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Design of Modified Release Dosage Form For Arthritis

Rathod Arun Lahudas, Prof. Komal A. Dongare, Dr. Surwase K. P.
Aditya Institute of Pharmaceutical Sciences, Beed
Dr. Babasaheb Ambedkar Technological University, Lonere

Abstract: *Arthritis is a chronic inflammatory disorder characterized by pain, stiffness, swelling, and reduced mobility of joints. Long-term administration of anti-arthritic drugs is often associated with frequent dosing, fluctuating plasma drug concentration, gastrointestinal irritation, and poor patient compliance. Modified release drug delivery systems are designed to overcome these limitations by providing controlled and prolonged release of medication over an extended period of time. The present project focuses on the design and evaluation of a modified release dosage form for the treatment of arthritis using suitable polymers and pharmaceutical excipients. The aim of the study is to formulate a dosage form capable of maintaining therapeutic drug concentration for prolonged duration while reducing dosing frequency and minimizing adverse effects. Modified release tablets were prepared using different concentrations of hydrophilic and hydrophobic polymers through direct compression or wet granulation technique.*

The prepared formulations were evaluated for pre-compression parameters such as angle of repose, bulk density, tapped density, Carr's index, and Hausner ratio. Post-compression studies including hardness, thickness, friability, weight variation, drug content uniformity, swelling index, and in-vitro dissolution studies were carried out. The release kinetics of the drug were analyzed using different kinetic models such as zero order, first order, Higuchi, and Korsmeyer–Peppas models. The optimized formulation demonstrated sustained drug release over an extended period with acceptable physicochemical characteristics and stability. The study concludes that modified release dosage forms can significantly improve therapeutic efficacy and patient compliance in arthritis management.

Keywords: Arthritis, Modified Release Dosage Form, Sustained Release Tablets, Controlled Drug Delivery, Hydrophilic Polymer, In-vitro Dissolution, Release Kinetics, Matrix Tablet

I. INTRODUCTION

1.1 Overview of study

Arthritis is a chronic inflammatory disorder affecting joints and surrounding tissues. It is characterized by pain, swelling, stiffness, redness, and limitation of movement. Arthritis is considered one of the major causes of disability worldwide and affects people of all age groups, especially elderly individuals. Long-term inflammation may lead to destruction of cartilage, bone erosion, and permanent joint deformity[1].

Conventional dosage forms used in arthritis treatment require frequent administration because many anti-arthritic drugs possess short biological half-life and rapid elimination. Frequent dosing often leads to poor patient compliance, fluctuating plasma drug concentration, and increased side effects such as gastrointestinal irritation.

Modified release dosage forms are developed to overcome these drawbacks. These systems release the drug at a controlled rate for prolonged duration, thereby maintaining therapeutic concentration for an extended period of time. Modified release systems improve therapeutic efficacy, reduce dosing frequency, and enhance patient convenience.

Modified release drug delivery systems include sustained release, controlled release, delayed release, extended release, and pulsatile release formulations. Among these, sustained release matrix tablets are commonly used because of simple manufacturing process and effective control of drug release[2].

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The present project focuses on the design and evaluation of modified release dosage forms for arthritis using suitable polymers and excipients.

1.2 Arthritis

1.2.1 Definition

Arthritis is defined as inflammation of one or more joints resulting in pain, swelling, stiffness, and reduced mobility.

1.2.2 Causes of Arthritis

- Aging
- Autoimmune disorders
- Joint injury
- Obesity
- Genetic factors
- Infection
- Metabolic disorders

1.2.3 Symptoms of Arthritis

- Joint pain
- Swelling
- Redness
- Stiffness
- Reduced flexibility
- Fatigue
- Tenderness

1.2.4 Types of Arthritis

Osteoarthritis

Osteoarthritis is a degenerative joint disorder caused by wear and tear of cartilage. It commonly affects elderly individuals.

Rheumatoid Arthritis

Rheumatoid arthritis is an autoimmune disease characterized by chronic inflammation of joints[3].

Gouty Arthritis

Gout is caused by deposition of uric acid crystals in joints.

Psoriatic Arthritis

Psoriatic arthritis is associated with psoriasis and chronic immune dysfunction.

Septic Arthritis

Septic arthritis occurs due to bacterial or fungal infection of joints.

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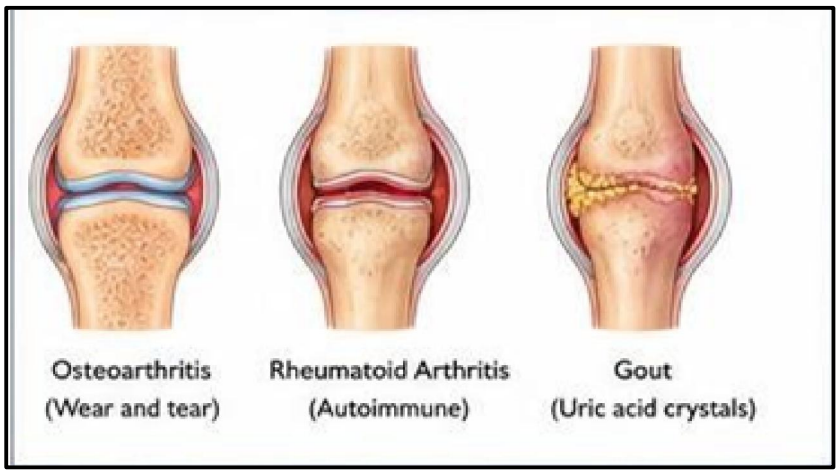

Fig. 1: Types of Arthritis

1.3 Drug Delivery Systems

1.3.1 Definition

Drug delivery systems are formulations or technologies used to transport pharmaceutical agents in the body to achieve desired therapeutic effect[2,4].

1.3.2 Conventional Drug Delivery Systems

Conventional dosage forms release drug immediately after administration and require repeated dosing.

1.3.3 Novel Drug Delivery Systems

Novel systems are designed to improve drug release pattern, therapeutic efficacy, and patient compliance.

