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Formulation and Evaluation of Fast Dissolving Tablets

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Abstract: *This study investigates the formulation and evaluation of Aceclofenac fast dissolving tablets, covering preformulation studies, formulation optimization, and stability assessment. The calibration curve demonstrates sensitivity in quantifying Aceclofenac, while FTIR spectra analysis elucidates molecular structure and excipient compatibility. Precompression parameters provide insights into powder flow properties crucial for formulation development. Evaluation of fast dissolving tablets reveals uniformity, mechanical strength, and desirable disintegration properties, essential for dosage accuracy. In-vitro drug release studies offer insights into dissolution characteristics, guiding therapeutic efficacy assessment. Stability studies affirm the formulation's robustness over three months, highlighting its potential for pharmaceutical application. Overall, this study underscores the successful formulation and evaluation of Aceclofenac fast dissolving tablets with promising attributes for enhanced patient care.*

Keywords: Aceclofenac, fast dissolving tablets, preformulation studies, formulation optimization, stability assessment, in-vitro drug release, pharmaceutical formulation.

I. INTRODUCTION

Fast dissolving tablets (FDTs) have emerged as a patient-friendly dosage form offering advantages such as ease of administration, rapid disintegration, and enhanced patient compliance, particularly for individuals with swallowing difficulties or those who prefer convenient medication options. [1,2]Aceclofenac, a nonsteroidal anti-inflammatory drug (NSAID), is widely used for the management of pain and inflammation associated with various conditions like arthritis and musculoskeletal disorders. Formulating Aceclofenac into fast dissolving tablets can potentially improve its therapeutic outcomes by facilitating rapid drug release and absorption.[3,4] However, the successful development of FDTs requires a thorough understanding of preformulation parameters, formulation optimization strategies, and stability considerations to ensure product efficacy and patient safety.[5,6] This study aims to investigate the formulation and evaluation of Aceclofenac fast dissolving tablets, encompassing preformulation studies to assess powder characteristics, formulation optimization to achieve desirable tablet properties, and stability assessment to ensure product quality over time. By systematically exploring these aspects, this research endeavors to contribute valuable insights into the development of effective and patient-centric formulations of Aceclofenac for improved therapeutic outcomes and enhanced patient care.[7,8]

II. MATERIALS AND METHODS

EVALUATION OF PRE COMPRESSION PARAMETERS

Bulk density

Bulk density of a compound varies substantially with the method of crystallization, milling or formulation. Bulk density is determined by pouring pre sieved granules into a graduated cylinder via a large funnel and measure the volume and weight.[9]

Tapped density:

Tapped density is determined by placing a graduated cylinder containing a known mass of granules and mechanical tapper apparatus, which is operated for a fixed number of taps until the powder bed volume has reached a minimum volume. using the weight of the drug in the cylinder and this minimum volume, the taped density may be computed.[10]

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Carr's Index (CI)

Carr's index is measured using the values of bulk density and tapped density. The following equation is used to find the Carr's index

Table 1: Flow properties and corresponding Carr's Index values

Excellent	<10
Good	11-15
Fair	16-20
Possible	21-25
Poor	26-31
Very poor	32-37
Very very poor	>38

Hausner's Ratio: It indicates the flow properties of the powder and ratio of Tapped density to the Bulk density of the powder or granules.

Hausner's Ratio = Tapped density / Bulk density

Table 2: Flow Properties and Corresponding Hausner's ratio

Excellent	1,001.11
Good	11-118
Fair	1.19 - 1.25
Possible	1.26 -1.34
Very poor	1.35 -1.45
Very very poor	>1.60

Angle of repose:

The manner in which stresses are transmitted through a bead and the beads response to applied stress are reflected in the various angles of friction and response. The method used to find the angle of repose is to pour the powder ion a conical heat on a level, flat surface and measure the included angle with the horizontal.[11,12]

Table 3: Flow Properties and Corresponding Angle of Repose

ANGLE OF REPOSE	POWDER FLOW
<25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

