"Novel Approaches in the Development of Mouth Dissolving Formulation for Analgesic and Anti-Inflammatory Drugs"

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Abstract

The present investigation was undertaken to develop and evaluate a novel mouth dissolving formulation of analgesic and anti-inflammatory drugs with the objective of improving patient compliance, enhancing dissolution characteristics, and achieving rapid therapeutic action. Conventional oral solid dosage forms frequently present swallowing difficulties, particularly among pediatric, geriatric, and dysphagic patient populations, thereby limiting treatment adherence and therapeutic effectiveness. Mouth dissolving tablets (MDTs) have emerged as a promising drug delivery platform capable of rapidly disintegrating in the oral cavity without the requirement for water, facilitating improved convenience and patient acceptability. In the current study, Tolperisone hydrochloride, a centrally acting muscle relaxant, and Celecoxib, a selective cyclooxygenase-2 inhibitor, were selected as model analgesic and anti-inflammatory agents for formulation development. Novel formulation strategies employing superdisintegrants, including crospovidone and sodium starch glycolate, were utilized to promote rapid tablet disintegration and enhance drug dissolution. Comprehensive pre- compression characterization of powder blends was performed through the determination of bulk density, tapped density, Carr's compressibility index, and Hausner ratio to assess flow properties and compressibility behavior. The prepared formulations were further evaluated for post-compression quality attributes, including hardness, friability, weight variation, thickness, wetting time, disintegration time, drug content uniformity, and in vitro dissolution performance.

The optimized formulation demonstrated acceptable physicochemical characteristics, satisfactory mechanical integrity, rapid disintegration behavior, and enhanced drug release profiles compared with conventional oral dosage forms. Furthermore, accelerated stability studies conducted in accordance with international regulatory guidelines confirmed the stability and integrity of the optimized formulation under stressed storage conditions. The findings of the present study suggest that the developed mouth dissolving formulation constitutes an effective and patient-centric drug delivery system with the potential to improve bioavailability, therapeutic efficacy, and treatment compliance in the management of pain and inflammatory disorders.

Keywords: Mouth dissolving tablets; Tolperisone hydrochloride; Celecoxib;
Superdisintegrants; Crospovidone; Sodium starch glycolate; Analgesic agents; Anti- inflammatory agents; Drug dissolution; Patient compliance; Novel drug delivery system; Bioavailability enhancement.

1. INTRODUCTION:

The oral route remains the most widely preferred and accepted method for the systemic administration of therapeutic agents owing to its convenience, precise dosing, non-invasive nature, cost-effectiveness, and high level of patient acceptance. Oral solid dosage forms, particularly tablets and capsules, offer significant advantages including formulation flexibility, ease of large-scale manufacturing, dosage accuracy, and suitability for a broad range of therapeutic agents and dose strengths.

Despite these advantages, conventional oral solid dosage forms may not be suitable for certain patient populations, particularly geriatric and pediatric patients, as well as individuals suffering from dysphagia or other swallowing disorders. Elderly patients frequently experience difficulty in swallowing conventional tablets and capsules due to age-associated physiological and neurological alterations. Factors contributing to impaired administration of solid dosage forms in geriatric populations include reduced neuromuscular coordination, hand tremors, visual impairment, hearing deficits, cognitive decline, and an increased risk of choking during swallowing.

Similarly, pediatric patients often encounter difficulties in swallowing solid dosage forms because of incomplete development of muscular coordination and swallowing reflexes. Furthermore, patients experiencing severe nausea, vomiting, neurological disorders, psychiatric conditions, or those who are uncooperative may exhibit poor compliance with conventional oral formulations. The administration of solid dosage forms may also become challenging during travel, acute allergic episodes, febrile conditions, and in situations where immediate access to potable water is unavailable.

A wide variety of oral tablet formulations have been developed to address diverse therapeutic requirements, including compressed tablets, buccal and sublingual tablets, molded tablets, enteric-coated tablets, layered tablets, film-coated tablets, multiple-coated tablets, press-coated tablets, controlled-release tablets, sugar-coated tablets, and tablets intended for solution preparation. However, these conventional dosage forms may not adequately address the needs of patients with swallowing difficulties or those requiring rapid onset of therapeutic action.

