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FORMULATION DEVELOPMENT AND EVALUATION OF MUCOADHESIVE BUCCAL TABLET CONTAINING ACECLOFENAC

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ABSTRACT
The present study aims to develop and evaluate Mucoadhesive Buccal Tablets of Aceclofenac to enhance its bioavailability and provide sustained drug release through buccal mucosa. Aceclofenac, a non-steroidal anti-inflammatory drug (NSAID), suffers from poor oral bioavailability due to extensive first-pass metabolism. Buccal delivery offers a promising alternative by passing hepatic metabolism and providing controlled drug release. The tablets were formulated using various concentrations of mucoadhesive polymer such as Carbopol 934 P through the Direct Compression Method. The prepared formulations were evaluated for physicochemical parameters including hardness, friability, weight variation, surface pH, swelling index, in vitro residence time, mucoadhesive strength, and in vitro drug release. Among all the formulations, the optimized batch exhibited satisfactory mucoadhesive strength, a prolonged residence time, and sustained drug release of more than 10 hours with a cumulative release of over 97%. The findings suggest that the developed Mucoadhesive Buccal Tablet of Aceclofenac is a potential candidate for effective systemic delivery with improved patient compliance.

KEYWORDS: mucoadhesion, bioadhesion, buccal drug delivery, mucoadhesive polymers, in vitro drug release.

INTRODUCTION
The patient prefers the oral route over all other dosing types. Hepatic first-pass metabolism and GI tract enzymatic degradation are two drawbacks of the oral drug delivery method that restrict the oral administration of some medication classes, including proteins and peptides. For systemic drug distribution, transmucosal methods of administration provide clear advantages over oral administration. Mucoadhesion is a type of drug delivery system that targets a drug to a specific area of the body for a prolonged amount of time by using the bioadhesion of some water-soluble polymers, which become sticky when hydrated. To treat both local and systemic disorders, buccal formulations are applied in the mouth between the cheek and upper gingiva (gums). The buccal mucosa lines the inner cheek. One of the possible ways for oligonucleotides, polysaccharides, and normally big, hydrophilic, and unstable proteins, as well as typical tiny drug molecules, is the buccal route.[1,2,3]

The oral cavity has been used as a site for local and systemic drug delivery. The buccal region of the oral cavity is an attractive site for the delivery of drugs owing to the ease of administration. Buccal drug delivery involves the administration of a desired drug through the buccal mucosal membrane lining of the oral cavity. This route is useful for mucosal (local effect) and trans-mucosal (systemic effect) drug administration. The goal in the initial instance is to achieve a site-specific release of the drug on the mucosa, whereas in the second case, the drug is absorbed through the mucosal barrier and into the systemic circulation. Trans-mucosal medication administration involves passing the medicine through the mucosal linings of the nasal, rectal, vaginal, ocular, and oral cavities. Among these mouth cavities is a novel location for medication administration. Several studies have looked into using the oral mucosa to deliver medicine both locally and systemically.[4,5]

MATERIAL
Aceclofenac was kindly provided by Dhamtec Pharma Limited, Taloja (Navi Mumbai), Xanthan Gum, Mg. Stearate, Guar Gum and Mannitol were received from Research- Lab Fine Chem Industries, Mumbai. Lactose and Carbopol 934P were supplied by Modern Industries, Malegaon (Sinnar).

METHOD
Spectrometric Analysis
- A standard stock solution of Aceclofenac was prepared by dissolving accurately weighed 10 mg of Aceclofenac in a small quantity of methanol in a 100 ml volumetric flask to obtain a stock solution of 100 µg/ml. From the standard stock solution, 2.5 mL was

pipetted into a 10 mL volumetric flask. The volume was then made up to 10 ml with methanol. The resulting solution containing 10µg/ml was scanned between 200 and 400 nm.[6]

- To determine the maximum wavelength (λmax) of Aceclofenac API, 10 mg of the drug was accurately weighed and dissolved in 20 ml of methanol in a 100 ml volumetric flask. The volume was then made up to 100 ml with methanol to prepare the standard stock solution.[7,8]
- From this solution, 1 ml was taken and diluted to 10 ml with methanol to obtain a 10 µg/ml working solution. This solution was scanned in between the range of 200 to 400 nm using a UV-visible spectrophotometer, with methanol used as the blank. The λmax of Aceclofenac was found to be 275 nm. For calibration purposes, a series of standard solutions with concentrations ranging from 5 to 25 µg/ml was prepared using methanol, and their absorbance was measured at 275 nm using UV spectroscopy.[9]

