International Journal of Technology and Applied Science (IJTAS)
E-ISSN: 2230-9004 ● Website: www.ijtas.com ● Email: editor@ijtas.com

Formulation and Evaluation of Aceclofenac Dispersible Tablet

Sumeet Pawar[1], Bhagyashali Baheti[2]

[1]Student, [2]Assistant Professor
[1,2]Department of Pharmacy, Sayali Charitable Trust's College of Pharmacy Chhatrapati Sambhajinagar

Abstract:
Aceclofenac dispersible tablets were formulated and evaluated to improve patient compliance and provide rapid drug release for the treatment of pain and inflammation. The present study aimed to prepare dispersible tablets of aceclofenac by the direct compression method using suitable superdisintegrants and excipients. Different formulations were developed using ingredients such as microcrystalline cellulose, sodium starch glycolate, mannitol, talc, and magnesium stearate in varying concentrations to achieve rapid disintegration and acceptable tablet characteristics. The prepared tablets were evaluated for pre-compression parameters including angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio to determine flow properties of the powder blend. Post-compression evaluation tests such as hardness, thickness, friability, weight variation, drug content uniformity, wetting time, dispersion time, disintegration time, and in-vitro dissolution studies were also carried out according to pharmacopeial standards. The results showed that all formulations possessed satisfactory physical properties with good mechanical strength and acceptable friability. Among the formulations, the optimized batch exhibited rapid disintegration, improved drug release, and good stability. The in-vitro dissolution study demonstrated faster release of aceclofenac from dispersible tablets compared to conventional tablets, indicating enhanced bioavailability and quick therapeutic action. The study concluded that aceclofenac dispersible tablets can be successfully prepared by direct compression using suitable superdisintegrants. The formulation provides better patient convenience, faster onset of action, and improved compliance, especially for pediatric and geriatric patients who experience difficulty in swallowing conventional tablets.

Keyword: fast dispersible tablet, aceclofenac, Magnesium stearate, starch, disintegration time, dissolution.

INTRODUCTION

Aceclofenac is a widely used non-steroidal anti-inflammatory drug (NSAID) that possesses analgesic, anti-inflammatory, and antipyretic properties. It is commonly prescribed for the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, musculoskeletal disorders, and other painful inflammatory conditions. Aceclofenac works by inhibiting the synthesis of prostaglandins through the blockage of cyclooxygenase (COX) enzymes, thereby reducing pain and inflammation.Oral administration is the most preferred route for drug delivery due to its convenience, ease of administration, and patient acceptance. However, many patients, especially pediatric and geriatric patients, experience difficulty in swallowing conventional tablets and capsules. To overcome this problem, dispersible tablets have been developed as an advanced oral dosage form that rapidly disintegrates or disperses in water before administration, providing ease of swallowing and faster drug action. Dispersible tablets are solid dosage forms designed to disintegrate quickly in water to form a uniform dispersion. These tablets offer several advantages such as improved patient compliance, accurate dosing, rapid onset of therapeutic action, enhanced dissolution rate, and better bioavailability. The formulation of dispersible tablets generally involves the use of superdisintegrants that facilitate quick breakup of the tablet upon contact with water. The present project focuses on the formulation and evaluation of aceclofenac dispersible tablets prepared by the direct

compression method. Direct compression is a simple, economical, and widely used manufacturing technique that requires fewer processing steps and provides good stability of the drug. Various excipients such as diluents, binders, lubricants, sweetening agents, and superdisintegrants are incorporated into the formulation to achieve desired tablet properties.The formulated aceclofenac dispersible tablets are evaluated for both pre-compression and post-compression parameters including flow properties, hardness, friability, weight variation, drug content, disintegration time, wetting time, and in-vitro dissolution studies. The objective of the study is to develop a stable, effective, and rapidly dispersing tablet formulation that improves patient convenience and therapeutic effectiveness. Thus, aceclofenac dispersible tablets represent a promising dosage form for achieving faster drug release and better patient acceptability compared to conventional oral tablets.