Mouth dissolving tablets (MDTs), also referred to as orally disintegrating tablets, have emerged as a promising alternative oral drug delivery system capable of rapidly disintegrating and dissolving in the oral cavity within a short period without the need for water or mastication. Upon administration, the dosage form disperses rapidly in

saliva, facilitating swallowing and subsequent gastrointestinal absorption. In addition, partial pregastric absorption through the oral mucosa may contribute to enhanced bioavailability and reduced first-pass metabolism when compared with conventional oral solid dosage forms. Consequently, MDTs represent an effective patient-centric approach for improving medication adherence, therapeutic efficacy, and overall treatment outcomes, particularly among pediatric, geriatric, and dysphagic patient populations.

1.2.Mouth Dissolving Tablets:

Mouth dissolving tablets (MDTs), also known as orally disintegrating tablets (ODTs), represent an advanced oral drug delivery system designed to disintegrate or dissolve rapidly in the oral cavity without the requirement for water. According to the definition provided by the United States Food and Drug Administration (FDA), an orally disintegrating tablet is a solid dosage form that disintegrates rapidly, generally within a matter of seconds, when placed on the tongue. Following contact with saliva, the tablet undergoes rapid disintegration and forms a dispersion or suspension that can be swallowed easily, thereby improving patient convenience and compliance.

Pharmacopoeial standards indicate that the disintegration time of mouth dissolving tablets typically ranges from a few seconds to approximately one minute, depending on the formulation characteristics and the type and concentration of superdisintegrants employed. The rapid disintegration behavior of MDTs facilitates prompt drug release and may contribute to a faster onset of therapeutic action compared with conventional oral solid dosage forms.

Ideal Characteristics of Mouth Dissolving Tablets

An ideal mouth dissolving tablet should possess the following characteristics:

- It should rapidly disintegrate or dissolve in the oral cavity without the need for water or chewing.
- The disintegration time should preferably be less than 30 seconds to ensure rapid administration and improved patient convenience.
- The formulation should exhibit acceptable organoleptic properties, including a pleasant taste and mouthfeel, to enhance patient acceptability.
- It should possess adequate mechanical strength to withstand handling, packaging, transportation, and storage without significant breakage or friability.
- The dosage form should demonstrate uniform drug content and consistent performance throughout its shelf life.
- The formulation should provide rapid drug release and facilitate efficient absorption to achieve the desired therapeutic effect.
- It should exhibit good stability under recommended storage conditions and maintain its physicochemical integrity during the product lifecycle.

Advantages of Mouth Dissolving Tablets

Mouth dissolving tablets (MDTs) combine the advantages of conventional solid oral dosage forms with those of liquid formulations, thereby offering improved patient convenience and therapeutic effectiveness. The major advantages of MDTs are summarized below:

1.2.1. Precise Dose Administration

MDTs provide accurate and reproducible dosing comparable to conventional tablets while eliminating the dosing inaccuracies commonly associated with liquid formulations. This feature is particularly beneficial for pediatric and geriatric patients requiring precise dose delivery.

1.2.2. Enhanced Bioavailability

The rapid disintegration of MDTs in the oral cavity facilitates partial pregastric absorption through the oral mucosa, pharynx, and esophagus, thereby potentially reducing first-pass hepatic metabolism and improving systemic bioavailability for suitable drug candidates.

1.2.3. Rapid Onset of Therapeutic Action

The immediate disintegration and dissolution of MDTs in saliva promote faster drug release and absorption, resulting in a more rapid onset of pharmacological action compared with conventional oral solid dosage forms.

1.2.4Improved Patient Compliance

MDTs can be administered without water, making them highly suitable for patients who experience difficulty swallowing conventional tablets or capsules, as well as for individuals traveling or lacking immediate access to drinking water.

1.2.5. Ease of Administration

These formulations are particularly advantageous for pediatric, geriatric, dysphagic, bedridden, and mentally challenged patients who may encounter difficulties in swallowing conventional oral dosage forms.

1.2.6. Reduced Risk of Aspiration

The rapid disintegration of MDTs within the oral cavity minimizes the risk of choking and aspiration associated with conventional tablets, thereby enhancing patient safety during administration.