1.3.4 Advantages of Novel Drug Delivery Systems

- Improved efficacy
- Reduced toxicity
- Better patient compliance
- Controlled drug release
- Reduced dosing frequency

1.3.5 Limitations of Novel Drug Delivery Systems

- High manufacturing cost
- Complex formulation process
- Stability problems

1.4 Modified Release Dosage Forms

1.4.1 Definition

Modified release dosage forms are formulations designed to alter the rate, time, or site of drug release.

1.4.2 Types of Modified Release Systems

- **Sustained Release Systems**
  - These systems release drug slowly over prolonged duration.

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- **Controlled Release Systems**
  - These formulations release drug at predetermined controlled rate.
- **Delayed Release Systems**
  - Drug release occurs after a lag time.
- **Extended Release Systems**
  - These formulations prolong therapeutic action of drugs.
- **Pulsatile Release Systems**
  - Drug is released in pulses at specific intervals.

1.5 Mechanism of Drug Release

Diffusion

Drug molecules diffuse through polymer matrix into surrounding medium.

Dissolution

Drug release occurs through dissolution of drug particles.

Osmosis

Drug release occurs due to osmotic pressure difference.

Erosion

Drug release takes place by erosion of polymer matrix.

Swelling

Hydrophilic polymers absorb water and swell, controlling drug release.

1.6 Advantages of Modified Release Dosage Forms

- Reduced dosing frequency
- Improved patient compliance
- Better therapeutic efficacy
- Reduced side effects
- Reduced plasma fluctuation
- Improved bioavailability
- Prolonged therapeutic action

1.7 Limitations of Modified Release Dosage Forms

- High manufacturing cost
- Dose dumping risk
- Complex formulation design
- Difficult dose adjustment
- Possibility of incomplete drug release

1.8 Applications of Modified Release Systems

- Arthritis treatment
- Hypertension management
- Diabetes therapy
- Asthma treatment

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- Pain management
- Cardiovascular disorders

II. LITERATURE REVIEW

2.1 Literature Review

Literature review provides information regarding previous research studies carried out on modified release dosage forms for arthritis treatment. Various researchers have developed sustained release and controlled release formulations using different polymers and formulation techniques to improve therapeutic efficacy and patient compliance.

2.2 Review of Research Work

2.2.1 Studies on Modified Release Formulations

Rao et al. developed sustained release matrix tablets of Diclofenac Sodium using Hydroxypropyl Methylcellulose (HPMC) and ethyl cellulose. The study reported prolonged drug release for up to 12 hours with improved anti-inflammatory activity and reduced gastrointestinal irritation compared to conventional tablets[3].

Patel and Shah investigated controlled release formulations of Ibuprofen using hydrophilic polymers. Their research demonstrated that increasing polymer concentration significantly decreased the drug release rate and improved sustained release characteristics[4].

Kumar et al. evaluated sustained release tablets of Naproxen prepared by wet granulation method. The formulations showed satisfactory hardness, friability, and prolonged dissolution profile indicating effective controlled release behavior[5].

Sharma and Verma studied the effect of natural polymers such as guar gum and xanthan gum in modified release formulations. Their findings indicated that natural polymers effectively controlled drug release and improved swelling characteristics of matrix tablets[11].

Singh et al. prepared matrix tablets of Diclofenac Sodium using HPMC K100M and sodium carboxymethyl cellulose. The study demonstrated uniform drug release and improved stability under accelerated conditions.

Mehta and Jain investigated the influence of polymer viscosity on sustained release behavior of anti-arthritic drugs. The results revealed that higher viscosity polymers produced slower drug release due to formation of stronger gel barriers.

Kulkarni et al. developed modified release tablets of Aceclofenac using combination of hydrophilic and hydrophobic polymers. The optimized formulation exhibited prolonged drug release and better patient compliance.

Desai and Patel studied the release kinetics of sustained release Diclofenac Sodium tablets. Their findings suggested that the formulations followed Higuchi diffusion model and Korsmeyer-Peppas mechanism of drug release[9].

Gupta et al. investigated the use of Eudragit polymers in controlled release formulations. The study demonstrated effective retardation of drug release and improved stability of tablets.

Nair and Reddy formulated sustained release tablets of anti-inflammatory drugs using wet granulation technique. The prepared formulations showed acceptable physical parameters and prolonged therapeutic action.

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2.2.2 Studies on Polymers Used in Modified Release Systems

• Hydrophilic Polymers

Patel et al. studied the application of HPMC in sustained release formulations and reported that HPMC effectively controlled drug diffusion by forming a hydrated gel matrix.

Shah and Mehta investigated sodium carboxymethyl cellulose in matrix tablets and observed improved swelling index and prolonged release profile.

Reddy et al. evaluated xanthan gum as a release retardant polymer and concluded that xanthan gum successfully sustained drug release over extended duration[10].

• Hydrophobic Polymers

Kumar and Singh studied ethyl cellulose based matrix systems and found that hydrophobic polymers reduced penetration of dissolution medium and slowed drug release.

Jain et al. investigated Eudragit polymers in modified release systems and reported improved stability and controlled release characteristics[7].

• Studies on Combination Polymers

Kulkarni et al. formulated sustained release tablets using combination of hydrophilic and hydrophobic polymers. Their research demonstrated better control over release profile compared to formulations prepared with single polymer.

Gupta and Shah studied matrix tablets containing HPMC and ethyl cellulose combinations and observed prolonged drug release with improved mechanical strength of tablets[8].

2.3 Studies on Anti-Arthritic Drugs

2.3.1 Diclofenac Sodium

Reddy and Kumar investigated sustained release formulations of Diclofenac Sodium for arthritis treatment. The study reported prolonged anti-inflammatory activity and reduction in gastrointestinal side effects compared to conventional dosage forms.

Mehta et al. evaluated controlled release Diclofenac Sodium tablets and concluded that sustained release systems effectively maintained therapeutic drug concentration for extended duration[12].

2.3.2 Ibuprofen

Patel and Trivedi developed modified release tablets of Ibuprofen using HPMC polymer. The prepared formulations showed satisfactory dissolution profile and prolonged analgesic activity.

Sharma et al. investigated sustained release formulations of Ibuprofen and reported improved patient compliance due to reduction in dosing frequency.