OBJECTIVE

- To formulate and develop aceclofenac dispersible tablets by using the direct compression method.
- To enhance the disintegration and dissolution rate of aceclofenac for faster onset of therapeutic action.
- To improve patient compliance, especially for pediatric and geriatric patients who have difficulty swallowing conventional tablets.
- To study the effect of different superdisintegrants on tablet disintegration and drug release.
- To evaluate the post-compression parameters including hardness, thickness, friability, weight variation, wetting time, dispersion time, disintegration time, and drug content uniformity.
- To perform in-vitro dissolution studies for determining the drug release profile of the prepared formulations.
- To compare different formulations and identify the optimized formulation with the best dispersibility and drug release characteristics.
- To prepare a stable and effective dispersible tablet dosage form with acceptable physical and pharmaceutical properties.
- To improve the bioavailability and therapeutic effectiveness of aceclofenac through rapid dispersion and dissolution.

PREFORMULATION STUDY

Preformulation studies are the first step in the development of a pharmaceutical dosage form. These studies are carried out to obtain information about the physical, chemical, and mechanical properties of the drug substance and excipients. The data obtained help in selecting suitable excipients, formulation methods, and processing conditions for the preparation of stable and effective dispersible tablets

DRUG PROFILE -ACECLOFENAC

Table:1 PHARMACOLOGICAL AND PHYSIOLOGICAL PROFILE OF ACECLOFENAC

Property	Description
IUPAC	2-[2-[2(2,6-Dicloroanilino)phenyl]acetyl]oxyacetic acid
Molecular formula	C16H13Cl2NO4
Appearance	OFF WHITE TO LIGHT TAN CRYSTALLINE POWDER
Solubility	SLIGHTLY SOLUBLE IN WATER:SOLUBLE IN DMSO
Pka	2.6
Melting point	149-153
BCS classification	BCS CLASS ll(Low solubility ,high permeability)
Protein binding	Approximately 90%
Half-life	Approximately 4
Dose	Aceclofenac tablet:usually 100 mg twice daily in adults

Mechanism	NSAID:Inhibit cyclo-oxygenase (cox-1 and mainly cox-2)enzyme and decrease prostaglandin synthesis, reducing pain and inflammation
Indication	Osteoarthritis, rheumatoid arthritis, spondylitis, pain and inflammation
Storage	Store below 30 C in a cool, dry place away from moisture and light

TABLE :2 FORMULA USED IN THE PREPRATION OF TABLET

SR.NO	Ingredients(mg)	F1	F2	F3	F4	F5
1	Aceclofenac	100	100	100	100	100
2	Lactose	120	125	110	120	120
3	Sodium saccharin	5	5	10	10	5
4	MCC	10	5	10	5	10
5	Magnesium stearate	5	5	5	5	5
6	Sodium starch glycolate	5	5	5	5	5
7	Talc powder	5	5	10	5	5
8	Total	250	250	250	250	250

DIRECT COMPRESSION METHOD

TABLE :2 FORMULA COMPOSITION OF ACECLOFENAC TABLET (Per tablet)

Sr.no	Ingredients	Amount in mg	Role
1	Aceclofenac	100mg	API
2	Lactose	120mg	Diluent
3	Sodium saccharin	5mg	Sweetener
4	MCC	10mg	Binder
5	Magnesium stearate	5mg	Lubricant
6	Sodium Starch glycolate	5mg	Disintegrant
7	Talc powder	5mg	Glidant
8	Total	250mg	

MATERIAL

1.Aceclofenac:

Aceclofenac acts as the main active drug used for relieving pain, inflammation, and swelling associated with arthritis and musculoskeletal disorders.

2.Lactose:

Lactose is used as a diluent/ filler to provide adequate tablet weight and improve compressibility

3.Sodium saccharin:

Sodium saccharin enhances taste and makes the dispersible tablet more acceptable to patients.

4.Microcrystalline cellulose (MCC):

Microcrystalline cellulose acts as a binder to maintain tablet integrity and assists in quick disintegration.