1.2.7. Improved Palatability

The incorporation of taste-masking technologies and flavoring agents significantly enhances the organoleptic properties of MDTs, leading to improved acceptability, especially among pediatric patients.

1.2.8. Convenient Packaging and Handling

MDTs can generally be packaged using conventional blister packaging systems, including push-through blisters, facilitating ease of handling and dispensing.

1.2.9. Cost-Effectiveness

Many MDT formulations can be manufactured using conventional tablet manufacturing equipment and standard pharmaceutical processing techniques, thereby minimizing production costs and enhancing commercial feasibility.

1.2.10. Silent Features of Mouth Dissolving Tablets

Mouth dissolving tablets possess several unique characteristics that distinguish them from conventional oral solid dosage forms:

- Rapid disintegration and dissolution in the oral cavity without the requirement for water.
- Improved patient acceptability and compliance, particularly among pediatric, geriatric, and dysphagic patient populations.
- Accurate and reproducible dose delivery compared with liquid formulations.
- Faster onset of therapeutic action due to enhanced dissolution and absorption characteristics.
- Potential improvement in drug bioavailability through partial pregastric absorption.
- Ease of administration under emergency conditions and in situations where access to water is limited.
- Enhanced portability, convenience, and patient adherence to treatment regimens.

Limitations of Mouth Dissolving Tablets

Despite their numerous advantages, MDTs exhibit certain limitations that must be considered during formulation development:

- Most MDT formulations are hygroscopic in nature and therefore require protection from moisture during storage and handling.
- Some formulations may produce an undesirable mouthfeel or gritty sensation following disintegration.
- Due to their relatively fragile structure and moisture sensitivity, specialized packaging systems may be required to maintain product stability and integrity.
- The incorporation of taste-masking agents and specialized excipients may increase formulation complexity and manufacturing costs.

1.2.11. Potential Drug Candidates for Mouth Dissolving Tablets

A variety of therapeutic agents have been successfully formulated as MDTs, particularly drugs requiring rapid onset of action or improved patient compliance. Suitable candidates include:

- Nonsteroidal anti-inflammatory drugs (NSAIDs)
- Antiemetic agents
- Antihistamines
- Antimigraine medications
- Antipsychotic and neuroleptic agents
- Cardiovascular drugs
- Drugs used in the management of erectile dysfunction
- Analgesics and antipyretics
- Antispasmodic agents

Need for Mouth Dissolving Tablets

The growing demand for patient-centric drug delivery systems has significantly increased the clinical importance of mouth dissolving tablets. MDTs are particularly beneficial for patients who experience difficulty swallowing conventional dosage forms, including pediatric, geriatric, dysphagic, and bedridden populations. Furthermore, their rapid onset of action and ease of administration make them suitable for emergency therapeutic situations and for use in environments where access to drinking water is limited. Consequently, optimization of manufacturing processes and formulation strategies is essential to improve product affordability, scalability, and accessibility while maintaining product quality and therapeutic performance. Challenges in formulating mouh dissolving tablets:

1.2.4. Palatability and Taste Masking:

Palatability represents one of the most critical determinants of patient acceptance and adherence in mouth dissolving tablet (MDT) formulations. Following placement in the oral cavity, MDTs undergo rapid disintegration, resulting in immediate exposure of the active pharmaceutical ingredient (API) to the taste receptors located on the tongue and oral mucosa. Consequently, drugs possessing an intrinsically bitter or unpleasant organoleptic profile may generate a negative sensory perception, thereby compromising patient compliance, particularly among pediatric and geriatric populations. The development of efficient taste-masking strategies therefore constitutes a major formulation challenge and often necessitates the incorporation of ion-exchange resins, polymeric coatings, cyclodextrin inclusion complexes, or microencapsulation technologies.