2.3.3 Naproxen

Singh and Rao studied sustained release matrix tablets of Naproxen and observed prolonged dissolution profile and better anti-inflammatory action compared to immediate release formulations.

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2.4 Studies on Formulation Methods

2.4.1 Wet Granulation Method

Kumar et al. studied wet granulation method for preparation of sustained release tablets and reported improved compressibility, flow properties, and uniformity of granules.

Patel and Shah evaluated sustained release tablets prepared by wet granulation and observed satisfactory hardness and dissolution profile[18].

2.4.2 Direct Compression Method

Mehta and Jain investigated direct compression method for sustained release tablets and concluded that direct compression is economical and simple when powders possess good flowability.

2.4.3 Melt Granulation Method

Reddy et al. evaluated melt granulation technique for sustained release systems and reported improved drug distribution and reduced processing time[1].

2.5 Studies on Evaluation Parameters

2.5.1 Pre-Compression Parameters

Sharma et al. evaluated angle of repose, bulk density, Carr's index, and Hausner ratio of sustained release granules. The results indicated good flow properties and compressibility.

Patel and Rao investigated flow properties of matrix granules and concluded that proper granulation significantly improves tablet compression characteristics[5].

2.5.2 Post-Compression Parameters

Singh et al. evaluated hardness, friability, thickness, and weight variation of sustained release tablets. Their findings demonstrated compliance with pharmacopoeial standards.

Gupta and Verma studied drug content uniformity and reported homogeneous distribution of drug throughout the formulations.

2.5.3 Dissolution Studies

Kulkarni et al. performed in-vitro dissolution studies of sustained release tablets and observed prolonged drug release over 12 hours.

Desai and Patel investigated dissolution behavior of HPMC based matrix tablets and concluded that increased polymer concentration effectively slowed drug release.

2.6 Studies on Drug Release Kinetics

Gupta and Shah analyzed release kinetics of sustained release formulations and reported that most matrix tablets followed Higuchi diffusion kinetics.

Reddy et al. investigated Korsmeyer-Peppas release model and concluded that drug release occurred through combined mechanism of diffusion and polymer erosion.

Mehta and Jain evaluated zero order and first order kinetics of modified release formulations and reported near zero order release behavior in optimized formulations[6].

2.7 Studies on Stability Testing

Nair and Reddy conducted accelerated stability studies according to ICH guidelines and found no significant changes in physical appearance, hardness, drug content, or dissolution profile after storage.

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Patel et al. evaluated long-term stability of sustained release formulations and reported satisfactory stability under recommended storage conditions.

Sharma and Gupta studied the effect of temperature and humidity on modified release tablets and concluded that suitable packaging materials are necessary to maintain stability[7].

2.8 Challenges in Modified Release Formulations

2.8.1 Dose Dumping

Dose dumping refers to sudden release of large amount of drug from dosage form resulting in toxicity and adverse effects.

2.8.2 Polymer Selection

Selection of suitable polymer is critical because polymer concentration and viscosity directly affect release profile of formulations.

2.8.3 Stability Issues

Environmental conditions such as temperature and humidity may affect physical and chemical stability of formulations.

2.8.4 Manufacturing Complexity

Modified release systems require specialized manufacturing techniques and careful optimization of formulation variables.

2.9 Recent Advances in Modified Release Systems

2.9.1 Nanoparticle Drug Delivery

Nanoparticles improve bioavailability and targeted delivery of anti-inflammatory drugs.

2.9.2 Osmotic Drug Delivery Systems

Osmotic systems provide controlled release using osmotic pressure mechanism.

2.9.3 Floating Drug Delivery Systems

Floating systems prolong gastric residence time and improve absorption of drugs.

2.9.4 Mucoadhesive Systems

Mucoadhesive formulations improve retention time at absorption site and enhance therapeutic efficacy.

2.9.5 Biodegradable Polymer Systems

Biodegradable polymers provide safer and environmentally friendly sustained release formulations.

III. AIM AND OBJECTIVES

3.1 Aim

The aim of the present study is to formulate and evaluate a modified release dosage form for arthritis using suitable polymers and excipients in order to achieve prolonged drug release, improved therapeutic efficacy, reduced dosing frequency, and enhanced patient compliance.

3.2 Objectives

3.2.1 Primary Objective

- To design and develop modified release tablets for arthritis treatment.

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3.2.2 Secondary Objectives

- To improve therapeutic effectiveness of anti-arthritic drugs.
- To prolong drug release over an extended period of time.
- To reduce frequency of administration.
- To maintain constant plasma drug concentration.
- To improve patient compliance in chronic therapy.
- To minimize gastrointestinal side effects associated with conventional dosage forms.
- To evaluate the effect of polymers on drug release profile.
- To study release kinetics of prepared formulations.
- To evaluate stability of prepared dosage forms according to ICH guidelines.

3.3 Plan of Work

3.3.1 Selection of Drug

Selection of suitable anti-arthritic drug possessing short biological half-life and suitable physicochemical properties for modified release formulation.

3.3.2 Selection of Polymers

Selection of hydrophilic and hydrophobic polymers for controlling drug release.

Examples:

- HPMC K100M
- Ethyl Cellulose
- Sodium CMC

3.3.3 Preformulation Studies

Preformulation studies are performed to evaluate physicochemical properties of drug and compatibility with excipients.

Parameters Evaluated

- Organoleptic properties
- Solubility
- Melting point
- Drug-excipient compatibility
- Flow properties

3.3.4 Formulation Development

Preparation of modified release tablets using suitable formulation technique such as wet granulation method.

3.3.5 Evaluation of Granules

Pre-compression evaluation includes:

- Angle of repose
- Bulk density
- Tapped density
- Carr's index
- Hausner ratio

3.3.6 Evaluation of Tablets

Post-compression evaluation includes:

- Thickness

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- Hardness
- Friability
- Weight variation

3.3.7 Drug Release Kinetics

Analysis of drug release mechanism using:

- Zero order kinetics
- First order kinetics
- Higuchi model
- Korsmeyer-Peppas model

3.4 Expected Outcome

- Development of stable modified release formulation.
- Prolonged drug release profile.
- Improved patient compliance.
- Reduced dosing frequency.