5.Magnesium stearate :

Magnesium stearate functions as a lubricant and prevents sticking during tablet compression.

6.Sodium starch glycolate

It acts as a superdisintegrant that allows the tablet to disperse rapidly in water.

7.Talc:
Talc improves flowability of powder blend and helps in smooth manufacturing process.
Apparatus Required
- *Morter and pestle
- *Weighing balance
- *Sieve no.60
- *Tablet punching machine
- *Spatula
- *Measuring cylinder

PROCEUDRE
STEP: 1 Weighing
All ingredients required for formulation are accurately weighed using a digital weighing balance according to the formula.
STEP: 2 Sieving
*Aceclofenac and all excipients are passed through sieve No. 60 separately.
* Sieving removes lumps and provides uniform particle size for better mixing and compression.
STEP: 3 Mixing of Drug and Excipients
*Aceclofenac is transferred into a clean morter.
*MCC, mannitol, sodium starch glycolate, and aspartame are added.
*The powders are mixed thoroughly for 10-15 minutes to obtain a uniform blend.
STEP: 4 Addition of Lubricants
*Talc and magnesium stearate are added at the end.
*The mixture is avoided because it may affect tablet hardness and disintegration.
STEP: 5 Compression
*The final powder blend is transferred into the hopper of the tablet compression machine.
*Tablets are compressed using suitable punches and dies.
*Required hardness and weight are maintained during compression.

ADVANTAGES OF DIRECT COMPRESSION METHOD
- Simple and economical method
- Less processing steps
- Require less equipment
- Suitable for heat sensitive drugs
- Better stability of formulation
- Fast manufacturing process

DISADVANTAGES
- REQUIRE GOOD FLOW PROPERTIES
- SEGREGATION MAY OCCUR
- NOT SUITABLE FOR POORLY COMPRESSIBLE DRUGS
- Content Uniformity Problems
- Limited Drug Selection
- Poor Mechanical Strength

PRECAUTIONS
- All powders should be dry
- Proper mixing should be added at the end

- Lubrication should be added at the end
- Overcompression should be avoided
- Tablets should be store in airtight containers

EVALUATION OF PREPARE TABLET

APPEARANCE

Tablet are check visually for

- Colour
- Shape
- Surface texture
- Cracks or defects

1 Shape and appearance: It is a round. The top surface has a convex (slightly curved outward) shape. The surface appears smooth and matte white.

2.Weight variation: Weigh 20 tablets individually using a calibrated analytical balance (sensitivity 0.1 mg). Calculate the average weight of all 20 tablets. Calculate the individual % deviation of each tablet from the average weight using the formula: **% Deviation = [(Individual weight − Average weight) / Average weight] × 100.**

Not more than 2 tablets should deviate beyond ±7.5 %. All the tablets are within the limit

TABLE:3 Weight variation results

Tablet	Avg wt (mg)	SD(+_mg)	Limit	Result
Formulated aceclofenac tablet	250.1	1.62	7.5%	PASS
Generic	250	1.41	7.5%	PASS
Branded	250.2	0.61	7.5%	PASS

3.HARDNESS TEST: Select tablets randomly from the batch. Place each tablet between the jaws of the Monsanto hardness tester with the diameter of the tablet perpendicular to the applied force. Apply force gradually until the tablet breaks. Note the force reading at the point of tablet fracture in kg/cm²

Table:4 hardness test result

parameter	Formulated aceclofenac tablet	Generic (kg/cm)	Branded (kg/cm)	Remark
Mean SD	4.12+0.18	6.98+0.21	7.84+0.16	-
Standard limit	3-5 (kg/cm)	4-8 (Kg/cm)	6-10	-
Result	PASS	PASS	PASS	ALL PASS

