19SC_2Acf$, $F20SC_2Acf$, and $F21SC_2Acf$) 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 robustness and storage stability.

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.

Acknowledgements: The authors wish to thank the RKDF University, Bhopal for infrastructure and facilities.

Conflict of Interest: The authors declare no conflicts of interest.

Author Contributions: All authors have equal contributions in the preparation of the manuscript and compilation.

Source of Support: Nil

Funding: The authors declared that this study has received no financial support.

Informed Consent Statement: Not applicable.

Data Availability Statement: The data presented in this study are available on request from the corresponding author.

Ethical approval: Not applicable.

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