

Formulation and Evaluation of Matrix Tablets for Sustained Drug Release

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ABSTRACT

Sustained release drug delivery systems are designed to release drugs at a controlled and predetermined rate to maintain a constant therapeutic concentration in the body, thereby enhancing patient compliance and therapeutic efficacy. The present study focuses on the formulation and evaluation of matrix tablets for sustained drug release using aceclofenac as the model drug. Aceclofenac is a non-steroidal anti-inflammatory drug widely used for the management of pain and inflammation but requires frequent dosing due to its short biological half-life. The study includes the evaluation of the drug profile followed by pre-formulation studies such as solubility analysis, drug-excipient compatibility, and flow properties. Based on these parameters, matrix tablets were formulated using suitable polymers to achieve controlled drug release. The prepared formulations were evaluated for pre-compression parameters like bulk density, tapped density, and angle of repose, as well as post-compression parameters including hardness, thickness, friability, weight variation, and drug content uniformity.

Keywords Sustained release tablet, matrix tablet, drug profile, Preformulation studies, formulation development, evaluation of precompression and post compression parameter.

INTRODUCTION

The most popular, affordable, and practical system of administering medicines systemically is oral delivery. Oral solid phrasings, particularly tablets and capsules, account for around 60 – 70 of pharmaceutical lozenge forms vended worldwide [1]. still, there are essential downsides to traditional immediate- release (IR) dosing phrasings. The drug is snappily released, absorbed, and dispersed following the ingestion of an IR tablet. This results in a distinctive, abrupt rise in tube attention that constantly surpasses the remedial threshold. Tube situations snappily drop below the minimum effective attention (MEC) when the body gets relieve of the drug. This results in:

- Variations in tube attention
- lowered effectiveness of treatment
- An advanced frequency of dosing

- An increased frequency of adverse consequences
- shy compliance with long- term treatment

Modified medicine Delivery Systems (MDDS) were created to get around these problems. These systems govern the release of medicines in a predictable, unremarkable, and regulated way. Among them, Sustained- Release (SR) phrasings are constantly utilised to sustain steady tube situations throughout time [2]. The sustained release medicine delivery consists of the mileage of physical and polymer chemistry. Those polymers sluggishly release the medicine in bio-system and maintain medicine blood stage inside remedial range for longer length. Some of the products signify the medicine saturation through the precise natural membrane and any first pass metabolic consequences former to the access of medicine into systemic rotation. The fact that the immersion and release rate of the medicine from the lozenge form, is one of the instigative and maximum

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rearmost enhancement in pharmaceutical discipline. There are multitudinous delineations of sustained release, but the only description is “Any medicine or lozenge form or remedy that prolongs the mending exertion of medicine”. The general thing is that, as soon as the medicine- carrier material has been fitted or else implanted or taken orally into the body, the medicine is released at a destined price for some favoured time frame. Controlled release generation is extensively new discipline and hence, studies on this field has been extremely rich and has produced numerous discoveries. Several terms had been used to explain the different kinds and modes of action meant to offer long length of medicine exertion. sorely, the expressions have been enforced approximately and are reciprocated constantly so that currently there’s no steady title for the extended action products available in the request. Several appellations had been applied synonymously to explain sustained launch medicinal medicines. Some of those are nonstop release(CR), depot release(DR), slow release(SR), long amusement(la), durable(LL), long term release(LTR), extended action(PA), managed release(CR), extended release(ER), gradational release(GR) etc.

still, the recent literature check suggests the bones as on moment the most extensively used terms are sustained release and controlled release [3, 4].

The thing of sustained- release systems is to attain a near- zero- order release profile, which guarantees that the drug is delivered gradationally and continuously in agreement with the body's rate of elimination. This enhances the safety profile, prolongs the remedial impact, and reduces tube medicine variations [5].

The matrix tablet is the most popular sustained-release oral device due to its affordability, scalability, adaptability, and convenience of use. The drug is integrated into a polymeric network in matrix tablets, which controls the release gets through processes including corrosion, swelling, proluxity, and dissolution. These benefits make SR matrix tablets perfect for specifics like Cyclofenil, which have short natural half- lives and need long- term therapy [6].