1.2.5. Mechanical Integrity

Mouth dissolving tablets are generally characterized by a highly porous internal architecture designed to facilitate rapid penetration of saliva and prompt tablet disintegration. However, this structural porosity frequently results in reduced tensile strength and increased susceptibility to chipping, abrasion, and fracture during manufacturing, packaging, transportation, and handling. Consequently, maintaining an optimal balance between rapid disintegration and adequate mechanical robustness remains a significant formulation challenge. Specialized technologies such as WOWTAB® and DuraSolv® have been developed to improve tablet

hardness without adversely affecting disintegration performance, thereby enabling packaging in conventional multidose containers rather than fragile peel-off blister systems.

1.2.6. Hygroscopic Nature and Moisture Sensitivity

Many MDT formulations contain highly hygroscopic excipients and superdisintegrants that readily absorb atmospheric moisture. Moisture uptake may induce premature swelling, alteration of tablet porosity, reduction in mechanical strength, and deterioration of disintegration characteristics, ultimately compromising product stability and shelf life. Preservation of physicochemical integrity therefore requires strict environmental control during manufacturing and storage, together with the use of moisture-resistant packaging materials such as aluminium-aluminium blister packs or desiccant-containing containers. These additional protective measures inevitably increase overall production costs.

1.2.7. Drug Loading Capacity

The incorporation of therapeutically relevant quantities of active pharmaceutical ingredients into MDTs remains challenging, particularly when employing highly porous technologies such as lyophilization. Freeze-dried dosage forms generally exhibit limited drug-loading capacity due to constraints associated with tablet fragility and matrix integrity. In many cases, these systems accommodate only relatively low doses of water-soluble drugs and even lower quantities of poorly soluble compounds, thereby restricting the applicability of MDT technology to low-dose therapeutic agents.

1.2.8. Influence of Aqueous Solubility

The aqueous solubility characteristics of both the active pharmaceutical ingredient and excipients exert a profound influence on formulation performance. Highly water-soluble constituents may undergo rapid dissolution during manufacturing or storage under humid conditions, potentially affecting tablet stability and structural integrity. Conversely, poorly soluble drugs may exhibit inadequate dissolution despite rapid tablet disintegration, thereby limiting bioavailability enhancement. To overcome these limitations, matrix-forming systems and solubility enhancement approaches such as solid dispersions, inclusion complexes, and co-processed excipients are frequently employed.

1.2.9. Optimization of Tablet Dimensions

Tablet dimensions constitute an important factor influencing patient acceptability and ease of administration. Clinical observations indicate that tablets with diameters ranging between approximately 7 and 8 mm provide an optimal compromise between swallowing comfort and handling convenience. However, the manufacture of tablets below this dimensional threshold presents considerable technical difficulties owing to challenges associated with powder flow, die filling, content uniformity, and mechanical strength. Therefore, careful optimization of tablet size is required to ensure both manufacturability and patient convenience.

1.3.Mechanism of Action of Mouth Dissolving Tablets (MDTs):

- Upon placement in the oral cavity, the mouth dissolving tablet comes into contact with saliva and begins to absorb moisture rapidly due to its highly porous structure.
- Saliva penetrates the tablet matrix through capillary action, initiating the hydration process and weakening the intermolecular bonds between tablet particles.
- Superdisintegrants such as **crospovidone** and **sodium starch glycolate** become activated upon contact with saliva.
- **Crospovidone** facilitates tablet disintegration primarily through a wicking mechanism by drawing water into the tablet through capillary channels.
- **Sodium starch glycolate** promotes rapid tablet breakup by absorbing water and swelling extensively, generating internal pressure within the tablet matrix.
- The combined effects of wicking, swelling, and strain recovery cause the tablet to disintegrate rapidly into fine particles, usually within a few seconds.
- The reduction in particle size significantly increases the surface area available for dissolution, thereby enhancing the dissolution rate of the active pharmaceutical ingredients.
- A small fraction of the dissolved drug may be absorbed through the buccal and sublingual mucosa, potentially reducing the extent of hepatic first-pass metabolism and contributing to a faster onset of action.
- The majority of the dissolved drug is swallowed with saliva and subsequently absorbed from the gastrointestinal tract.
- In the developed formulation, **Celecoxib** produces its therapeutic effect by selectively inhibiting the cyclooxygenase-2 (COX-2) enzyme, thereby reducing prostaglandin synthesis and alleviating pain and inflammation.
- **Tolperisone hydrochloride** exerts its action by blocking voltage-gated sodium and calcium channels in neuronal pathways, resulting in reduced nerve excitability and skeletal muscle relaxation.
- The rapid disintegration and enhanced dissolution characteristics of MDTs improve drug availability, reduce the onset time of therapeutic action, and enhance patient compliance, particularly among pediatric, geriatric, and