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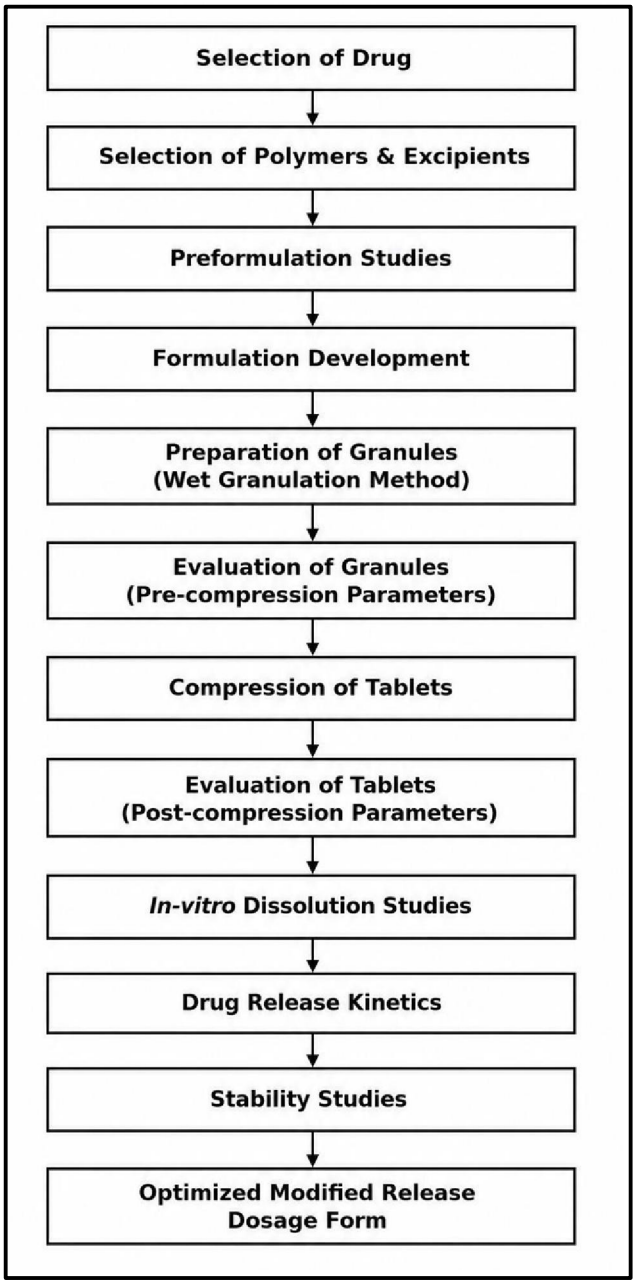

IV. MATERIALS AND METHODS

4.1 Materials

The following materials were used in the formulation of modified release dosage form for arthritis.

4.1.1 Drug

- Diclofenac Sodium

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4.1.2 Polymers

- Hydroxypropyl Methylcellulose (HPMC K100M)
- Ethyl Cellulose

4.1.3 Excipients

- Lactose
- Magnesium Stearate
- Talc
- Microcrystalline Cellulose
- Polyvinyl Pyrrolidone (PVP)

4.2 Equipment Used

The following instruments and equipment were used during formulation and evaluation studies.

Sr.No.	Equipment	Purpose
1	ElectronicBalance	Weighingof ingredients
2	MortarandPestle	Mixingof powders
3	SieveSet	Particlesizeseparation
4	Hot AirOven	Dryingofgranules
5	TabletPunchingMachine	Compressionof tablets
6	MonsantoHardness Tester	Hardnesstesting
7	Roche Friabilator	Friabilitytesting
8	USPDissolution Apparatus	Dissolution study
9	VernierCalipers	Thickness measurement
10	UVSpectrophotometer	Drugcontent analysis

4.3 Method of Preparation

4.3.1 Wet Granulation Method

Wet granulation method was used for preparation of modified release tablets because it improves flow properties and compressibility of granules[7].

4.4 Procedure

4.4.1 Weighing of Ingredients

All ingredients including drug, polymers, and excipients were weighed accurately using electronic balance.

4.4.2 Mixing of Drug and Polymers

The weighed ingredients were mixed uniformly in mortar and pestle to obtain homogeneous powder mixture.

4.4.3 Preparation of Granules

Binder solution containing PVP was added slowly to prepare damp mass. The damp mass was passed through sieve to prepare granules.

4.4.4 Drying of Granules

Prepared granules were dried in hot air oven at suitable temperature until optimum moisture content was achieved.

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4.4.5 Lubrication

The dried granules were mixed with magnesium stearate and talc to improve flow properties and prevent sticking during compression.

4.4.6 Compression of Tablets

Lubricated granules were compressed using tablet punching machine to obtain modified release tablets.

4.5 Formulation Table

Ingredients	F1	F2	F3
DiclofenacSodium	100 mg	100 mg	100 mg
HPMCK100M	50 mg	75 mg	100 mg
EthylCellulose	20 mg	20 mg	20 mg
Lactose	q.s	q.s	q.s
MagnesiumStearate	5 mg	5 mg	5 mg
Talc	5 mg	5 mg	5 mg

4.6 Flow Chart of Formulation Proce

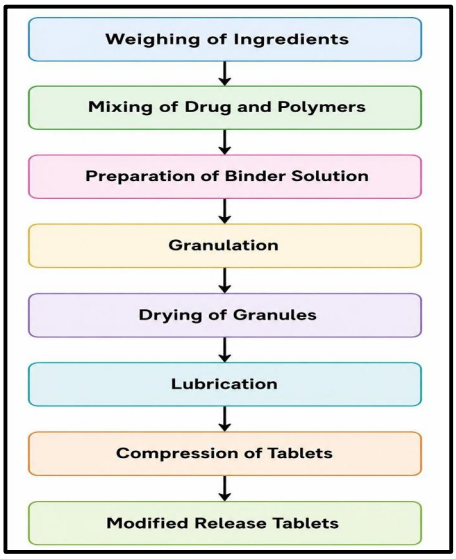

Fig. 2: Formulation Process Flowchart

4.7 Mechanism of Drug Release

- **Diffusion Mechanism**

Drug diffuses slowly through polymer matrix into dissolution medium.