I. Drug Profile: Aceclofenac [7]

Table.1: Drug profile of Aceclofenac

Parameter	Details
Drug Name	Aceclofenac
Chemical Name	2-[2-(2,6-dichlorophenyl) amino] phenyl] acetic acid
Molecular Formula	C ₁₆ H ₁₃ Cl ₂ NO ₄
Molecular Weight	354.19 g/mol
CAS Number	89796-87-0
Class	Non-Steroidal Anti-Inflammatory Drug (NSAID)
Mechanism of Action	Aceclofenac inhibits cyclooxygenase (COX-1 and COX-2) enzymes, thereby reducing prostaglandin synthesis responsible for pain, inflammation, and fever.
Therapeutic Category	Anti-inflammatory, Analgesic, Antipyretic
Pharmacological Uses	Management of osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, musculoskeletal pain, and post-operative pain.
Route of Administration	Oral
Dosage Forms	Tablets (50 mg, 100 mg), Capsules, Suspension (less common)
Half-life	4–5 hours



Bioavailability	Approximately 60–70% (oral)
Protein Binding	~99%
Solubility	Slightly soluble in water; freely soluble in methanol, ethanol, and dimethylformamide
pKa	4.7
Partition Coefficient (Log P)	2.3
Metabolism	Primarily hepatic via hydroxylation and glucuronidation
Excretion	Mainly renal (urine), small fraction in bile
Stability	Stable under normal conditions; sensitive to strong acids and bases
Side Effects	Gastrointestinal disturbances (nausea, dyspepsia), dizziness, headache, rare renal and hepatic effects
Precautions	Avoid in patients with peptic ulcer, GI bleeding, severe renal or hepatic impairment; caution in elderly patients
Regulatory Status	Approved by FDA, WHO essential medicines list (NSAID category)

Chemical structure of Aceclofenac-

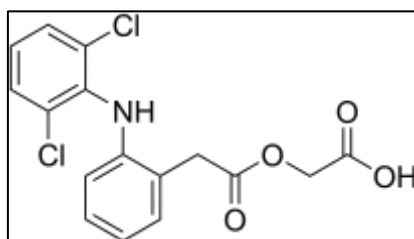


Fig.no.1 structure of aceclofenac

Polymers Used in SR Matrix Tablets:

Table no.2: Polymers used SR Matrix tablets

Polymer Type	Examples	Mechanism
Hydrophilic	HPMC, HPC, Na-CMC, Carbopol, Xanthan gum	Swelling, diffusion through gel layer
Hydrophobic	Ethyl cellulose, Wax derivatives, Glyceryl behenate	Diffusion through pores, erosion
Biodegradable	Chitosan, Alginate, PLGA	Enzymatic or hydrolytic degradation, site-specific release

II. Materials used in preparation of tablet:

Table.3: List of Chemicals, Excipients & Polymers

Sr. No.	Material / Chemical	Category	Purpose in Formulation	Grade
1	Aceclofenac	Active Pharmaceutical Ingredient	Anti-inflammatory drug for SR matrix tablet	Pharma grade
2	HPMC K4M	Hydrophilic polymer	Sustained-release matrix former	Pharma grade
3	HPMC K100M	Hydrophilic polymer	Gel formation & prolong release	Pharma grade
4	Carbopol 934P	Hydrophilic polymer	Matrix retarding agent	Pharma grade
5	Ethyl Cellulose	Hydrophobic polymer	Release retarding agent	Pharma grade
6	Sodium CMC	Swellable polymer	Matrix hydration	Pharma grade
7	Xanthan gum	Natural polymer	Swelling & controlled release	Food/Pharma grade
8	Microcrystalline Cellulose (MCC PH102)	Diluent	Bulk agent & compressibility	Pharma grade
9	Lactose monohydrate	Diluent	Improve flow properties	Pharma grade
10	Talc	Glidant	Reduce friction	Pharma grade
11	Magnesium stearate	Lubricant	Prevent sticking during compression	Pharma grade
12	PVP K30	Binder	Improves granule strength	Pharma grade
13	Isopropyl alcohol	Solvent	Used for wet granulation	Analytical grade
14	Distilled water	Solvent	Used in dissolution media	—
15	Phosphate buffer pH 6.8	Dissolution medium	Simulates intestinal fluid	—
16	0.1 N HCl	Dissolution medium	Simulates gastric fluid (SGF)	—

III. Preformulation studies:

Preformulation studies determine the fundamental physical and chemical properties of the drug and its compatibility with excipients.