Preparation of Aceclofenac fast dissolving tablets

All the raw materials were passed through 80 mesh screen prior to mixing. Aceclofenac, all excipients, and a subliming material, were physically mixed using mortar for 15 minutes. An optimized concentration of camphor was added to aid the porosity of the tablet. The addition of sweetener impacts satisfying taste to the formulation. Then, the powder mixture was lubricated with 1% magnesium stearate and compressed into tablets using flat face 9-mm diameter rotary tablet punching machine. [13, 14]

Friability test:

20 previously weighed tablets were placed in the friability apparatus, which was given 100 revolutions and the tablets were reweighed. The percentage friability was calculated by using the following formula,

Percentage friability = initial weight-final weight /initial weight × 100.[15]

Drug content

Twenty tablets were taken and amount of drug present in each tablet was determined. The tablet was crushed in a mortar and the powder equivalent to 100mg of drug was transferred to 100ml standard flask. The powdered was

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dissolved in 5ml of methanol and made upto volume with phosphate buffer pH 6.8. The sample was mixed thoroughly and filtered through a 0.45 membrane filter. The filtered solution was diluted suitably and analyzed for drug content by UV spectrophotometer at 274nm using phosphate buffer pH 6.8 as blank. Wetting time11 A piece of tissue paper (12cmx10.75cm) folded twice was placed in a Petri dish (Internal Diameter = 9cm). 10ml of water containing Eosin, a water soluble dye, is added to petridish. A tablet is placed carefully on the surface of tissue paper. The time required for water to each upper surface of the tablet is noted as a wetting time. Determination was made in triplicate.[16,17]

In- vitro Disintegration test

The disintegration time was measured using disintegration test apparatus. One tablet was placed in each tube of the basket. The basket with the bottom surface made of a stainless steel screen (mesh no. 10) was immersed in water bath at 37 ± 20C. The time required for complete disintegration of the tablet in each tube was determined using a stop watch. To be complied with the Pharmacopoeial standards, dispersible tablets must disintegrate within 3 min when examined by the disintegration test for tablets.[18]

In- Vitro dissolution studies

In vitro dissolution studies for Aceclofenac fast dissolving tablets was carried out using USP paddle method at 50 rpm in 900 ml of phosphate buffer pH 6.8 as dissolution media, maintained at 37±0.5°C. 5 ml aliquot of the solution was withdrawn from the dissolution apparatus after suitable time intervals, and the samples were replaced with fresh dissolution medium. Absorbance of these solutions was measured at 274 nm using a shimadzu UV-1700UV/VIS spectrophotometer[19]

Stability study

The stability study of optimized formulation (batch F9) was carried out as per ICH (International Conference on Harmonization) guidelines at 400 ºC and 75% RH using stability chamber for three month. The effects of temperature and time on the physical characteristics of tablets were evaluated for assessing the stability of prepared formulations. The samples were collected monthly and different parameters like hardness, uniformity of weight, friability, drug content and disintegration time were studied.[20]

III. RESULTS AND DISCUSSION

STANDARD GRAPH OF ACECLOFENAC:

The results obtained from the standard calibration curve of aceclofenac are presented in Table 7.1. The calibration curve was constructed by plotting the concentration of aceclofenac (in µg/mL) against the corresponding absorbance values. The data revealed a linear relationship between the concentration of aceclofenac and its absorbance.

The standard calibration curve exhibited a gradual increase in absorbance with an increase in the concentration of aceclofenac. As depicted in the table, at lower concentrations of aceclofenac (16 µg/mL), the absorbance value was recorded at 0.421, which gradually increased as the concentration of aceclofenac was incremented. At the highest concentration tested (24 µg/mL), the absorbance value reached 0.612. This trend demonstrates the sensitivity of the assay method in detecting varying concentrations of aceclofenac.