FIGURE 1: Monsanto hardness tester

3.Friability test: Weigh 10 whole tablets (pre-dusted) accurately and record initial weight (W_o). Place the tablets in the Roche friabilator drum. Operate at 25 rpm for 4 minutes (100 rotations). Remove tablets, remove any loose dust, and reweigh accurately (W). Calculate % friability using the formula above. The test passes if the % friability is not more than 1.0% and no tablet is cracked, cleaved, or broken

% Friability = [(Wi – Wf)/Wi] *100
Wi : Initial weight of Tablets , Wf : Final weight of Tablets after Tumbling

TABLE :5 Friability test results

Parameter	formulated	generic	Branded
No.of tablets taken	10	10	10
Initial weight wi (mg)	2500	2502.0	2501.0
Final weight w (mg)	2483	2491.5	2493.0
Weight lost (mg)	17.0	10.5	8.0
%friability	0.68%	0.42	0.32%
Pharmacological limit	NMT 1.0%	NMT 1.0%	NMT 1.0%
RESULT	PASS	PASS	PASS

FIGURE : 2 Roche friabilator

4.Disintegration time /test: The in-vitro disintegration test was performed by using a disintegration test apparatus. The test is carried out for a total of 6 tablets, and distilled water at 37°C ± 2°C was used as a disintegration medium. The time taken for the complete disintegration of the tablets was noted.

FIGURE :3 Disintegration apparatus

Table :6 Disintegration time result

parameter	formulated	Generic (min)	Branded(min)	Remark
Mean+SD	24.5+2.3 sec	5.2+0.4Min	4.8+0 Min	-
Standard limit	NMT 30 sec	NMT 15 min	NMT 30 Min	-
Pass	Pass	Pass	Pass	ALL PASS

5. Dissolution Rate Study: In vitro dissolution studies were performed for the tablets (n = 6) using USP dissolution apparatus II at 50 rpm, thermostatically maintained at a temperature of 37 ± 0.50C. Samples of dissolution fluid (1 ml) were withdrawn through a filter at different time intervals and assayed for Montelukast at 294 nm

FIGURE :4 dissolution apparatus

Table :7 Dissolution condition

APPARATUS	USP TYPE ll (paddle)
Dissolution medium	Phosphate buffer
Temperature	37+0.5 C
Paddle speed	50 rpm
Detection wavelenth	294 nm

Table :8 : In- Vitro Dissolution Data – Formulated aceclofenac tablet

TIME	MARKETED TABLET	GENERIC TABLET	ACECLOFENAC
5 MIN	12.458	10.326	18.214
10 MIN	28.764	24.518	36.742
15 MIN	41.935	43.127	52.684
30 MIN	59.842	68.395	72.158
45 MIN	76.214	81.547	88.436
60 MIN	84.693	87.925	96.214

RESULT

The present study was carried out to formulate and evaluate Aceclofenac dispersible tablets by using the direct compression method. The prepared tablets were evaluated for various pharmaceutical parameters such as appearance, weight variation, hardness, friability, disintegration time, and dissolution study. The results obtained from all evaluation tests indicated that the prepared formulation possessed satisfactory quality and complied with pharmacopeial standards.

The prepared Aceclofenac tablets showed a smooth surface, uniform colour, round shape, and acceptable appearance without any visible cracks or defects. This indicated proper blending and compression of the powder mixture during tablet manufacturing.

The weight variation test showed that the average weight of the formulated tablets was found to be 250.1 mg with a standard deviation of ±1.62 mg. All tablets were within the acceptable pharmacopeial limit of ±7.5%, indicating uniform distribution of drug and excipients in the formulation. Uniformity in tablet weight ensures dose accuracy and consistency of the product.

The hardness test was performed using a Monsanto hardness tester. The formulated Aceclofenac tablets showed a hardness value of 4.12 ± 0.18 kg/cm², which was within the acceptable range for dispersible tablets. Adequate hardness is essential to withstand mechanical stress during handling, packaging, and transportation while still allowing rapid disintegration.

The friability study revealed that the percentage friability of the formulated tablets was 0.68%, which was below the official limit of not more than 1.0%. This result confirmed that the prepared tablets possessed good mechanical strength and resistance to abrasion during handling and storage.