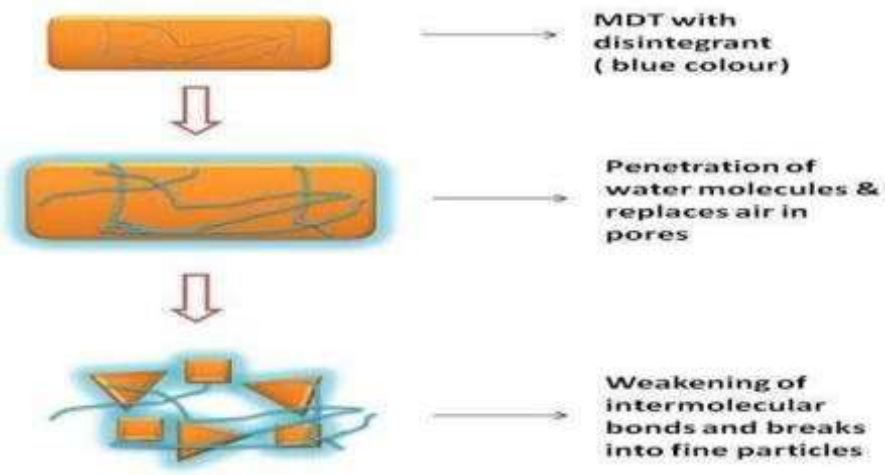

Fig 1. Mechanism of disintegration of MDTs

1.4.Technologies Employed in the Formulation of Mouth Dissolving Tablets

Mouth Dissolving Tablets (MDTs), also referred to as orally disintegrating tablets, are designed to disintegrate rapidly upon contact with saliva, thereby eliminating the need for water during administration. Rapid ingress of saliva into the porous tablet matrix facilitates swift tablet disintegration and drug dissolution. The incorporation of suitable superdisintegrants and highly water-soluble excipients enhances the formation of a porous structure, leading to improved wetting characteristics and accelerated drug release. Several conventional and advanced manufacturing technologies have been developed for the preparation of MDTs, including lyophilization, moulding, sublimation, direct compression, spray drying, mass extrusion, nanonization, melt granulation, cotton candy processing, phase transition technology, and three-dimensional printing.

1.5.1Lyophilization (Freeze-Drying)

Lyophilization is one of the most widely employed techniques for manufacturing rapidly disintegrating tablets. In this process, the drug is dissolved or dispersed in an aqueous carrier system, filled into preformed blisters, and subjected to rapid freezing followed by sublimation under reduced pressure. Removal of water by sublimation generates a highly porous and sponge-like structure that enables extremely rapid penetration of saliva and subsequent tablet disintegration. The resulting dosage forms exhibit excellent dissolution characteristics and rapid onset of therapeutic action. However, the technique requires specialized equipment and involves high manufacturing and operational costs, thereby limiting its large-scale industrial applicability.

1.5.2. Moulding Technique

The moulding method involves preparing tablets from a moist blend of drug and water-soluble excipients using relatively low compression forces. Following shaping, the solvent is removed by drying, leaving behind a porous matrix structure that facilitates rapid dissolution and disintegration. Tablets prepared by this method generally possess enhanced mouth feel and rapid dissolution profiles due to the presence of highly soluble components. Nevertheless, moulded tablets often exhibit poor mechanical strength and may require additional taste-masking approaches for bitter drugs.

1.5.3. Sublimation Technique

The sublimation approach utilizes volatile materials such as camphor, ammonium bicarbonate, ammonium carbonate, urea, naphthalene, or benzoic acid as pore-forming agents. These volatile substances are incorporated into the tablet blend and subsequently removed by sublimation after compression, resulting in the formation of a porous matrix structure. The increased porosity significantly enhances saliva penetration and promotes rapid tablet disintegration, often within a few seconds after administration.