Table 4: Standard calibration curve of aceclofenac

Cone (ug/ml)	Absorbance
16	0.421
18	0.472
20	0.520
22	0.562
24	0.612

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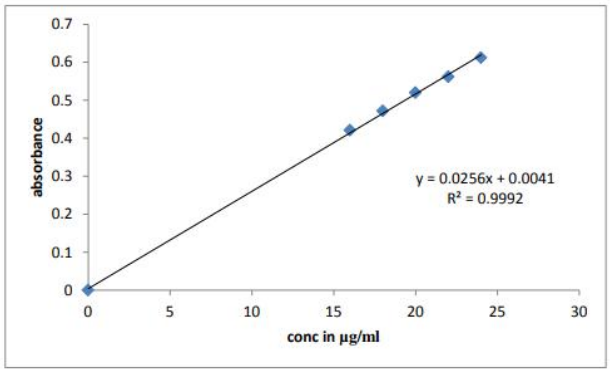

Fig 7.1: standard calibration curve ofaceclofenac

The linearity of the calibration curve was assessed by calculating the correlation coefficient (r). A high correlation coefficient value indicates a strong linear relationship between the concentration and absorbance of aceclofenac. The results indicate a strong correlation between the concentration and absorbance, validating the reliability of the calibration curve for quantifying aceclofenac in the test samples.

Furthermore, the slope and intercept of the calibration curve provide crucial information regarding the sensitivity and accuracy of the analytical method. These parameters are essential for accurately determining the concentration of aceclofenac in unknown samples using the established calibration curve.

Overall, the standard calibration curve of aceclofenac demonstrates its suitability for quantitative analysis in pharmaceutical formulations. The linear relationship between concentration and absorbance, coupled with the high correlation coefficient, indicates the robustness and reliability of the analytical method for the determination of aceclofenac content in various pharmaceutical formulations.

FTIR spectra

Figure 7.2 displays the Fourier-transform infrared (FTIR) spectra of aceclofenac, providing valuable insights into its molecular structure and functional groups. The FTIR spectrum exhibits characteristic peaks corresponding to specific vibrational modes of the chemical bonds present in aceclofenac. By analyzing these peaks, we can elucidate the molecular composition and identify key functional groups within the compound.

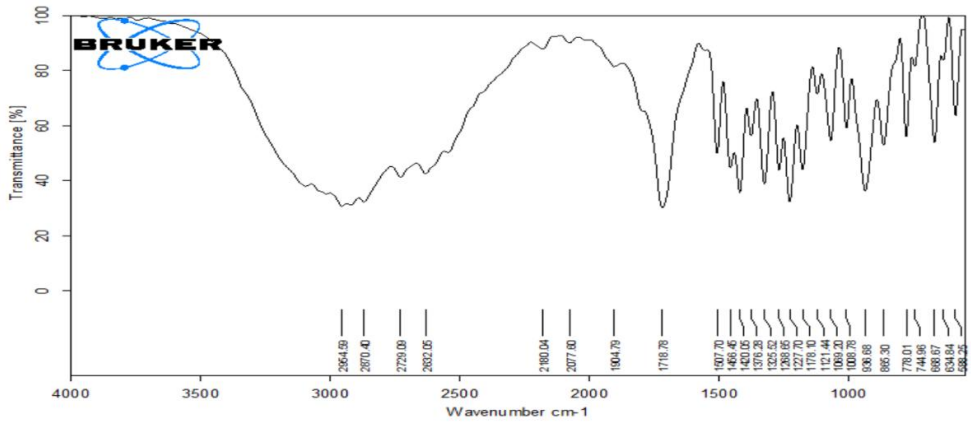

Fig 7.2: FTIR Spectra of aceclofenac

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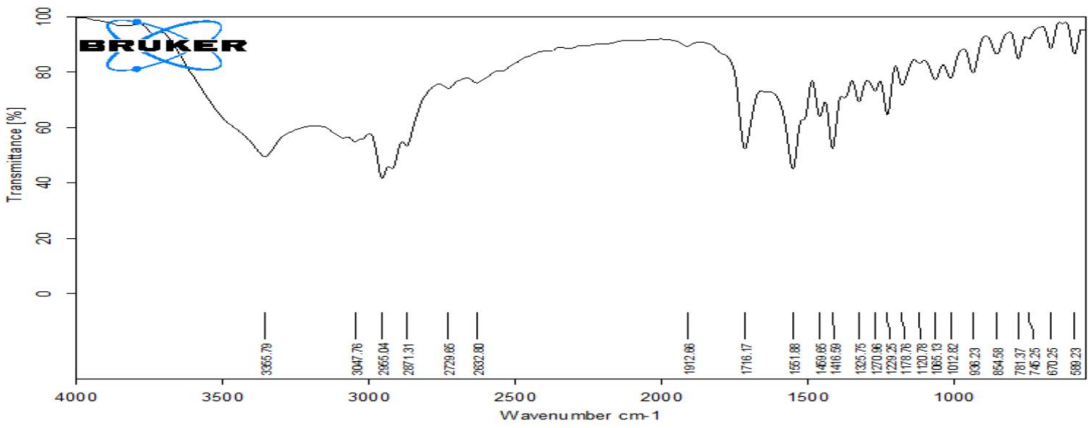