The disintegration test demonstrated that the prepared Aceclofenac dispersible tablets disintegrated rapidly within 24.5 ± 2.3 seconds, which satisfied the official requirement for dispersible tablets (not more than 30 seconds). The rapid disintegration was mainly due to the presence of superdisintegrants and hydrophilic excipients that promoted quick penetration of water into the tablet matrix.

CONCLUSION

From the present investigation, it can be concluded that Aceclofenac dispersible tablets were successfully prepared by the direct compression method using suitable excipients such as lactose, microcrystalline cellulose, starch, talc, magnesium stearate, and sodium saccharin. The direct compression technique proved to be a simple, cost-effective, and convenient method for the preparation of dispersible tablets.

The prepared tablets showed satisfactory physicochemical properties including acceptable appearance, uniform weight variation, sufficient hardness, low friability, rapid disintegration time, and excellent dissolution profile. The formulation demonstrated rapid tablet dispersion in aqueous medium and effective release of the drug, which can improve the onset of therapeutic action.

The disintegration time of the formulated tablet was found to be less than 30 seconds, indicating efficient performance of the superdisintegrating agents used in the formulation. The friability value below 1% confirmed adequate mechanical strength of the tablets, while the dissolution study indicated nearly complete drug release within 60 minutes.

Aceclofenac belongs to BCS Class II drug category, having low solubility and high permeability. Therefore, preparation of dispersible tablets significantly improved the dissolution behavior of the drug, which may enhance bioavailability and therapeutic effectiveness. The prepared formulation may also improve patient compliance, especially in pediatric, geriatric, and dysphagic patients who face difficulty swallowing conventional tablets.

Hence, it was concluded that the formulated Aceclofenac dispersible tablets prepared by direct compression possess good pharmaceutical properties and can be considered a promising dosage form for rapid drug release and effective pain management therapy.

REFERENCES:

1. Dooley M, Spencer CM, Dunn CJ. Aceclofenac: a reappraisal of its use in the management of pain and rheumatic disease. Drugs. 2001;61(9):1351–1378. doi:10.2165/00003495-200161090-00012
2. . Brogden RN, Wiseman LR. Aceclofenac. A review of its pharmacodynamic properties and therapeutic potential in the treatment of rheumatic disorders and in pain management. Drugs. 1996;52 (1):113–124. doi:10.2165/00003495-199652010-00008
3. LinC -W ,ChamT- M. Compression behavio randtensile strength of heat-treated polyethylene glycols. International journal of pharmaceutics. 1995; 118(2):169–79.
4. Martin TP, Hayes P, Collins DM. Tablet dispersion as an alternative to formulation of liquid dosage forms. Australian Journal of Hospital Pharmacy. 1993; 23(6):378–86.
5. Bhardwaj S,Jain V,JatR,MangalA ,JainS. Formulation and evaluation of fast dissolving tablet of aceclofenac. International journal of drug delivery. 2010; 2(1).
6. Sharma AJA.;Purohit ;JatavR.;SheoreyR.Formulation and evaluation of aceclofenac fast dissolving tablets. International Journal Of Pharmacy & Life Sciences. 2011; 4(2):681–6.
7. Mustapha ,IgwiloCI,SilvaBO.Influenceof Concentration of Modified Maize Starch on Compaction Characteristics and Mechanical Properties of Paracetamol Tablet Formulations. Medical Journal of Islamic World Academyof Sciences. 2013; 109(893):1–7.
8. MohammedB,IsahA,IbrahimM.Influenceofcompactionpressuresonmodifiedcassavastarchas a binder in paracetamol tablet formulations. Nigerian Journal of Pharmaceutical Sciences. 2009; 8(1):808.
9. Adetunji OA ,OdeniyaMA,Itiola OA.Compression,mechanicaland release properties of chloroquine phosphate tablets containing corn and trifoliate yam starches as binders. Tropical journal of pharmaceutical research. 2006; 5(2):589–96.