- **Swelling Mechanism**

Hydrophilic polymers absorb water and swell, controlling drug release.

- **Erosion Mechanism**

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Drug release occurs due to erosion of polymer matrix[12].

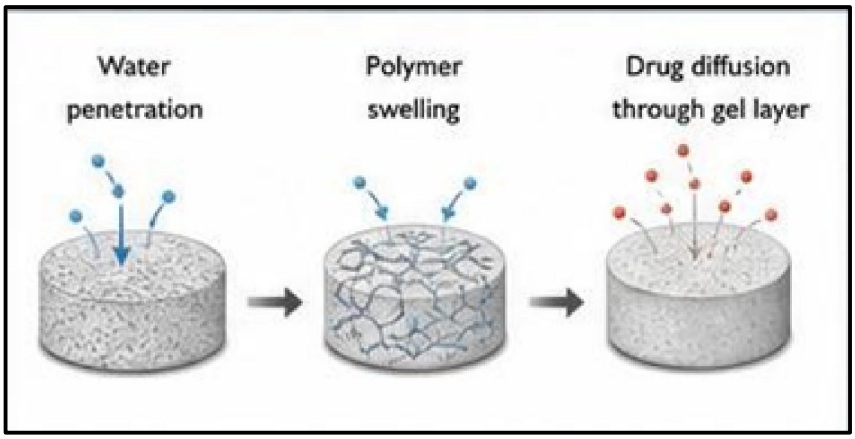

Fig. 3: Mechanism of Drug Release Hydrophilic Matrix Tablet

4.8 Advantages of Wet Granulation Method

- Improves flow properties
- Enhances compressibility
- Produces uniform granules
- Improves content uniformity
- Suitable for sustained release formulations

4.9 Classification Based on Mechanism

4.9.1 Diffusion Controlled Systems

Drug release occurs through diffusion of drug molecules across polymer membrane.

4.9.2 Dissolution Controlled Systems

Drug release depends upon dissolution rate of polymer or drug.

4.10.3 Osmotic Controlled Systems

Drug release occurs through osmotic pressure generated inside dosage form.

4.10.4 Ion Exchange Systems

Drug release occurs through exchange of ions in gastrointestinal fluids[17].

V. EVALUATION PARAMETERS

Evaluation parameters are important quality control tests performed to ensure the quality, safety, stability, and effectiveness of modified release tablets. These parameters help in determining flow properties of granules, mechanical strength of tablets, drug content uniformity, and drug release behaviour.

Evaluation studies are generally divided into:

- Pre-compression parameters
- Post-compression parameters
- In-vitro dissolution studies
- Drug release kinetics

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These studies ensure that the prepared formulation complies with pharmacopoeial standards and provides desired sustained release characteristics.

5.1 Evaluation of Granules

Evaluation of granules before compression is known as pre-compression evaluation. These studies help in determining flow properties and compressibility of granules[22].

5.2 Pre-Compression Parameters

5.2.1 Angle of Repose

Angle of repose is used to determine flow properties of granules.

Principle

It is the maximum angle formed between surface of powder pile and horizontal plane.

Formula

$$\theta = \tan^{-1}(h / r)$$

Where:

- θ = Angle of repose
- h = Height of pile
- r = Radius of pile

Interpretation

AngleofRepose	FlowProperty
<25°	Excellent
25°–30°	Good
30°–40°	Passable
>40°	Poor

Importance

- Determines flowability of granules
- Ensures uniform die filling
- Improves compression process

5.2.2 Bulk Density

Bulk density is defined as mass of powder divided by bulk volume.

Formula

$$Pb = M / Vb$$

Where:

- ρb = Bulk density
- M = Mass of powder
- Vb = Bulk volume

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Importance

- Determines packing characteristics
- Helps in formulation design
- Evaluates compressibility

5.2.3 Tapped Density

Tapped density is determined after mechanically tapping the measuring cylinder containing powder[21,27,28].

Formula

$$Pt = M / Vt$$

Where:

- ρt = Tapped density
- M = Mass of powder
- Vt = Tapped volume

Importance

- Determines packing characteristics
- Helps in formulation design
- Evaluates compressibility

5.2.4 Carr's Index

Carr's index indicates compressibility of granules.

Formula

$$Carr's\ Index = \rho t - \rho b / \rho t \times 100$$

Interpretation

Carr'sIndex	FlowProperty
5–15%	Excellent
16–20%	Good
21–25%	Fair
>25%	Poor

Importance

- Determines compressibility
- Evaluates flow behavior

5.2.5 Hausner Ratio

Hausner ratio is used to evaluate flow characteristics of powder blend.

Formula

$$Hausner\ Ratio = \rho t / \rho b$$

Interpretation

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HausnerRatio	FlowProperty
1.00–1.11	Excellent
1.12–1.18	Good
1.19–1.25	Fair
>1.25	Poor

5.3 Evaluation of Tablets

Post-compression parameters are evaluated after tablet compression to ensure quality, stability, and uniformity[16].

5.4 Post-Compression Parameters

5.4.1 Thickness

Tablet thickness was measured using Vernier calipers.

Importance

- Ensures uniform tablet size
- Indicates proper compression

5.4.2 Hardness

Hardness determines mechanical strength of tablets.

Instrument Used

- Monsanto Hardness Tester

Importance

- Prevents tablet breakage
- Maintains integrity during handling

5.4.3 Friability

Friability measures resistance of tablets to abrasion and shock.

Instrument Used

- Roche Friabilator

Formula

$$\textbf{Friability (\%)} = W1 - W2 / W1 \times 100$$

Where:

- W1 = Initial weight
- W2 = Final weight

Acceptance Criteria

Friability should be less than 1%.

5.4.4 Weight Variation Test

Weight variation test ensures uniformity of tablet weight.

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Procedure
Twenty tablets were weighed individually and average weight was calculated.