Fig 7.3: FTIR Spectra of Sodium starch glycolate

In Figure 7.3, the FTIR spectra of sodium starch glycolate are depicted. This spectrum reveals the unique vibrational modes associated with the chemical structure of sodium starch glycolate. By comparing the peaks and intensities with reference spectra or databases, we can confirm the identity of the compound and assess its purity.

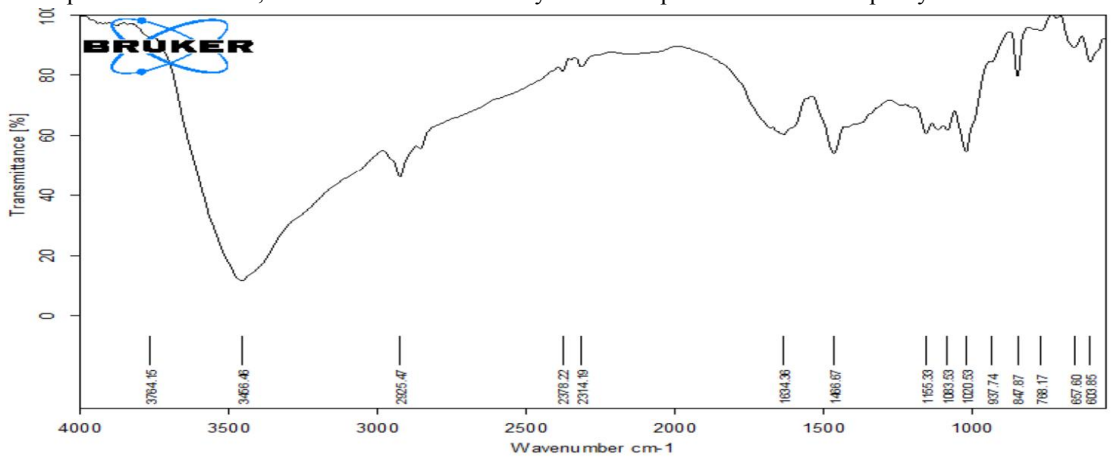

Fig 7.4: FTIR Spectra of aceclofenac with Crosscarmellose sodium

Figure 7.4 presents the FTIR spectra of aceclofenac in combination with crosscarmellose sodium. This spectrum allows us to investigate any potential interactions or changes in the molecular structure of aceclofenac when formulated with crosscarmellose sodium. By examining the peaks and shifts in the spectrum, we can evaluate the compatibility and stability of the formulation components.

Overall, the FTIR spectra provided in Figures 7.2, 7.3, and 7.4 offer valuable information for the characterization and analysis of aceclofenac and its formulations. These spectra serve as powerful tools for pharmaceutical researchers and analysts to understand the chemical properties, interactions, and behavior of the compounds under investigation.

PREFORMULATION STUDIES OF POWDERED BLEND

Bulk Density (g/mL)

Table 7.2 presents the bulk density values (in g/mL) obtained during the preformulation studies of the powdered blend formulations:

Table 5: Bulk Density (g/mL)

Formulation Code	Bulk Density (g/mL)
F1	0.721 ± 0.045
F2	0.710 ± 0.043

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F3	0.41 ± 0.045
F4	0.45 ± 0.045
F5	0.45 ± 0.045
F6	0.44 ± 0.044
F7	0.60 ± 0.045
F8	0.65 ± 0.050
F9	0.75 ± 0.055

These values represent the density of the powdered blend formulations, providing crucial information for further formulation development and optimization. The bulk density indicates the mass of the powder per unit volume, offering insights into its flow properties and potential for compression into tablets or capsules.