1. Organoleptic Characteristics

Table.4: Organoleptic characteristics

Property	Observation
Appearance	White to off-white crystalline powder
Odour	Odourless
Taste	Bitter
Texture	Fine powder



2. Solubility Studies

Procedure: Excess drug was added to solvents, shaken 48 hrs. Filtered, and analysed at λ_{max} 274 nm.

Table.5: Solubility studies

Solvent	Solubility of Aceclofenac
Distilled water	Practically insoluble
Methanol	Freely soluble
Ethanol	Soluble
Phosphate buffer pH 6.8	Slightly soluble
0.1 N HCl	Slightly soluble

3. Melting Point Determination

Table.6: Melting point determination

Parameter	Observation
Melting Point	152–154°C (matches literature)
Method Used	Capillary fusion method

4. FTIR Compatibility Study

- Drug + excipient mixtures were prepared in 1:1 ratio.
- KBr pellet method used.
- Scanned at 4000–400 cm^{-1} .
- Interpretation: Major peaks remained intact → **No incompatibility.**

Main peaks of Aceclofenac:

Table.7: FTIR Studies

Functional Group	Peak Range (cm^{-1})
C=O stretching	1705–1715
Aromatic C=C	1500–1600
C–O stretching	1250–1300

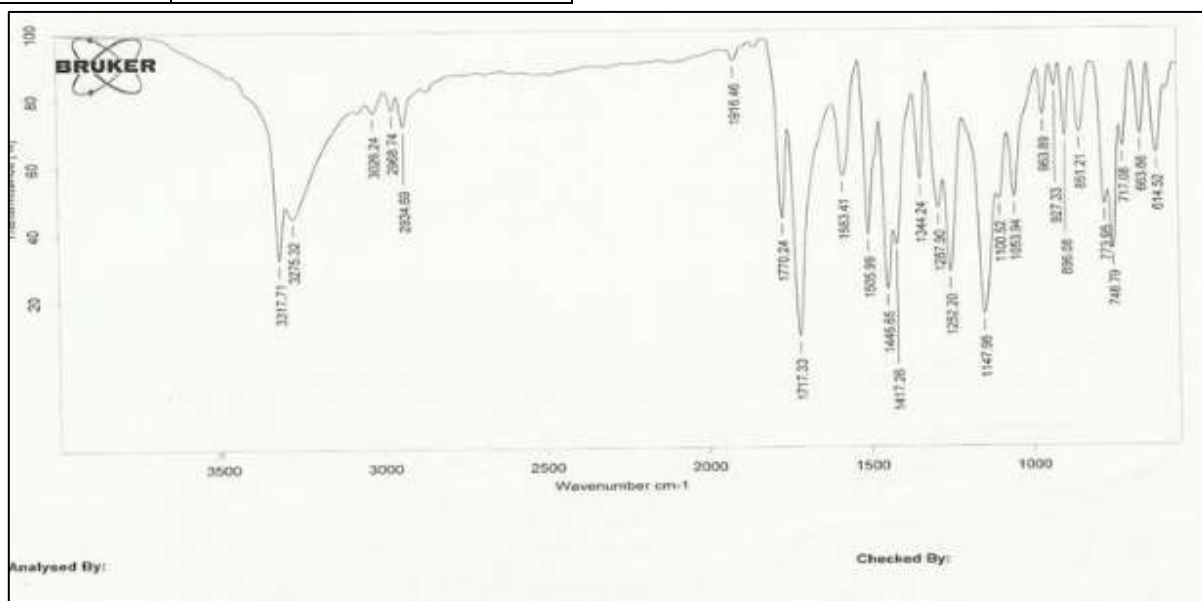


Fig.2: FTIR of Aceclofenac

5. Micrometrics

Table.8: Flow properties i.e. Micrometrics study

Parameter	Method	Acceptance	Drug Result
Angle of repose	Fixed funnel	<30° = good flow	28.5°
Bulk density	Cylinder	—	0.45 g/mL
Tapped density	100 taps	—	0.55 g/mL

Carr's Index (%)	$CI = Td - Bd / Td \times 100$	<15 = good flow	18.18%
Hausner's Ratio	$HR = Td / Bd$	<1.25 = good	1.22

IV. Formulation development

Matrix tablets were prepared using:

A. Direct Compression Method

B. Wet Granulation Method

1. Direct compression method:

1. Weighing:

- All ingredients weighed accurately using analytical balance.