Importance
- Ensures dose uniformity
- Maintains formulation consistency

5.4.5 Drug Content Uniformity
Drug content uniformity determines uniform distribution of drug within tablets.

Importance
- Ensures accurate dosing
- Prevents dose variation

5.4.6 Swelling Index
Swelling index determines swelling behavior of hydrophilic polymers.

Formula

$$\text{Swelling Index} = Wt - W0 / W0 \times 100$$

Where:
- Wt = Weight after swelling
- W0 = Initial weight

5.5 In-vitro Dissolution Studies
Dissolution studies are performed to evaluate drug release pattern from modified release tablets.

5.5.1 Dissolution Conditions

Parameter	Condition
Dissolution Medium	Phosphate Buffer pH6.8
Temperature	37 ± 0.5°C
RPM	50
Apparatus	USP Type IIPaddle Apparatus
TimeInterval	12 Hours

5.5.2 Procedure
- Dissolution medium was prepared.
- Tablets were placed in dissolution apparatus.
- Samples were withdrawn at regular intervals.
- Drug concentration was analyzed using UV spectrophotometer[14].

5.6 Drug Release Kinetics
Drug release kinetics help in understanding mechanism of drug release from dosage forms.

5.6.1 Zero Order Kinetics
Drug release occurs at constant rate independent of concentration.

$$Q_t = Q_0 + k_0 t$$

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ISSN: 2581-9429
Volume 6, Issue 14, May 2026
Impact Factor: 8.2

5.6.2 First Order Kinetics

Drug release depends upon concentration gradient.

$$\log C = \log C_0 - \frac{kt}{2.303}$$

5.6.3 Higuchi Model

Describes diffusion controlled drug release.

$$Q = k_H t^{1/2}$$

5.6.4 Korsmeyer-Peppas Model

Used to determine mechanism of drug release.

$$\frac{M_t}{M_\infty} = kt^n$$

5.7 Importance of Evaluation Parameters

- Ensures quality of formulation
- Determines stability of tablets
- Evaluates drug release behavior
- Predicts therapeutic performance
- Ensures patient safety and efficacy

VI. RESULT AND DISCUSSION

6.1 Result and Discussion

The modified release tablets of Diclofenac Sodium were successfully formulated using HPMC K100M and Ethyl Cellulose by the wet granulation method. The prepared granules exhibited satisfactory pre-compression characteristics, including good flowability, compressibility, and packing properties. The angle of repose, Carr's index, and Hausner ratio values were found within acceptable limits, indicating suitability of the granules for tablet compression. Post-compression evaluation of the tablets showed acceptable pharmaceutical properties. The tablets demonstrated uniform thickness, adequate hardness, low friability (below 1%), and satisfactory weight variation, confirming compliance with pharmacopoeial standards. Drug content uniformity studies indicated homogeneous distribution of Diclofenac Sodium throughout the formulations.

In-vitro dissolution studies carried out in phosphate buffer pH 6.8 for 12 hours revealed effective sustained drug release from all formulations. The rate of drug release was influenced by the concentration of HPMC K100M. An increase in polymer concentration resulted in slower drug release due to the formation of a thicker and stronger gel matrix around the tablet. Among the formulations, F3 containing the highest concentration of HPMC K100M exhibited the most prolonged release profile and sustained drug release up to 12 hours. Drug release kinetic analysis suggested that the optimized formulation followed the Higuchi model, indicating diffusion-controlled release. The Korsmeyer–Peppas model further confirmed that drug release occurred through a combination of diffusion and polymer erosion mechanisms. Stability studies conducted under accelerated conditions showed no significant changes in appearance, hardness, drug content, or dissolution profile.

6.2 Overall Discussion

The prepared modified release tablets showed satisfactory pre-compression and post-compression characteristics. Hydrophilic polymer HPMC K100M effectively controlled drug release and prolonged therapeutic action.

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Volume 6, Issue 14, May 2026
Impact Factor: 8.2

The study confirmed that modified release dosage forms can successfully improve arthritis therapy by reducing dosing frequency and maintaining sustained drug release for extended duration.

VII. FACTORS AFFECTING MODIFIED RELEASE DOSAGE FORMS

7.1 Introduction

Modified release dosage forms are designed to release the drug at a predetermined rate for prolonged duration in order to maintain therapeutic drug concentration and improve patient compliance. The release pattern of drugs from modified release formulations depends upon various formulation, processing, physiological, and environmental factors.

Understanding these factors is essential for successful formulation development because they directly influence drug release kinetics, stability, therapeutic efficacy, and overall performance of dosage forms.

7.2 Physicochemical Properties of Drug

Physicochemical characteristics of drug play an important role in development of modified release formulations.

7.2.1 Solubility of Drug

Drug solubility significantly affects release behavior from matrix tablets.

Highly Soluble Drugs

Highly water-soluble drugs dissolve rapidly and may produce faster release from dosage forms.

Poorly Soluble Drugs

Poorly soluble drugs show slower dissolution and prolonged release.

Importance

- Affects dissolution rate
- Influences bioavailability
- Determines release kinetics

7.2.2 Particle Size of Drug

Particle size influences surface area available for dissolution.

Small Particle Size

Smaller particles possess larger surface area and dissolve rapidly.

Large Particle Size

Larger particles dissolve slowly and prolong drug release.

Importance

- Influences dissolution rate
- Affects uniform mixing
- Determines drug release profile

7.2.3 Biological Half-Life

Biological half-life is time required for elimination of half amount of drug from body.

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Volume 6, Issue 14, May 2026
Impact Factor: 8.2

Ideal Drugs for Sustained Release

Drugs possessing short half-life are ideal candidates for modified release systems.

Importance

- Determines dosing frequency
- Influences formulation design

7.2.4 Dose Size

Drugs requiring smaller dose are preferred for modified release formulations because high dose drugs may produce large tablet size.

Importance

- Influences patient compliance
- Affects tablet formulation

7.2.5 Stability of Drug

Drug should remain stable during formulation and storage conditions.

Importance

- Prevents degradation
- Maintains therapeutic efficacy

7.3 Polymer Related Factors

Polymers are major components responsible for controlling drug release from modified release dosage forms.