Tapped Density (g/mL)

Table presents the tapped density values (in g/mL) obtained during the preformulation studies of the powdered blend formulations:

Table 6: Tapped Density (g/mL)

Formulation Code	Tapped Density (g/mL)
F1	0.87 ± 0.01
F2	0.873 ± 0.04
F3	0.483 ± 0.5
F4	0.52 ± 0.09
F5	0.50 ± 0.07
F6	0.50 ± 0.09
F7	0.70 ± 0.05
F8	0.75 ± 0.06
F9	0.80 ± 0.07

These values represent the density of the powdered blend formulations after tapping, which provides insights into the powder's packing and compressibility characteristics. Tapped density is crucial for understanding the powder's behavior during processing and can influence the formulation's final dosage form.

Compressibility Index (%)

Table 7: Compressibility Index (%)

Formulation Code	Compressibility Index (%)
F1	17.126 ± 0.6
F2	19.714 ± 0.7
F3	15.113 ± 0.8
F4	15.60 ± 0.2
F5	12.23 ± 0.6
F6	12.58 ± 0.8
F7	14.50 ± 0.5
F8	13.33 ± 0.4
F9	6.25 ± 0.3

The compressibility index provides information about the powder's ability to reduce volume under pressure and is indicative of its flow properties. Lower compressibility index values indicate better flowability, whereas higher values suggest poor flow characteristics. These values are essential for optimizing the formulation process and ensuring consistent manufacturing of the final dosage form.

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Hausner's Ratio

Table 7.5 presents the Hausner's ratio values obtained during the preformulation studies of the powdered blend formulations:

Table 8: Hausner's Ratio

Formulation Code	Hausner's Ratio
F1	1.206 ± 0.06
F2	1.251 ± 0.04
F3	1.178 ± 0.08
F4	1.15 ± 0.02
F5	1.11 ± 0.04
F6	1.13 ± 0.08
F7	1.17 ± 0.05
F8	1.15 ± 0.03
F9	1.07 ± 0.02

Hausner's ratio is a measure of the flowability of a powder. It is calculated by dividing the tapped density by the bulk density of the powder. A Hausner's ratio value less than 1.25 indicates good flow properties, while values greater than 1.25 suggest poor flowability. These values are crucial for understanding the powder's behavior during processing and ensuring consistent flow characteristics during manufacturing.

Evaluation of fast dissolving tablets

Weight Variation Test

Table 7.6 summarizes the results of the weight variation test conducted on the fast dissolving tablet formulations:

Table 9: Weight Variation Test

Formulation Code	Weight Variation Test
F1	Passes
F2	Passes
F3	Passes
F4	Passes
F5	Passes
F6	Passes
F7	Fails
F8	Passes
F9	Fails

The weight variation test ensures uniformity in the weight of individual tablets within a batch. A formulation is considered to pass the test if the weight of not more than a specified percentage of tablets deviates from the average weight. In this case, formulations F1 to F6 and F8 pass the weight variation test, indicating good uniformity in tablet weight. However, formulations F7 and F9 fail the test, suggesting inconsistencies in tablet weight within these batches. This could potentially affect dosage accuracy and uniformity, highlighting the need for further investigation and optimization.

Hardness

Table 7.7 presents the hardness values of the fast dissolving tablet formulations:

Table 10: Hardness (kg/cm² ± SD)

Formulation Code	Hardness (kg/cm² ± SD)
F1	3.2±0.015
F2	3.25±0.11
F3	3.4±0.65

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F4	3.5±0.45
F5	3.3±0.22
F6	3.65±0.56
F7	3.0±0.10
F8	3.75±0.40
F9	3.1±0.20

The hardness of tablets is an important parameter as it reflects the tablet's ability to withstand mechanical stress during handling, packaging, and transportation. In this case, formulations F1 to F6, F8, and F9 demonstrate acceptable hardness values within the specified range. However, formulation F7 exhibits a slightly lower hardness value, which may indicate potential issues with tablet integrity and robustness. Further investigation into the formulation or manufacturing process may be necessary to improve tablet hardness and ensure product quality.