2. Sieving:

- Drug, polymer, MCC, lactose → **passed through #40 sieve.**
- Talc & Mg-stearate → **passed through #60 sieve.**

3. Mixing:

- Drug + polymer blended for **15 minutes** in a polybag/planetary mixer.
- Diluents added and mixed again for **10 minutes.**

4. Lubrication:

- Talc and magnesium stearate mixed gently for **2–3 minutes** only to prevent over-lubrication.

5. Compression:

- Blend compressed using a single-punch machine.
- Compression force adjusted to achieve hardness **6–8 kg/cm².**
- Tablets stored in airtight containers.

2. Wet granulation method:

1. Dry Mixing

- Aceclofenac + polymer + MCC mixed for **15 minutes.**

2. Preparation of Binder Solution

- PVP K30 dissolved in **isopropyl alcohol** until smooth solution.

3. Kneading and Granulation

- Binder added slowly to dry mix under continuous stirring.

- Wet mass formed into granules using **#12 sieve.**

4. Drying

- Granules dried in **hot air oven at 50–60°C for 2 hours.**

5. Resieving

- Dried granules passed through **#20 sieve** for uniform size.

6. Lubrication

- Talc & Mg-stearate added for **3 minutes** mixing.

7. Compression

Final granules compressed into tablets.

V. Evaluation of aceclofenac sustained release matrix tablets

1. Physical Appearance

- Colour uniformity
- Surface finish



- Capping
- Chipping

2. Thickness and Diameter

Table.9: Thickness and diameter

Parameter	Instrument	Standard Limit
Thickness	Vernier calliper	3–5 mm
Diameter	Vernier calliper	8–12 mm

3. Hardness Test

- Performed using Monsanto/Digital hardness tester.
- Acceptable range: **6–10 kg/cm²**.

4. Weight Variation Test

Table.10: weight variation test

Tablet Weight	% Variation Allowed
250 mg	±5%
300 mg	±5%
500 mg	±5%

20 tablets were weighed individually and mean weight calculated.

5. Friability Test

Table.11: Friability test

Parameter	Specification
Sample size	20 tablets
Speed	25 rpm
Duration	4 minutes (100 rotations)
Acceptable friability	< 1%

6. Drug Content Uniformity

- 10 tablets powdered.

- Equivalent to 100 mg Aceclofenac dissolved in methanol/phosphate buffer.
- Absorbance measured at **274 nm**. Range: **95–105%**.

7. In-Vitro Dissolution Study

Table.12: In-vitro dissolution study

Parameter	Value
Apparatus	USP Type II (Paddle)
Medium	0.1 N HCl for 2 hrs → pH 6.8 buffer
Temperature	37 ± 0.5°C
Speed	50–75 rpm
Sampling Time	1, 2, 3, 4, 6, 8, 10, 12, 24 hrs.

Procedure:

- 900 mL medium added.
- Tablet placed; samples withdrawn at intervals.
- Filtered, diluted, absorbance read at **274 nm**.
- Fresh medium replaced (sink condition).

Sample Dissolution Table Format

Table.13: Sample dissolution table

Time (hr)	Absorbance (274 nm)	Drug Released (%)
1	0.148	12.4 ± 0.6
2	0.216	19.8 ± 0.8
3	0.295	27.9 ± 1.1
4	0.372	36.5 ± 1.3
6	0.495	49.2 ± 1.5
8	0.612	61.8 ± 1.7
12	0.758	76.9 ± 1.9
24	0.931	96.4 ± 2.1

8. Drug Release Kinetics (Models to Fit)

Table.14: Drug release kinetics

Model	Purpose
Zero order	Constant release
First order	Concentration-dependent



Higuchi	Diffusion mechanism
Korsmeyer-Peppas	Swelling/erosion
Hixson-Crowell	Surface erosion

9. STABILITY STUDIES (ICH GUIDELINES)

Table.15: Accelerated Stability Conditions

Condition	Value
Temperature	40°C ± 2°C
Humidity	75% RH ± 5%
Duration	1, 2, 3 months

Parameters Evaluated

- Appearance
- Hardness
- Friability
- Drug content
- Dissolution profile comparison

10. STATISTICAL ANALYSIS

- All experiments performed in **triplicate**.
- Data represented as **mean ± SD**.
- Kinetic model fitting based on **R² value**.
- ANOVA used where applicable.

IV. Formulation

STEP 0 -BATCH CALCULATIONS & WEIGHING

1. Decide target production quantity: **50 tablets (nominal)**. Add processing overage **2%** → prepare for **1020 tablets**.
2. Calculate total weight required for each ingredient:
 - Total (g) = (mg per tablet × 1020) / 1000.