1.5.4. Direct Compression Technique

Direct compression remains the simplest, most economical, and industrially preferred method for manufacturing MDTs. The technique relies primarily on the incorporation of superdisintegrants and sugar-based excipients to achieve rapid tablet disintegration. Due to its operational simplicity, reduced processing steps, and compatibility with conventional tablet manufacturing equipment, direct compression has become the most widely adopted method for MDT production.

1.5.5. Role of Superdisintegrants

Superdisintegrants play a critical role in promoting rapid tablet breakup through mechanisms such as swelling, capillary action, and deformation recovery. Their presence significantly reduces disintegration time and enhances dissolution rates, thereby improving drug availability.

1.5.6. Role of Sugar-Based Excipients

Water-soluble excipients including mannitol, sorbitol, xylitol, maltose, fructose, dextrose, polydextrose, starch hydrolysates, and isomalt are extensively employed as bulking agents in MDT formulations. In addition to improving aqueous solubility, these excipients impart sweetness, mask unpleasant tastes, and provide an acceptable mouth feel, thereby improving patient compliance.

1.5.7. Spray Drying Technique

Spray drying produces highly porous and low-density particles through rapid solvent evaporation from atomized droplets. The resulting powder exhibits excellent compressibility and high porosity, enabling the preparation of tablets with exceptionally short disintegration times, frequently below 20 seconds upon contact with aqueous media.

1.5.8. Mass Extrusion Technique

In the mass extrusion process, the drug and excipients are blended with hydrophilic polymers such as polyethylene glycol in the presence of suitable solvents to form a homogeneous mass. The wet mass is extruded through a syringe or extruder to produce cylindrical segments that are subsequently cut and dried. This technique is particularly useful for taste masking and improving the palatability of bitter drugs.

1.5.9. Nanonization Technique

Nanonization involves reducing drug particle size to the nanometer range using milling or high-energy processing techniques. Following stabilization, the resulting nanocrystals are incorporated into MDT formulations. Reduction in particle size increases surface area and dissolution rate, thereby enhancing bioavailability, particularly for poorly water-soluble drugs.

1.5.10. Melt Granulation Technique

Melt granulation utilizes hydrophilic waxes or low melting point binders as granulating agents. The molten binder promotes agglomeration of powder particles without the need for water or organic solvents. The technique improves content uniformity and flow properties while maintaining rapid disintegration characteristics.

1.5.11. Cotton Candy Process

The cotton candy process employs flash heat and centrifugal force to convert saccharides and polysaccharides into a floss-like amorphous matrix. The resulting material is blended with active pharmaceutical ingredients and compressed into tablets. Although this technology produces highly porous tablets with rapid disintegration properties, the elevated processing temperatures may limit its applicability for thermolabile drugs.

1.5.12. Phase Transition Technique

The phase transition method involves the use of combinations of low and high melting point sugar alcohols. Controlled heating induces partial fusion of the matrix components, resulting in improved tablet hardness without adversely affecting disintegration performance. One of the major advantages of this approach is the absence of specialized manufacturing equipment.

1.5.13. Three-Dimensional Printing Technology

Three-dimensional printing (3DP) has emerged as an advanced manufacturing platform for the fabrication of personalized MDT formulations. Using rapid prototyping technology, highly porous and precisely engineered dosage forms can be produced with tailored drug loading and release characteristics. The porous architecture generated through 3DP enables significantly faster disintegration compared with many conventional manufacturing approaches.

1.5.Anti-inflammatory and analgesic mouth dissolving tablets:

Anti-inflammatory and analgesic mouth dissolving tablets (MDTs) are solid oral dosage forms designed to disintegrate rapidly in the oral cavity without the need for water, resulting in quick drug release and faster onset of therapeutic action. These formulations are particularly beneficial for the management of pain and inflammation where immediate symptomatic relief is desirable. Conventional tablets used for the treatment of pain and inflammation may exhibit delayed onset of action due to gastric disintegration and dissolution processes. In contrast, MDTs rapidly disintegrate in saliva, allowing faster dissolution and absorption of the drug, thereby reducing the time required to achieve therapeutic plasma concentrations. The formulation of anti-inflammatory and analgesic drugs into MDTs is especially advantageous for pediatric, geriatric, dysphagic, bedridden, and postoperative patients who experience difficulty swallowing conventional tablets or capsules. Furthermore, MDTs improve patient compliance by eliminating the requirement for water during administration and providing greater convenience during travel and emergency situations.