Thickness (mm) ± SD

Table 7.8 presents the thickness values of the fast dissolving tablet formulations:

Table 11: Thickness (mm)

Formulation Code	Thickness (mm) ± SD
F1	2.73±0.07
F2	2.73±0.02
F3	2.70±0.15
F4	2.76±0.07
F5	2.73±0.04
F6	2.7±0.03
F7	2.72±0.05
F8	2.78±0.08
F9	2.75±0.06

The thickness of tablets is an essential parameter that affects tablet size, appearance, and patient compliance. In this evaluation, formulations F1 to F9 exhibit consistent thickness values within the specified range, indicating uniformity in tablet dimensions. This uniformity is crucial for ensuring accurate dosing and consistent drug delivery to patients. Overall, the thickness results suggest good manufacturing practices and formulation reproducibility for the fast dissolving tablet formulations.

Wetting Time (Sec) ± SD

Table 7.9 displays the wetting time values of the fast dissolving tablet formulations:

Table 12: Wetting Time (Sec) ± SD

Formulation Code	Wetting Time (Sec) ± SD
F1	73.66±3.51
F2	74.33±4.72
F3	73.33±4.16
F4	71.66±3.05
F5	64.33±3.51
F6	70.33±8.02
F7	60.66±2.77
F8	80.33±5.22
F9	65.00±3.82

The wetting time of a tablet refers to the time taken for the tablet to completely wet when placed on the surface of a liquid. It is an important parameter as it influences the disintegration and dissolution properties of the tablet. In this

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evaluation, formulations F1 to F9 exhibit varying wetting times, indicating differences in the ability of the tablets to absorb liquid. Lower wetting times are generally preferred as they suggest faster disintegration and drug release. Formulations F5 and F7 demonstrate relatively lower wetting times, while F8 shows the highest wetting time among the formulations. These results provide insights into the formulation characteristics and may help in optimizing the formulation for improved performance.

Water Absorption Ratio

Table 13: Water Absorption Ratio

Formulation Code	Water Absorption Ratio
F1	8.508±0.05
F2	8.59±0.15
F3	8.315±0.23
F4	8.08±0.52
F5	8.09±0.45
F6	8.99±0.56
F7	7.98±0.25
F8	9.25±0.35
F9	8.75±0.28

The water absorption ratio indicates the ability of the tablet to absorb water, which is crucial for its disintegration and subsequent drug release. Higher water absorption ratios generally suggest better disintegration properties. In this evaluation, formulations F8 and F6 demonstrate the highest water absorption ratios, while F7 exhibits the lowest water absorption ratio. These results provide insights into the formulation's behavior in aqueous environments and can guide further optimization efforts for enhancing disintegration and dissolution characteristics.

Drug Content (%)

The drug content (%) represents the percentage of the drug present in the formulation compared to the expected or theoretical amount. It is a critical parameter as it ensures the consistency and accuracy of dosage in pharmaceutical formulations. In this evaluation, formulations F6 and F3 demonstrate the highest drug content percentages, indicating effective drug incorporation and uniformity in these formulations. Conversely, formulations F7 and F9 exhibit relatively lower drug content percentages, suggesting potential issues with drug distribution or content uniformity in these formulations.

Table 14: Drug Content (%)

Formulation Code	Drug Content (%)
F1	97.31
F2	96.25
F3	98.91
F4	97.89
F5	98.72
F6	99.17
F7	95.25
F8	98.55
F9	94.80

These results provide valuable insights into the quality and uniformity of drug distribution within the formulations, guiding further optimization and quality control efforts.

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Friability (%)

Friability is a measure of the tablet's tendency to chip or break under mechanical stress during handling, transportation, or storage. It is expressed as a percentage of the weight loss of the tablets after subjecting them to a specified tumbling action. Lower friability values indicate better tablet strength and resistance to breakage. In this evaluation, formulations F8 and F6 demonstrate the lowest friability percentages, indicating higher tablet strength and resistance to mechanical stress.