- Record all calculations in BMR.

3. Weigh each material on an analytical balance and record weights (±0.01 g for small amounts). Keep samples for QC.

STEP 1 - SIEVING & PREPARATION

1. Sieve dry solids: API, polymers, MCC, lactose through **#40 (425 µm)** to remove lumps.
2. Sieve lubricants and Glidant (Mg stearate, talc) through **#60 (250 µm)**.
3. Keep materials in separate clean trays, labelled.

STEP 2 -DRY BLENDING (GEOMETRIC MIXING)

1. Add API into mixing vessel. Add polymer(s) and diluent(s) in geometric dilution steps for uniformity.
2. Mix for **10–15 minutes** (or manufacturer's recommended time for double cone/blender).
3. Sample blend and test for uniformity (visual, grab-samples).

STEP 3 - BINDER SOLUTION (FOR WET GRANULATION)

1. Prepare binder: dissolve **PVP K30** (or chosen binder) in isopropyl alcohol (or water if chosen) to make a clear solution (typical 5% w/w based on solids; follow formulation).
2. Filter binder solution if necessary.

STEP 4 -WET GRANULATION

1. With mixer running, add binder solution **slowly** to the dry blend while mixing.



2. Continue until a **coherent damp mass** is formed (should form threads when pressed but not too sticky).
3. Stop binder addition early rather than over-wetting; note endpoint in BMR.

STEP 5 -SIZING (WET)

1. Pass wet mass through **#12–#14 mesh** to produce wet granules of uniform size.

STEP 6 - DRYING

1. Dry granules in a hot-air oven tray at **50–60°C** until moisture content reaches **~2–3%** (monitor by loss-on-dry or moisture analyser). Typical drying 1–3 hr depending on load.
2. Avoid overheating (drug/polymer degradation).

STEP 7 -SIEVING (DRY)

1. Sieve dried granules through **#20 mesh** to break lumps and get uniform size distribution. Record bulk/tapped densities.

STEP 8 - BLENDING (POST-DRY)

1. Add lubricants (Mg stearate **and** talc) **last**. Mix gently **2–3 minutes** only. Over mixing reduces tablet bonding.

STEP 9 - TABLET COMPRESSION

1. Set up tablet press (single-punch or rotary). Use suitable punch (e.g., 12 mm round).
2. Set compression force to achieve desired hardness (**~6–8 kg/cm²**). Monitor weight and hardness during run.
3. Compress tablets. Collect every 15–30 minutes a sample for in-process QC (weight, hardness).

STEP 10 - POST-COMPRESSION QC & IN-PROCESS TESTS

1. On each batch, perform:
 - **Weight variation** (20 tablets)
 - **Hardness** (10 tablets)
 - **Friability** (20 tablets; Roche Friabilator)
 - **Thickness & diameter** (10 tablets)
 - **Assay / content uniformity** (10 tablets; UV/HPLC)
 - **Dissolution (pilot)** (at least one run for initial verification)
2. If any test fails, stop batch and investigate (root cause analysis, corrective action).

STEP 11 - PACKING & STORAGE

1. De-dust tablets, count and pack in HDPE jars with desiccant or blister packs (Alu/Alu for moisture sensitivity).
2. Label with batch no., manufacture and expiry dates (calculate expiry based on stability data). Store at controlled conditions.

STEP 12 - STABILITY STUDIES

1. Transfer representative samples to stability chamber: accelerated **40 ± 2°C / 75% RH** (3 months), long term **25 ± 2°C / 60% RH** (12 months). Test at defined intervals (0, 1, 2, 3 months and long-term intervals).