Several analgesic and anti-inflammatory drugs have been investigated for MDT formulations owing to their need for rapid onset of action. Commonly studied drugs include Diclofenac Sodium, Aceclofenac, Ibuprofen, Ketorolac Tromethamine, Meloxicam, and Tolperisone combinations used in musculoskeletal disorders The rapid disintegration characteristics of MDTs are primarily achieved through the incorporation of superdisintegrants such as crospovidone, croscarmellose sodium, and sodium starch glycolate. Water-soluble excipients including mannitol, sorbitol, xylitol, and directly compressible sugars are frequently employed to improve mouth feel and mask unpleasant taste. The major advantages of anti-inflammatory and analgesic MDTs include rapid onset of action, improved patient compliance, enhanced convenience of administration, reduced risk of choking, improved bioavailability through pregastric absorption, and better acceptability among geriatric and pediatric populations.

Consequently, anti-inflammatory and analgesic MDTs represent a promising drug delivery strategy for achieving rapid pain relief and improving therapeutic outcomes in the treatment of inflammatory and painful conditions.

The formulation development involved the design and preparation of mouth dissolving tablets/films employing advanced and conventional techniques such as the incorporation of superdisintegrants, sublimation, lyophilization, spray drying, and direct compression methods. Optimization studies were performed to determine the ideal concentrations of polymers, superdisintegrants, and other functional excipients to achieve rapid disintegration and enhanced drug release characteristics. The prepared formulations were systematically evaluated for their physicochemical parameters, including thickness, hardness, friability, uniformity of weight, drug content, wetting time, and

disintegration time, to ensure compliance with standard quality requirements. In-vitro dissolution studies were further carried out to investigate drug release behavior and to compare the performance of different formulation batches. The optimized formulation was subjected to stability studies under appropriate storage conditions in accordance with ICH guidelines to assess its physical and chemical integrity over time. Additionally, comparative evaluation with conventional dosage forms was performed to determine improvements in therapeutic performance and patient acceptability.

2. DRUG PROFILE:

2.1.TOLPERISONE:

Tolperisone is a centrally acting skeletal muscle relaxant that exhibits spasmolytic and antispastic properties and has been in clinical use for more than three decades. It primarily acts on the central nervous system by modulating spinal reflex pathways, thereby reducing muscle tone without producing significant sedation, which distinguishes it from many conventional muscle relaxants.

Tolperisone, a centrally acting muscle relaxant agent, and it is used as spasmolytic for more than three decades. In our country Tolperisone is used for the management of acute and chronic back pain. Moreover it is also used as spasticity of neurological origin. It has also been used in treatment of condition, which includes dysmenorrhoea, climacteric complaints, lockjaw, and neurolatyrism.

2.1.1. Structure:

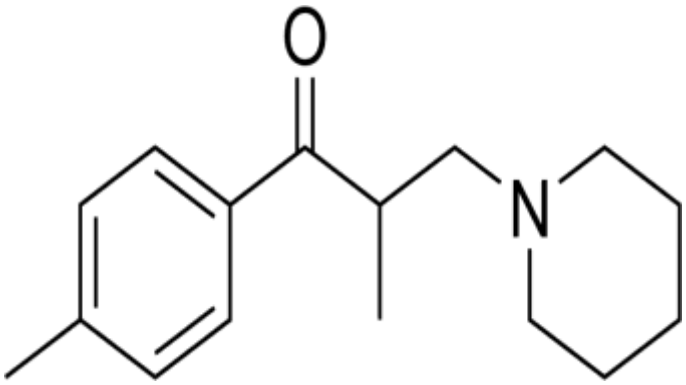

Fig 2. Structure of Tolperisone

2.1.2. Chemical Information:

- **IUPAC Name:** 2-Methyl-1-(4-methylphenyl)-3-(1-piperidinyl)-1-propanone hydrochloride (1:1)
- **Empirical Formula:** $C_{16}H_{23}NO$
- **CAS Registry Number:** 728-88-1
- **Appearance**: White crystalline powder