Determination of Preformulation Parameters

In the evaluation of powder and granule properties, key parameters such as bulk density, tapped density, Hausner's ratio, Carr's index, and angle of repose are crucial. Bulk and tapped densities indicate the amount of material occupying a given volume before and after tapping, respectively. The angle of repose reflects the frictional forces between particles and their ability to stack or flow. Hausner's ratio assesses flowability, while Carr's index measures the compressibility of the powder. These parameters play a vital role in ensuring proper powder flow and handling in industries like pharmaceuticals, food processing, and material science.[10,11]

FTIR

IR spectroscopy is a useful technique to study how drugs interact with polymers and other excipients during storage. In this case, it was used to examine how excipients interact with Aceclofenac. In order to look for any chemical changes, the IR spectra of the drug by itself and a physical mixture of the drug and excipients were compared. An interaction between the compounds is indicated if the spectra differ. A FTIR spectrophotometer operating in the wavelength range of 4000-400 cm^{-1} was used to evaluate samples that were kept in a stability chamber. Aceclofenac and excipients were combined in a 1:1 ratio, and other drug-loaded powders were analyzed using the same technique.[12,13]

Differential Scanning Colorimetry (DSC)

Differential scanning calorimetry (DSC) of Aceclofenac and its excipients was conducted using a Shimadzu DSC-60 plus instrument to study their thermal properties. Samples of Aceclofenac and the excipients, mixed in a 1:1 ratio, were heated in aluminum pans from 25°C to 300°C at a rate of 10°C per minute to observe their thermal behavior.[14,15]

Saturation Solubility of API

Aceclofenac saturation solubility experiments aid in figuring out how much of the drug dissolves in different solvents. At a specific temperature, excess Aceclofenac is added to the various solvents and agitated until it dissolves completely. Using techniques like UV spectroscopy, the amount of dissolved Aceclofenac is determined after the remaining undissolved medication has been isolated. This study contributes to our understanding of the drug's solubility, which is critical to both its efficacy and the body's ability to absorb it.[16]

Tablet Peparation

To prepare Mucoadhesive Buccal Tablet, Aceclofenac and Mucoadhesive polymers (Xanthum Gum, Carbopol 934P, and Guar Gum) are mixed, and by using a mortar & pestle, Mannitol (Vehicle) is introduced gradually while being continuously mixed. The necessary amount of Mg. stearate (Lubricant), Carbopol 934P (Binder) were well combined. After the mixture was run through sieves 40 and 60. Lastly, a tablet punch was used to compress the tablet.[17]

Composition of Tablet

Table 1: Composition of Mucoadhesive Buccal Tablet containing Aceclofenac.

Ingredient	F1	F2	F3	F4	F5	F6	F7	F8
Aceclofenac	100	100	100	100	100	100	100	100
Xanthan Gum	25	25	2.5	25	2.5	2.5	25	2.5
Guar Gum	12.5	25	12.5	25	25	25	12.5	12.5
Carbopol 934P	30	20	20	30	30	20	20	30
Mannitol	10	10	10	10	10	10	10	10
Mg. Stearate	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Lactose	70	67.5	102.5	57.5	80	90	80	92.5
Total	250	250	250	250	250	250	250	250

**All ingredients in mg only*

Determination of Post-formulation Parameters

The result of tablets is assessed through several tests: thickness is measured using a Vernier Caliper in mm; hardness is determined using a hardness tester, with force

gradually applied until the tablet breaks, and results are expressed in kg/cm²; weight variation is checked by weighing 20 randomly selected tablets; and friability is measured using a friabilator, This refers to calculating the percentage of tablet weight lost after the tablets are rotated. These tests ensure the tablets meet required standards for uniformity and durability.[18]

Drug Content

To determine the drug content, 20 tablets were ground into powder, and 100 mg of the powder was mixed with 100 ml of a 6.6 pH phosphate buffer solution. The mixture was stirred for 30 minutes, then filtered. The absorbance of the filtered solution was measured at 275 nm using a UV-visible spectrophotometer, after the solution was diluted with the same 6.6 pH phosphate buffer.[19]

***In-vitro* drug release studies**

The USP-II tablet dissolution testing instrument can be used to measure the release rate of Aceclofenac from Mucoadhesive Buccal Tablet (corresponding to 10 mg of Aceclofenac) at a rotation speed of 50 rpm. At 37±2ºC, 900ml of 6.6 Phosphate Buffer solutions were used for the dissolving test. A 5 ml aliquot sample was removed and replaced with new media every two minutes. Using a spectrophotometer set to 275 nm, the quantity of Aceclofenac in each pharmaceutical solution was determined.[20]

Table 2: In vitro drug release studies for Mucoadhesive Buccal Tablet.