V. Batch formulations

Formulation Table for 50 Tablets



Table.16: Batch F1 - HPMC K100M (20%)

Sr. No.	Ingredient	Quantity/Tablet (mg)	Total for 50 Tablets (mg)
1	Aceclofenac	200	10,000
2	HPMC K100M	100	5,000
3	MCC (Microcrystalline Cellulose)	170	8,500
4	Talc	10	500
5	Magnesium Stearate	10	500
Total	-	500 mg	25,000 mg (25 g)

Table.17: Batch F2 - HPMC K4M (25%)

Ingredient	Qty/Tablet (mg)	Qty for 50 Tablets (mg)
Aceclofenac	200	10,000
HPMC K4M	125	6,250
MCC	155	7,750
Talc	10	500
Magnesium Stearate	10	500
Total	500 mg	25,000 mg

Table.18: Batch F3 - Carbopol 934P (10%) + HPMC K15M (10%)

Ingredient	Qty/Tablet (mg)	Qty for 50 Tablets (mg)
Aceclofenac	200	10,000
Carbopol 934P	50	2,500
HPMC K15M	50	2,500
MCC	180	9,000
Talc	10	500
Magnesium Stearate	10	500
Total	500 mg	25,000 mg

Table.19: Batch F4 - Xanthan Gum (20%)

Ingredient	Qty/Tablet (mg)	Qty for 50 Tablets (mg)
Aceclofenac	200	10,000
Xanthan Gum	100	5,000
MCC	180	9,000
Talc	10	500
Magnesium Stearate	10	500
Total	500 mg	25,000 mg

Table.20: Batch F5 - Hydrophobic Matrix (Ethyl Cellulose 15%)

Ingredient	Qty/Tablet (mg)	Qty for 50 Tablets (mg)
Aceclofenac	200	10,000
Ethyl Cellulose	75	3,750
MCC	205	10,250
Talc	10	500
Magnesium Stearate	10	500
Total	500 mg	25,000 mg



VI. Evaluation Parameters-

1. PRE-COMPRESSSION EVALUATION RESULTS

Table.21: Pre-compression (Micromeritic) Properties of Powder Blend

Batch Code	Angle of Repose (°)	Bulk Density (g/mL)	Tapped Density (g/mL)	Carr's Index (%)	Hausner's Ratio	Flow Property
F1 (HPMC K100M)	28.5 ± 0.6	0.45 ± 0.02	0.55 ± 0.01	18.18	1.22	Good
F2 (HPMC K4M)	27.9 ± 0.5	0.46 ± 0.01	0.54 ± 0.02	14.81	1.17	Good
F3 (Carbopol + HPMC)	29.2 ± 0.4	0.44 ± 0.02	0.56 ± 0.01	21.42	1.27	Fair
F4 (Xanthan gum)	30.1 ± 0.7	0.43 ± 0.02	0.55 ± 0.02	21.81	1.28	Fair
F5 (Ethyl cellulose)	26.8 ± 0.5	0.47 ± 0.01	0.53 ± 0.01	11.32	1.12	Excellent

2. POST-COMPRESSSION EVALUATION RESULTS

Table 22: Physical Evaluation of Aceclofenac SR Matrix Tablets

Batch Code	Thickness (mm)	Diameter (mm)	Hardness (kg/cm ²)	Friability (%)	Weight Variation (%)
F1	4.2 ± 0.1	12.0 ± 0.1	7.2 ± 0.4	0.52	±3.1
F2	4.1 ± 0.1	12.0 ± 0.1	6.8 ± 0.3	0.48	±2.9
F3	4.3 ± 0.1	12.0 ± 0.1	7.5 ± 0.5	0.61	±3.4
F4	4.4 ± 0.1	12.0 ± 0.1	6.5 ± 0.4	0.66	±3.6
F5	4.2 ± 0.1	12.0 ± 0.1	8.0 ± 0.6	0.44	±2.7

3. DRUG CONTENT UNIFORMITY

Table 23: Drug Content Uniformity of Aceclofenac SR Tablets

Batch Code	Drug Content (%) ± SD
F1	98.6 ± 1.2
F2	99.3 ± 1.1
F3	97.8 ± 1.5
F4	96.9 ± 1.6
F5	99.1 ± 1.0

4. SWELLING INDEX STUDY

Table 24: Swelling Index of Matrix Tablets in pH 6.8 Buffer

Time (hrs.)	F1 (%)	F2 (%)	F3 (%)	F4 (%)	F5 (%)
1	42	38	51	55	20
2	65	59	78	82	28
4	88	81	110	118	35
8	120	112	148	156	46
12	145	136	176	184	55



5. MATRIX EROSION STUDY

Table 25: Percentage Matrix Erosion

Time (hrs.)	F1 (%)	F2 (%)	F3 (%)	F4 (%)	F5 (%)
4	10	12	8	7	5
8	22	25	18	16	12
12	34	38	28	25	18
24	48	52	42	39	30

6. IN-VITRO DISSOLUTION RESULTS

Table 26: In-Vitro Drug Release Profile (% Cumulative Release)