7.3.1 Polymer Concentration

Increase in polymer concentration generally decreases drug release rate due to formation of thicker matrix barrier.

Importance

- Controls release profile
- Determines release duration

7.3.2 Polymer Viscosity

High viscosity polymers form stronger gel matrix and prolong drug release.

Example

HPMC K100M produces slower drug release compared to low viscosity polymers.

Importance

- Influences swelling behavior
- Controls diffusion rate

7.3.3 Polymer Swelling

Hydrophilic polymers absorb water and swell after contact with dissolution medium.

Importance

- Controls drug diffusion
- Determines matrix integrity

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Volume 6, Issue 14, May 2026
Impact Factor: 8.2

7.3.4 Polymer Solubility

Soluble polymers dissolve rapidly while insoluble polymers prolong release by controlling diffusion.

Importance

- Influences release mechanism
- Affects dissolution behavior

7.4 Formulation Related Factors

Various formulation variables influence release profile of modified release tablets.

7.4.1 Hardness of Tablets

Hardness affects penetration of dissolution medium into tablets.

High Hardness

High hardness reduces drug release rate.

Low Hardness

Low hardness may produce rapid drug release.

Importance

- Determines mechanical strength
- Influences dissolution behavior

7.4.2 Porosity of Tablets

Porosity determines penetration of dissolution medium into matrix tablets.

High Porosity

Increases penetration and accelerates drug release.

Low Porosity

Produces slower drug release.

7.4.3 Compression Force

Compression pressure influences density and hardness of tablets.

Importance

- Affects tablet integrity
- Influences drug release rate

7.4.4 Type of Excipients

Excipients such as binders, lubricants, and diluents influence formulation characteristics.

Importance

- Affects compressibility
- Influences release pattern

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ISSN: 2581-9429 Volume 6, Issue 14, May 2026 Impact Factor: 8.2

7.5 Physiological Factors

Physiological conditions of gastrointestinal tract affect modified release formulations.

7.5.1 Gastric Emptying Time

Variation in gastric emptying affects residence time of dosage forms.

Importance

- Influences absorption
- Affects drug release duration

7.5.2 Gastrointestinal pH

Different regions of gastrointestinal tract possess different pH conditions.

Importance

- Influences polymer swelling
- Affects drug solubility

7.5.3 Gastrointestinal Motility

Movement of gastrointestinal tract influences dissolution and absorption of drugs.

Importance

- Affects residence time
- Influences bioavailability

7.6 Environmental Factors

Environmental conditions affect stability and performance of dosage forms.

7.6.1 Temperature

High temperature may alter stability and release characteristics.

Importance

- Influences chemical degradation
- Affects polymer behavior

7.6.2 Humidity

Moisture may affect hardness and stability of tablets.

Importance

- Causes degradation
- Alters dissolution profile

7.6.3 Light Exposure

Some drugs are sensitive to light and may undergo degradation.

Importance

- Reduces potency
- Affects shelf life

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ISSN: 2581-9429 Volume 6, Issue 14, May 2026 Impact Factor: 8.2

7.7 Importance of Studying Factors Affecting Drug Release

- Helps optimize formulation
- Improves therapeutic efficacy
- Ensures product stability
- Reduces formulation failure
- Enhances patient compliance

7.8 Conclusion

Various factors such as physicochemical properties of drug, polymer characteristics, formulation variables, physiological conditions, and environmental factors significantly influence modified release dosage forms. Proper understanding and optimization of these factors are essential for successful development of sustained release formulations with desired therapeutic performance.

VIII. PACKAGING AND STORAGE OF MODIFIED RELEASE TABLETS

8.1 Introduction

Packaging and storage are essential components of pharmaceutical formulation development. Proper packaging protects modified release tablets from environmental factors such as moisture, light, oxygen, and contamination, thereby maintaining stability, safety, and therapeutic efficacy throughout shelf life.

Modified release dosage forms require suitable packaging because changes in environmental conditions may alter release profile and stability of formulation.

8.2 Objectives of Packaging

The main objectives of pharmaceutical packaging are:

- Protection from environmental conditions
- Prevention of contamination
- Maintenance of stability
- Prevention of mechanical damage
- Improvement of patient convenience
- Identification and labeling of product

8.3 Ideal Requirements of Packaging Materials

Packaging materials should possess the following characteristics:

- Non-toxic
- Chemically inert
- Moisture resistant
- Light resistant
- Durable
- Economical
- Easy to handle

8.4 Types of Packaging Materials

Various packaging materials are used for modified release tablets.

8.4.1 Blister Packaging

Blister packs consist of plastic cavity sealed with aluminum foil.

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ISSN: 2581-9429
Volume 6, Issue 14, May 2026
Impact Factor: 8.2

Advantages

- Protection from moisture
- Unit dose packaging
- Improved patient compliance
- Easy handling

Disadvantages

- Expensive
- Difficult recycling

8.4.2 Strip Packaging

In strip packaging, tablets are sealed between two layers of aluminum foil.

Advantages

- Protection from light and moisture
- Economical packaging

Disadvantages

- Less attractive appearance
- Lower mechanical strength

8.4.3 HDPE Containers

High Density Polyethylene containers are commonly used for tablet storage.

Advantages

- Good moisture protection
- Durable
- Economical

Disadvantages

- May not provide complete protection against oxygen

8.4.4 Glass Containers

Glass containers are chemically inert and highly protective.

Advantages

- Excellent chemical resistance
- Protection from contamination

Disadvantages

- Fragile
- Heavy weight

8.5 Storage Conditions

Modified release tablets should be stored under controlled conditions to maintain stability and release characteristics.

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Volume 6, Issue 14, May 2026
Impact Factor: 8.2

8.5.1 Temperature Conditions

Tablets should be stored at room temperature unless otherwise specified.

Recommended Temperature

- 25°C ± 2°C

Importance

- Prevents degradation
- Maintains stability

8.5.2 Humidity Conditions

High humidity may affect hardness and dissolution behavior.