Sr. No	Parameters	Specifications
1.	USP Dissolution Device	Type II [Paddle Method]
2.	Dissolution medium	Phosphate Buffer pH 6.6
3.	Volume of Dissolution medium	900ml
4.	Temperature	37°C ± 2
5.	Speed of Paddle	50 rpm
6.	Sampling intervals	1 Hrs
7.	Withdraw Sample	5ml
8.	Absorbance measure	275 nm

Optimization by 2^3 full factorial Design

Optimization is the key parameter in the development of any product. Factorial designs are used to evaluate two or more factors simultaneously interactions can be determined in the factorial design. A study in which three factors and two levels are involved is called a 2^3 factorial design. For the present work, a 2^3 factorial design was selected, and 3 factors were evaluated at two possible levels by formulating all possible 8 formulation combinations.[21]

RESULT AND DISCUSSION

Spectrometric Analysis

- Using UV spectroscopy, Aceclofenac's maximum absorption wavelength (λmax) was determined to be 275 nm, as shown in **Fig. 1.**

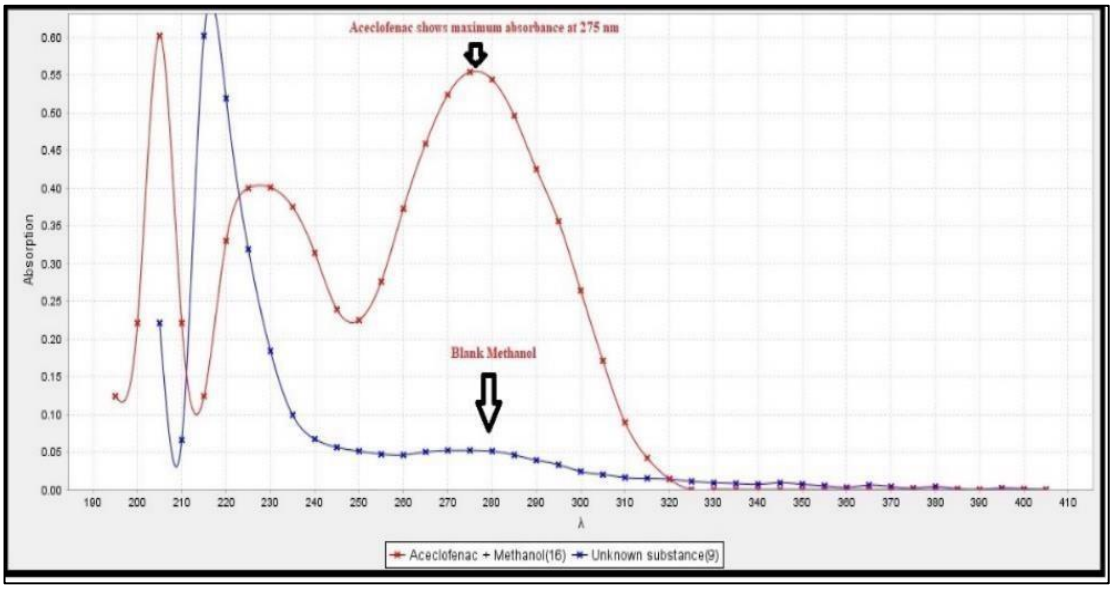

Fig.1: Analytical Wavelength (λmax) of Aceclofenac.

Table 3: Concentration and Absorbance value for Aceclofenac in Methanol.

Sr. No	Concentration (µg/ml)	Absorbance (275nm)
1.	5	0.125
2.	10	0.260
3.	15	0.371
4.	20	0.488
5.	25	0.605

- A good linear relationship between concentration and absorbance is demonstrated by the standard calibration curve for Aceclofenac, its slope is y = 0.0238x + 0.0134, and its coefficient of regression value is R2 = 0.999, as shown in **Fig. 2.**