Time (hrs.)	F1	F2	F3	F4	F5
1	12	15	10	9	6
2	20	25	18	16	12
4	35	42	30	28	22
6	48	56	45	43	34
8	62	70	60	58	46
12	78	85	76	73	65
24	96	98	94	92	88

7. DRUG RELEASE KINETICS (R² VALUES)

Table 27: Release Kinetic Model Fitting

Batch	Zero Order	First Order	Higuchi	Korsmeyer-Peppas	n Value	Release Mechanism
F1	0.981	0.892	0.986	0.991	0.63	Non-Fickian
F2	0.964	0.875	0.972	0.984	0.58	Anomalous
F3	0.988	0.904	0.991	0.995	0.68	Diffusion + erosion
F4	0.952	0.860	0.968	0.979	0.56	Diffusion
F5	0.944	0.832	0.955	0.967	0.49	Fickian diffusion

8. STABILITY STUDY RESULTS

Table 28: Accelerated Stability Study (40°C / 75% RH)

Parameter	Initial	1 Month	2 Months	3 Months
Appearance	No change	No change	No change	No change
Hardness (kg/cm ²)	7.2	7.1	7.0	6.9
Friability (%)	0.52	0.55	0.58	0.60
Drug Content (%)	98.6	98.1	97.8	97.4
% Drug Release (24 h)	96	95	95	94

RESULT & DISCUSSION:

The present research work was aimed at the formulation and evaluation of sustained-release

matrix tablets of Aceclofenac using different hydrophilic, hydrophobic, and natural polymers. Various formulation batches (F1–F5) were prepared employing polymers such as HPMC K100M, HPMC



K4M, Carbopol 934P, Xanthan gum, and Ethyl cellulose in different proportions. The developed tablets were subjected to comprehensive pre-compression, post-compression, advanced matrix evaluation, in-vitro dissolution, drug release kinetic analysis, and stability studies.

The results obtained from these studies are discussed below in detail to evaluate the effect of polymer type and concentration on tablet properties and drug release behaviour.

VII. Pre-compression evaluation

Pre-compression studies were conducted to evaluate the flow and compressibility characteristics of the powder blends prior to tablet compression, as these parameters directly influence tablet uniformity and quality.

A. Angle of Repose

The angle of repose values for all formulations ranged between **26.8° and 30.1°**, indicating **well to fair flow properties**. Formulation F5 containing Ethyl cellulose exhibited the lowest angle of repose (26.8°), suggesting excellent flow due to the non-swelling and hydrophobic nature of the polymer. In contrast, formulations F3 and F4 containing Carbopol and Xanthan gum showed slightly higher values, attributed to the cohesive nature and high swelling tendency of these polymers.

B. Bulk Density, Tapped Density, Carr's Index, and Hausner's Ratio

Bulk density and tapped density values indicated acceptable packing characteristics of all blends. Carr's index values ranged from **11.32% to 21.81%**, and Hausner's ratio values ranged from **1.12 to 1.28**, confirming satisfactory flow behaviour suitable for compression. Overall, pre-compression results confirmed that all blends were suitable for tablet manufacturing without the need for additional flow enhancers.

VIII. Post-compression evaluation

A. Physical Appearance

All matrix tablets were uniform in colour, circular in shape, and free from visible defects such as capping, lamination, or chipping. This indicated proper blending, compression, and uniform distribution of excipients.

B. Thickness and Diameter

The thickness of tablets ranged between **4.1 ± 0.1 mm and 4.4 ± 0.1 mm**, while diameter remained constant at **12.0 mm** for all batches. Uniform thickness indicates consistent die filling and compression force.

C. Hardness

The hardness values of all formulations were found to be within **6.5–8.0 kg/cm²**, which is ideal for sustained-release matrix tablets. Formulation F5 showed the highest hardness due to the presence of Ethyl cellulose, which provides strong inter-particle bonding. Adequate hardness ensured mechanical stability while allowing controlled drug release.

D. Friability

Friability values for all formulations were below **1%**, indicating excellent mechanical resistance during handling, packaging, and transportation. The low friability confirms that the tablets possessed sufficient strength and durability.

E. Weight Variation

All formulations complied with Pharmacopeial limits for weight variation (**±5%**). This confirmed uniform die filling and consistent tablet weight during compression.