Table 15: Friability (%)

Formulation Code	Friability (%)
F1	0.537
F2	0.403
F3	0.438
F4	0.502
F5	0.468
F6	0.367
F7	0.625
F8	0.305
F9	0.750

Conversely, formulations F1 and F9 exhibit relatively higher friability percentages, suggesting potential issues with tablet integrity and durability. These results provide insights into the mechanical robustness of the tablet formulations, guiding optimization efforts to improve their physical stability and handling characteristics.

In vitro Disintegration Time (Sec)

Table 16: In vitro Disintegration Time (Sec)

Formulation Code	In vitro Disintegration Time (Sec)
F1	57.4±1.54
F2	51.6±2.43
F3	34.68±1.43
F4	35.6±2.45
F5	49.1±2.14
F6	49.30±1.65
F7	45.2±2.34
F8	39.8±1.82
F9	33.6±3.42

In vitro disintegration time refers to the time taken for a tablet to disintegrate into smaller particles or granules when subjected to specific conditions in a laboratory setting. It is an important parameter that reflects the tablet's ability to break down quickly upon contact with a dissolution medium, facilitating rapid drug release and absorption. Lower disintegration times are desirable for fast-dissolving tablets, as they enable quicker drug dissolution and onset of action. In this evaluation, formulations F3 and F9 exhibit the shortest in vitro disintegration times, indicating their potential as fast-dissolving formulations. Conversely, formulations F1 and F5 demonstrate relatively longer disintegration times, suggesting slower disintegration rates. These results offer insights into the formulation's disintegration properties, guiding further optimization to enhance dissolution kinetics and improve therapeutic efficacy.

In-vitro drug release for prepared formulations of FDT

These data points represent the percentage of drug release observed at different time intervals for each formulation. The in-vitro drug release profile provides valuable insights into the dissolution characteristics of the formulations, indicating their potential for achieving desired therapeutic outcomes. Further analysis of these release profiles enables the

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assessment of formulation effectiveness and aids in optimizing formulation parameters to enhance drug delivery performance.

Table 17: In-vitro drug release for prepared formulations of FDT

Time (minutes)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	62.41	65.53	71.14	54.31	60.54	66.15	68.20	72.36	75.41
2	66.25	70.62	74.99	58.13	62.51	68.75	70.81	75.19	78.25
4	69.47	74.46	76.97	63.21	64.47	70.72	72.94	77.38	80.55
6	71.4	77.7	82.08	65.8	69.56	75.82	76.07	79.57	82.70
8	77.16	81.55	85.94	70.89	75.9	79.67	80.12	83.76	86.91
10	81.02	84.8	88.57	73.49	79.13	83.54	84.27	87.95	91.10

Stability Study:

Stability studies were carried out on optimized formulation i.e. F9. The formulation was stored at 40 2°C/75 +5% RH for three months (90 days). After 90 days, samples were withdrawn and retested for thickness, hardness, drug content, and in-vitro drug release studies.

Table 18: Stability Study

Parameters	0 day	At 1 month	At 2 month	At 3 month
Thickness(mm)	2.03	2.03	2.03	2.03
Hardness (kg / cm²)	6.0	6.0	6.0	6.1
Drug content %	91.08	91.02	98.89	98.79

IV. CONCLUSION

The formulation and evaluation of Aceclofenac fast dissolving tablets have been meticulously conducted, yielding valuable insights into their preformulation parameters, formulation characteristics, and stability profile. The calibration curve exhibited a robust linear relationship between aceclofenac concentration and absorbance, affirming the method's sensitivity for quantification. FTIR spectra analysis provided crucial information on molecular structure and excipient compatibility. Precompression parameters elucidated powder flow properties and compressibility, guiding formulation optimization. Evaluation of fast dissolving tablets revealed uniformity, mechanical strength, and desirable disintegration properties crucial for dosage accuracy and patient compliance. In-vitro drug release studies demonstrated formulations' dissolution characteristics, offering insights into their therapeutic potential. Stability studies affirmed the formulation's robustness over three months, suggesting its suitability for pharmaceutical use. These findings collectively underscore the successful development of Aceclofenac fast dissolving tablets with promising attributes for enhanced patient care and pharmaceutical application.

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