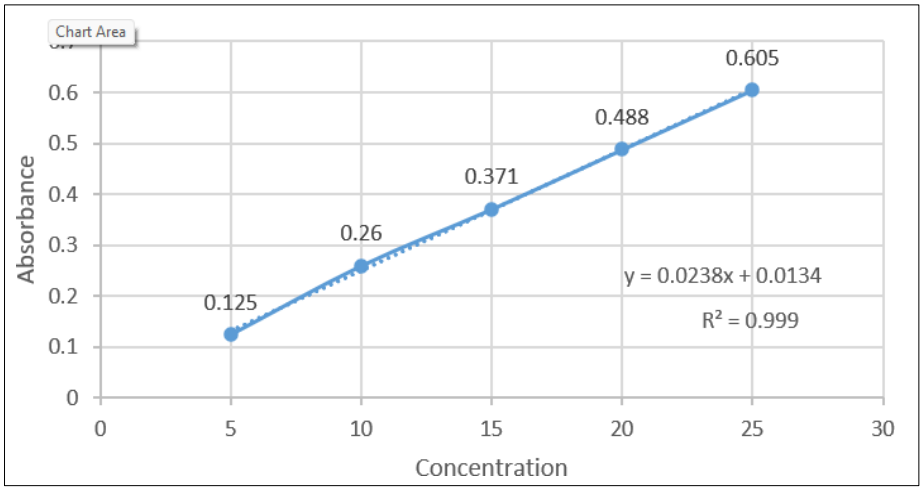

Fig.2: Calibration curve of Aceclofenac in Methanol.

Pre-compression Evaluation of Mucoadhesive Buccal Tablet

The formulation powder of different ratios was evaluated for powder blend properties like Bulk density, Tapped Density, Carr's index, Hausner Ratio, and Angle of Repose. Results obtained are given in **Table 3.**

Table 3: Precompression Evaluation of Mucoadhesive Buccal Tablet.

Formulation	Bulk density (g/ml)	Tapped density (g/ml)	Carr's index (%)	Hausner ratio	Angle of repose (θ)
F1	0.34±0.03	0.48±0.02	10.46±0.08	1.16±0.41	28.90±1.15
F2	0.38±0.08	0.44±0.06	11.66±0.04	1.11±0.30	31.42±1.24
F3	0.36±0.11	0.42±0.04	11.28±0.08	1.15±0.63	27.21±1.20
F4	0.39±0.02	0.45±0.02	10.41±0.04	1.12±0.58	29.96±1.28
F5	0.35±0.06	0.43±0.01	10.22±0.03	1.13±0.29	28.94±1.30
F6	0.34±0.04	0.40±0.08	11.26±0.08	1.11±0.38	31.62±1.24
F7	0.37±0.08	0.42±0.02	12.29±0.06	1.12±0.54	29.65±1.42
F8	0.36±0.05	0.42±0.04	10.34±0.02	1.15±0.21	28.07±1.30

The powder mixes of all eight formulations showed tapped densities between 0.40 and 0.48 g/ml and bulk densities between 0.34 and 0.39 g/ml when pre-compression parameters were taken into consideration. There was a range of 27.21º to 31.62º for the angle of repose, 1.11 to 1.16 for the Hausner's ratio, and 10.22% to 12.29% for the Carr's index. These findings demonstrate the blends' superior flowability and compressibility as well as their compliance with approved pharmaceutical standards.

Fourier Transform Infrared Spectroscopy (FTIR)

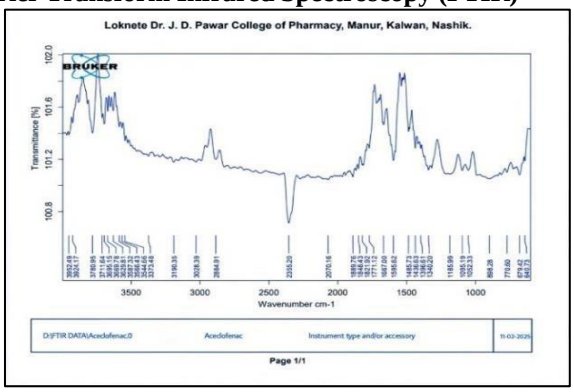

Fig 3: Pure drug Aceclofenac

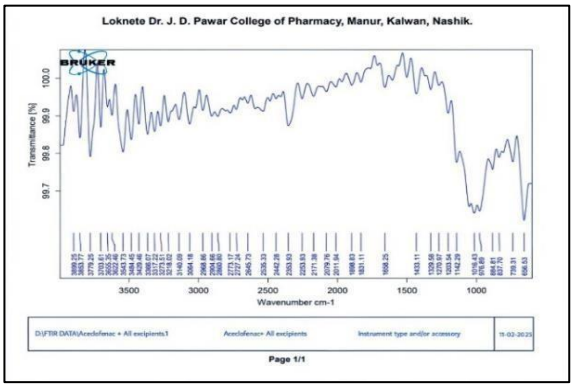

Fig 4: Aceclofenac + All Excipients

A 1:1 mixture of Aceclofenac and other excipients was prepared. These mixtures were then analyzed with an FTIR spectrophotometer, which recorded their IR spectra in the range of 4000 to 400 cm^{-1}.