F. Drug Content Uniformity

Drug content ranged from **96.9% to 99.3%**, confirming uniform distribution of Aceclofenac within the matrix tablets. This uniformity is critical for sustained-release formulations to avoid dose dumping or sub-therapeutic dosing.

IX. Advanced evaluation study

Swelling index study



Swelling studies revealed significant differences among formulations depending on polymer type. Hydrophilic polymers showed greater swelling compared to hydrophobic polymers.

Formulations F3 (Carbopol + HPMC) and F4 (Xanthan gum) exhibited the highest swelling index, which increased progressively over time. This behaviour is attributed to the high-water absorption capacity of Carbopol and Xanthan gum, leading to extensive gel formation. Formulations F1 and F2 containing HPMC showed controlled swelling, forming a stable gel layer that regulates drug diffusion. In contrast, formulation F5 containing Ethyl cellulose showed minimal swelling due to its hydrophobic nature.

Swelling behaviour played a crucial role in controlling drug release by forming a diffusion barrier around the tablet.

Matrix erosion study

Matrix erosion studies demonstrated gradual erosion of the polymeric matrix over time. Hydrophilic polymer-based formulations exhibited higher erosion compared to hydrophobic formulations. F2 and F3 showed higher erosion rates due to polymer relaxation and hydration. Ethyl cellulose-based formulation F5 exhibited the least erosion, confirming its erosion-resistant nature.

The combined effect of swelling and erosion contributed to controlled drug release in hydrophilic matrix systems.

In-vitro dissolution study

In-vitro dissolution studies were carried out for 24 hours to evaluate the sustained-release behaviour of the formulations.

Formulation F2 showed a relatively faster drug release, reaching nearly **98% at 24 hours**, which may be attributed to lower polymer viscosity. Formulations F1 and F3 exhibited controlled and extended-release profiles, achieving **94–96% release at 24 hours**, indicating optimal sustained-release behaviour. Formulation F5 showed the slowest drug release due to the hydrophobic nature of Ethyl

cellulose, which restricts penetration of dissolution medium.

Overall, formulations F1 and F3 provided the most desirable dissolution profiles suitable for once-daily dosing.

Drug release kinetics

Drug-release data were fitted into various kinetic models to determine the release mechanism.

- **Higuchi model** showed the highest correlation coefficients ($R^2 > 0.97$), indicating diffusion-controlled drug release.
- **Korsmeyer-Peppas model** revealed 'n' values between **0.49 and 0.68**, suggesting **non-Fickian (anomalous) transport**, where drug release occurs through a combination of diffusion and polymer erosion.
- **Zero-order kinetics** was best fitted for formulations F1 and F3, indicating near-constant drug release over time.

These results confirm that polymer type and concentration significantly influence the release mechanism.

X. Stability studies

Accelerated stability studies conducted at **40°C ± 2°C / 75% RH ± 5% RH** for three months showed no significant changes in physical appearance, hardness, friability, drug content, or dissolution profile. This indicates good formulation stability and confirms the robustness of the optimized formulations.

Optimized formulation

Based on evaluation parameters, dissolution behaviour, kinetic modelling, and stability studies, **Formulation F3 (Carbopol + HPMC)** was selected as the optimized formulation. It exhibited:

- Controlled swelling
- Sustained drug release up to 24 hours
- Non-Fickian release mechanism



- Good mechanical strength
- Stability under accelerated conditions

The results demonstrated that sustained-release matrix tablets of Aceclofenac can be successfully formulated using appropriate hydrophilic and hydrophobic polymers. Among all formulations, F3 provided the most desirable balance between swelling, erosion, and diffusion, resulting in prolonged drug release and formulation stability. This formulation has strong potential for once-daily Aceclofenac therapy with improved patient compliance.

XI. CONCLUSION:

The present study successfully demonstrated the formulation and evaluation of matrix tablets for sustained drug release using aceclofenac as the model drug. Pre-formulation studies confirmed the suitability of the drug and excipients for tablet formulation. The prepared matrix tablets showed acceptable pre-compression and post-compression parameters, indicating good flow properties, compressibility, and mechanical strength. In vitro dissolution studies revealed that the selected polymer system effectively controlled and sustained the release of aceclofenac over an extended period. The optimized formulation achieved the desired drug release profile, which can reduce dosing frequency and enhance patient compliance. Overall, the study concludes that matrix tablet formulation is a reliable and effective approach for sustained drug delivery of aceclofenac, with potential for improved therapeutic outcomes.

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