Recommended Humidity

- 60% RH ± 5%

Importance

- Prevents moisture absorption
- Maintains tablet integrity

8.5.3 Protection from Light

Light sensitive formulations should be stored in light resistant containers.

Importance

- Prevents photodegradation
- Maintains potency

8.6 Labeling Requirements

Proper labeling is essential for safe use of pharmaceutical products. Information Included on Label

- Product name
- Strength of dosage form
- Batch number
- Manufacturing date
- Expiry date
- Storage instructions
- Manufacturer details

8.7 Stability and Shelf Life

Packaging materials directly affect stability and shelf life of dosage forms. Factors Affecting Shelf Life

- Temperature
- Humidity
- Light exposure
- Oxygen exposure Importance of Stability Studies
- Determines expiration date
- Ensures product quality

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- Maintains therapeutic efficacy

8.8 Packaging Evaluation Tests
Packaging materials are evaluated using different tests.

8.8.1 Leak Test
Detects leakage in packaging material.

8.8.2 Moisture Permeation Test
Determines moisture resistance.

8.8.3 Compatibility Test
Evaluates interaction between product and packaging material.

8.9 Importance of Proper Storage
- Maintains therapeutic efficacy
- Prevents degradation
- Preserves release characteristics
- Ensures patient safety
- Extends shelf life

IX. SUMMARY AND CONCLUSION

9.1 Summary
Arthritis is a chronic inflammatory disorder affecting joints and surrounding tissues, leading to pain, swelling, stiffness, and reduced mobility. Long-term treatment of arthritis generally requires repeated administration of anti-inflammatory drugs, which may result in poor patient compliance and increased side effects. Modified release dosage forms are developed to overcome these limitations by providing prolonged and controlled release of drugs over an extended period of time.
The present project focused on the design and evaluation of modified release dosage forms for arthritis treatment using suitable polymers and excipients. Sustained release matrix tablets of Diclofenac Sodium were prepared using hydrophilic and hydrophobic polymers such as Hydroxypropyl Methylcellulose (HPMC K100M) and Ethyl Cellulose.
The project included detailed study of arthritis, modified release drug delivery systems, polymers used in sustained release formulations, anti-arthritic drugs, formulation methods, evaluation parameters, drug release kinetics, and stability studies.
Wet granulation method was selected for preparation of modified release tablets because it improves flow properties, compressibility, and uniformity of granules. Different formulations were prepared by varying concentration of polymers in order to achieve prolonged drug release profile.
The prepared formulations were evaluated for pre-compression parameters including:
- Angle of repose
- Bulk density
- Tapped density
- Carr's index
- Hausner ratio

The granules showed satisfactory flow properties and compressibility indicating suitability for tablet compression.

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Post-compression evaluation studies included:

- Thickness
- Hardness
- Friability
- Weight variation
- Drug content uniformity
- Swelling index
- In-vitro dissolution studies

The tablets showed acceptable hardness, low friability, uniform thickness, and satisfactory drug content indicating good quality formulations.

Dissolution studies demonstrated prolonged drug release over extended duration. Increase in polymer concentration significantly slowed drug release due to formation of thicker gel matrix barrier. Formulation containing higher concentration of HPMC showed maximum sustained release effect.

Drug release kinetics studies indicated that the formulations followed Higuchi diffusion model and Korsmeyer-Peppas mechanism suggesting diffusion and polymer erosion controlled release behavior. Stability studies performed according to ICH guidelines demonstrated that prepared formulations remained stable under accelerated storage conditions without significant changes in appearance, hardness, drug content, or dissolution profile.

The project also highlighted importance of packaging and storage conditions in maintaining stability and therapeutic efficacy of modified release dosage forms. Overall, the study confirmed that modified release systems provide significant advantages over conventional dosage forms in management of arthritis and chronic inflammatory disorders.

9.2 Conclusion

The present study successfully focused on the formulation and evaluation of modified release dosage forms for arthritis treatment using suitable polymers and excipients. Modified release tablets of Diclofenac Sodium were prepared by wet granulation method and evaluated for various pharmaceutical parameters. The prepared formulations showed satisfactory pre-compression properties including good flowability, compressibility, and packing characteristics. Post-compression evaluation parameters such as hardness, friability, thickness, weight variation, and drug content uniformity were found within acceptable pharmacopoeial limits.

In-vitro dissolution studies demonstrated prolonged and controlled drug release over an extended period of time. The study revealed that increase in polymer concentration effectively reduced the drug release rate by forming a stronger gel matrix barrier around the tablet. Among all formulations, formulation F3 containing higher concentration of HPMC K100M exhibited better sustained release characteristics and prolonged drug release up to 12 hours. Drug release kinetics studies indicated that the release mechanism followed diffusion controlled and polymer erosion pathways.

Stability studies performed according to ICH guidelines showed no significant changes in physical appearance, drug content, or dissolution profile, indicating stability of the prepared formulations.

Overall, the study confirmed that modified release dosage forms are highly effective in management of arthritis by:

- Providing prolonged therapeutic action
- Reducing frequency of administration
- Improving patient compliance
- Minimizing side effects
- Maintaining steady plasma drug concentration

The developed modified release formulation can serve as an effective alternative to conventional dosage forms for long-term arthritis therapy.

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Volume 6, Issue 14, May 2026
Impact Factor: 8.2

9.3 Future Scope

Modified release drug delivery systems have wide applications in treatment of chronic diseases. Future research may focus on advanced technologies for improving therapeutic efficacy and patient convenience.

9.3.1 Advanced Drug Delivery Systems

Future studies can involve:

- Nanoparticle based delivery systems
- Liposomal formulations
- Microspheres and nanoparticles
- Targeted drug delivery systems

9.3.2 Use of Natural Polymers

Natural polymers such as:

- Guar gum
- Chitosan
- Xanthan gum
- Pectin

can be further explored for safer and biodegradable modified release formulations.

9.3.3 Combination Therapy

Combination of multiple anti-arthritic drugs in single modified release dosage form may improve therapeutic response and reduce treatment duration.

9.3.4 Targeted Drug Delivery

Development of site-specific drug delivery systems can improve effectiveness and reduce systemic side effects.

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Impact Factor: 8.2

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