Differential Scanning Calorimetry (DSC)

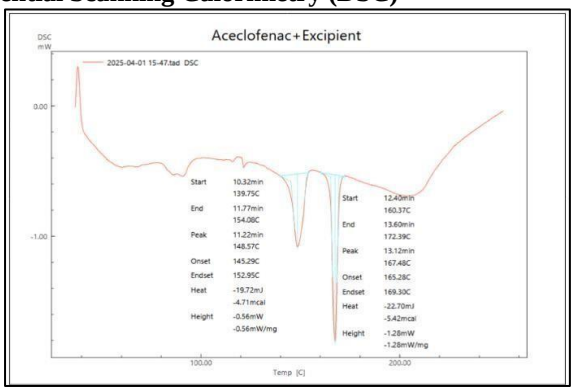

Fig 5: Pure drug Aceclofenac.

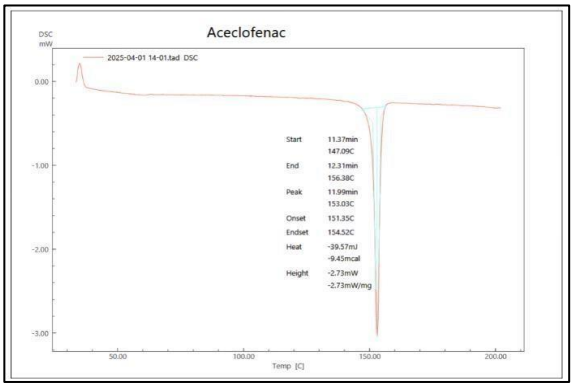

Fig 6: Aceclofenac + All Excipients

The preparation's thermal behavior was analyzed using Differential Scanning Calorimetry (DSC) to determine its melting point, crystallinity, breakdown, and drug-excipient interaction. The compatibility of Aceclofenac and all excipients is demonstrated by their DSC, with the latter showing a noticeable endothermic peak at 153.03°C at 11.99 minutes.

Saturation Solubility Studies for Drug

Table 4: Aceclofenac pure drug in various solvents Evaluation result of Tablet.

Sr. No	Solvent	Solubility (mg/ml)
1.	Acetone	Freely Soluble
2.	Ethanol	95% Soluble
3.	Methanol	95% Soluble
4.	Water	Insoluble

Table 5: Evaluation result of the Tablet.

Formulation	Weight Variation	Hardness (kg/cm^2)	Thickness (mm)	Friability (%)
F1	249 ± 2.20	3.86±0.10	3.93±0.20	0.6±0.07
F2	249 ± 2.39	4.67±0.25	3.92±0.17	0.8±0.08
F3	250 ± 1.12	3.41±0.20	4.02±0.24	0.6±0.05
F4	252 ± 0.30	5.56±0.82	4.04±0.26	0.4±0.05
F5	251 ± 1.24	3.41±0.20	3.90±0.28	0.3±0.02
F6	248 ± 2.50	3.52±0.50	3.96±0.26	0.8±0.06
F7	250 ± 1.05	4.88±0.10	4.02±0.08	0.1±0.02
F8	251 ± 0.52	5.38±0.20	4.04±0.21	0.2±0.06

Drug Content

Table 6: Mucoadhesive Buccal Tablet Drug Content.

Formulation Code	Drug Content (%)
F1	94.32±0.15
F2	95.34±0.10
F3	98.70±0.12
F4	96.88±0.13
F5	95.99±0.25
F6	94.75±0.50
F7	96.16±0.10
F8	95.82±0.20

According to Table 5, the drug content ranges from 94.32% to 98.70%. The findings show that the methods used in this investigation to create the Mucoadhesive Strength were able to create a formulation with a consistent amount of medication.

Swelling Index

Table 7: Swelling Index of F1-F8 Batch.

Time (Hrs)	F1	F2	F3	F4	F5	F6	F7	F8
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
1	14.20±0.11	12.39±0.24	24.10±0.15	15.65±0.20	13.45±0.19	11.78±0.14	20.12±0.10	16.68±0.12
2	28.45±0.21	24.86±0.18	40.33±0.25	30.78±0.30	26.92±0.22	22.13±0.20	35.60±0.15	24.32±0.16
4	36.20±0.20	35.78±0.19	55.67±0.20	45.40±0.25	40.88±0.18	33.87±0.18	48.05±0.21	32.24±0.14
6	39.55±0.29	36.14±0.32	56.78±0.25	48.43±0.25	42.89±0.27	34.97±0.27	48.65±0.30	46.12±0.15
8	40.32±0.18	38.95±0.22	60.11±0.28	50.76±0.21	45.21±0.30	36.42±0.22	51.26±0.29	50.28± 0.22
10	42.80±0.25	40.67±0.24	62.45±0.33	56.66±0.38	47.32±0.27	39.12±0.24	53.98±0.33	58.11± 0.16

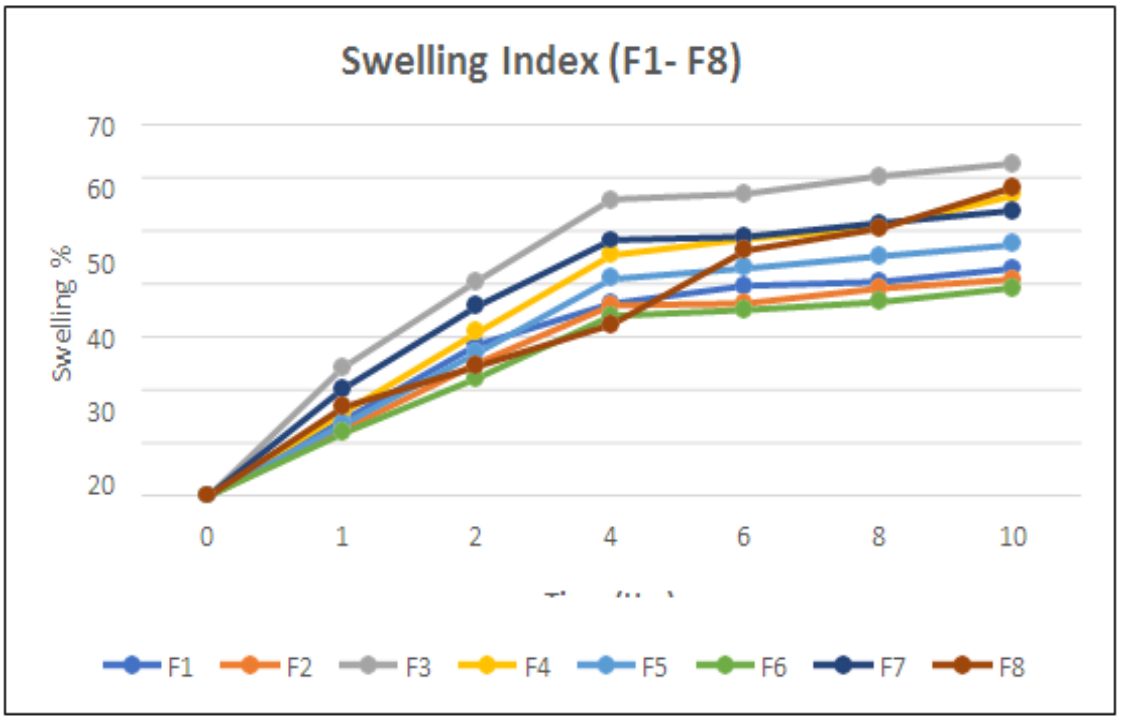

Fig. 7 Swelling Index for F1-F8 batches.

The swelling index data of Aceclofenac mucoadhesive buccal tablets for batches F1 to F8 show a gradual increase in swelling over 10 hours, indicating time-dependent hydration of the polymer matrix. Among all batches, F3 exhibited the highest swelling index (62.45 ± 0.33%) at 10 hours, suggesting a superior water absorption capacity, likely due to an optimal concentration of polymers.

Mucoadhesive Strength

Table 8. Mucoadhesive Strength of F1-F8 Batch.

Formulation Code	Mucoadhesive Strength (gm)
F1	15.20 ± 0.24
F2	19.14 ± 0.11
F3	32.28 ± 0.08
F4	16.39 ± 0.30
F5	21.10 ± 0.22
F6	26.64 ± 0.18
F7	22.32 ± 0.26
F8	18.30 ± 0.12

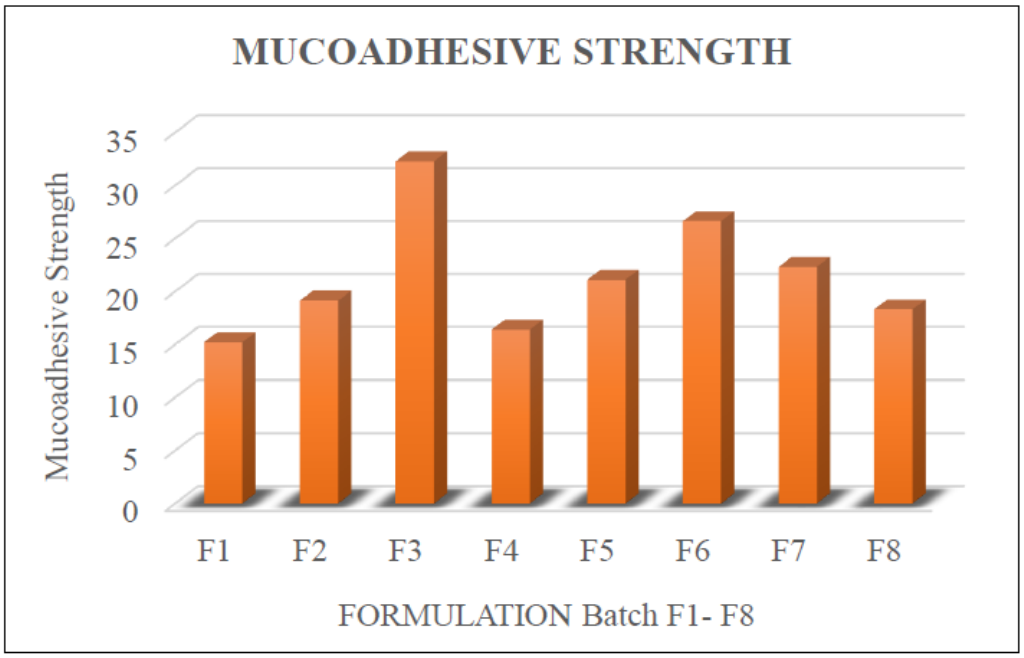

Fig 8: Mucoadhesive Strength of F1- F8 Batch.

The mucoadhesive strength data for the Aceclofenac buccal tablet formulations F1 to F8 reveals significant variation among the batches. Formulation F3 exhibited the highest mucoadhesive strength (32.28 ± 0.08 g), indicating strong adhesion to the mucosal surface, which is crucial for prolonged retention and effective drug delivery.

In vitro Dissolution Study

The table shows of drug in phosphate buffer 6.6 the drug is approximately linear. The percentage drug release was found to be 98.19±0.02 % at the end of 10 Hrs.

Table 9: Cumulative % Drug release of Mucoadhesive Tablet.

Time (Hrs)	F1	F2	F3	F4	F5	F6	F7	F8
0	0	0	0	0	0	0	0	0
1	22.20±0.02	26.82±0.04	34.02±0.02	31.11±0.04	22.37±0.08	27.68±0.02	25.45±0.08	26.82±0.08
2	28.66±0.08	30.92±0.06	48.44±0.06	47.23±0.04	30.38±0.06	34.95±0.04	35.54±0.08	47.20±0.04
4	44.13±0.04	47.57±0.02	60.69±0.08	56.57±0.02	47.39±0.04	56.90±0.02	48.45±0.04	52.80±0.02
6	60.67±0.02	67.55±0.04	81.33±0.04	77.88±0.08	64.12±0.04	77.88±0.06	67.55±0.06	79.57±0.06
8	76.1±0.12	81.37±0.06	93.45±0.06	89.14±0.06	79.64±0.02	90.00±0.08	81.37±0.02	90.01±0.02
10	87.42±0.04	93.45±0.08	98.19±0.02	90.06±0.04	93.44±0.04	96.92±0.02	95.16±0.04	96.82±0.02

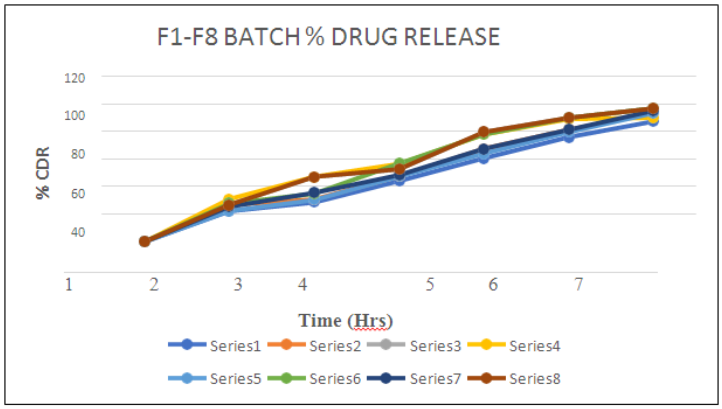

Fig 9: % drug release of tablet formulation for F4-F8 batches Analysis of Data.

It was found that the independent variables, viz. Xanthan Gum, Guar Gum, and Carbopol 934 P had a positive effect on drug release. Effect of Xanthan Gum, Guar Gum, and Carbopol 934 P on the drug release Time of Aceclofenac in 3D response surface plot is confirmed. From the figure response curve of Y1 (% CDR). It is observed that as the concentration of Xanthan Gum increases from 2.5 mg to 25 mg, Guar Gum increases from 12.5 mg to 25 mg, and Carbopol 934 P from 20 mg to 30 mg drug release increases significantly.

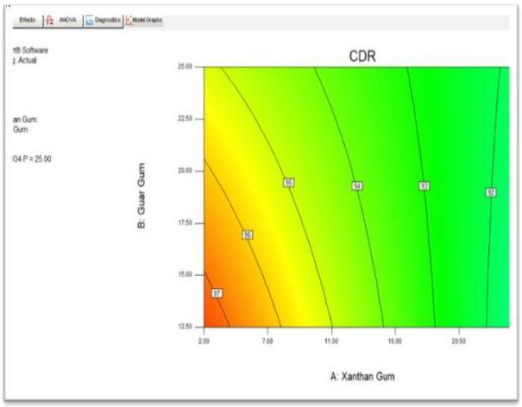

Fig 10: Contour plot of % drug release.

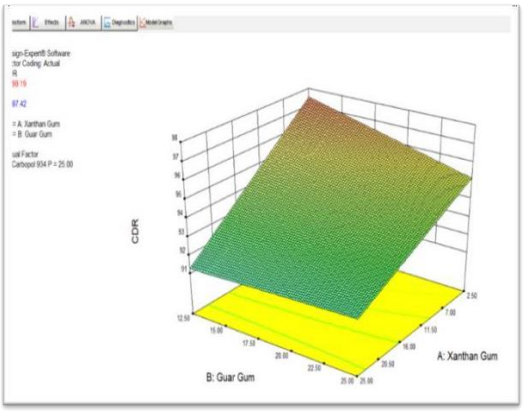

Fig 10: 3D Response Surface Plot.

The impact of independent variables on friability (Y2) was assessed using a polynomial equation, which revealed that Xanthan Gum, Guar Gum, and Carbopol 934 P negatively affected friability. Curved Y2 (Friability) Effect of Xanthan Gum, Guar Gum, and Carbopol 934 P on the friability of Aceclofenac in a 3D response surface plot confirmed. From the figure response curve of Y2 (% Friability). It is observed that as the concentration of Xanthan Gum increases from 2.5 mg to 25 mg, Guar Gum increases from 12.5 mg to 25 mg, and Carbopol 934 P increases from 20 mg to 30 mg, drug release increases significantly.

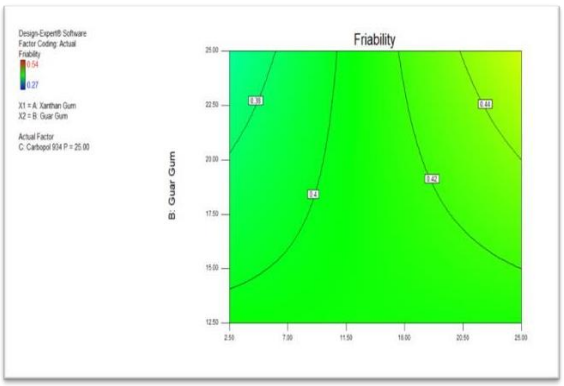

Fig 11: Contour plot of % drug release.

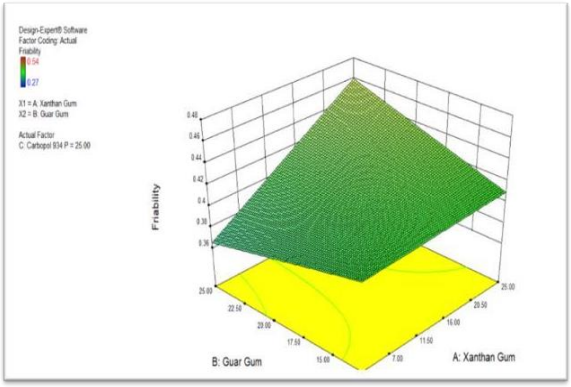

Fig 11: 3D Response Surface Plot.

CONCLUSION AND DISCUSSION

This study showed that Aceclofenac, a poorly water-soluble drug. The drug was effectively turned into a dry, free- flowing, and compressible powder by replacing

Mannitol with Mg. stearate for the carrier materials, and using Lactose vehicle. Due to the optimal disintegrant combination, F3 demonstrated the most constant and quick drug release among the studied formulations, with a 10 hours half-life. While FTIR and DSC experiments revealed that Aceclofenac and excipients were compatible, evaluation of pre- and post-compression characteristics confirmed good flowability, tablet uniformity, and mechanical strength. All things considered, the mucoadhesive method provides an easy, affordable, and expandable way to increase Aceclofenac's bioavailability.

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