2.1.3. Physicochemical Properties:

- **Molecular Weight:** 245.36 g/mol
- **Melting Range:** 176–178 °C
- **Solubility:** Soluble in water, methanol, and chloroform

2.1.4. Pharmacology:

Tolperisone is a centrally acting skeletal muscle relaxant that exhibits spasmolytic and antispastic properties and has been in clinical use for more than three decades. It primarily acts on the central nervous system by modulating spinal reflex pathways, thereby reducing muscle tone without producing significant sedation, which distinguishes it from many conventional muscle relaxants. Clinically, Tolperisone is widely employed in the management of musculoskeletal and neurological conditions associated with increased muscle spasm. It is commonly prescribed for the treatment of acute and chronic back pain, where it helps in relieving painful muscle stiffness and improving mobility. In addition, it is indicated in spasticity of neurological origin, including conditions arising from upper motor neuron lesions, where it reduces involuntary muscle contractions and improves functional outcomes.

Beyond these primary indications, Tolperisone has also been utilized in a variety of other clinical conditions associated with smooth and skeletal muscle spasm. These include dysmenorrhoea, where it may help alleviate menstrual cramps by reducing uterine muscle tension, and climacteric complaints associated with menopausal transition. It has also been reported to provide therapeutic benefit in conditions such as lockjaw (trismus), where severe muscle rigidity affects jaw movement, and neurolathyrism, a neurological disorder characterized by spastic paralysis due to consumption of certain Lathyrus species.

2.2.CELECOXIB:

Celecoxib is a selective cyclooxygenase-2 (COX-2) inhibitor belonging to the class of sulfonamide-derived non-steroidal anti-inflammatory drugs (NSAIDs). It exerts its pharmacological action by selectively inhibiting the COX-2 enzyme, which is primarily responsible for the synthesis of pro-inflammatory prostaglandins at sites of inflammation, thereby reducing pain, inflammation, and fever while exhibiting comparatively reduced

gastrointestinal side effects than non-selective NSAIDs.

2.2.1. Structure:

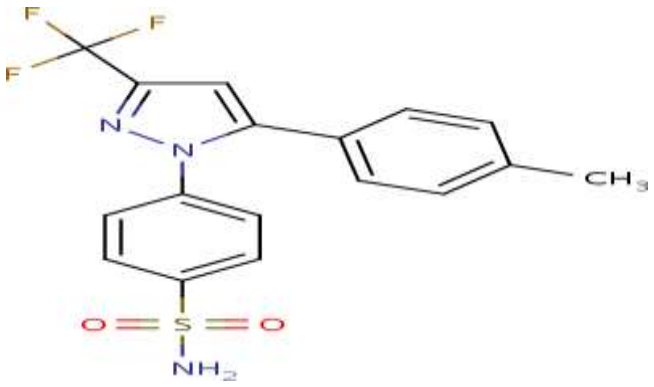

Fig 4. Structure of CELECOXIB

2.2.2. Chemical Information:

- **IUPAC Name:** 4-[5-(4-methylphenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide
- **Chemical Class:** Selective COX-2 inhibitor (Sulfonamide NSAID)
- **CAS Number:** 169590-42-5
- **Molecular Formula:** $C_{17}H_{14}F_3N_3O_2S$
- **Molecular Weight:** 381.37 g/mol

2.2.3. Physicochemical Properties:

- **Appearance:** White to off-white crystalline powder
- **Odor:** Odorless
- **Crystal Nature:** Stable crystalline solid

2.2.4. Pharmacology:

2.3.Excipeints:

2.3.1. Crospovidone:

- **Name: Crospovidone**
- **Synonym: Polyvinylpolypyrrolidone (PVPP)**
- **Chemical Class: Cross-linked polyvinylpyrrolidone**
- **Function: Superdisintegrant used in tablet and capsule formulations**
- **CAS Number: 9003-39-8**
- **Chemical name:** 1-Ethenyl-2-pyrrolidinone homopolymer
- **Structure:**

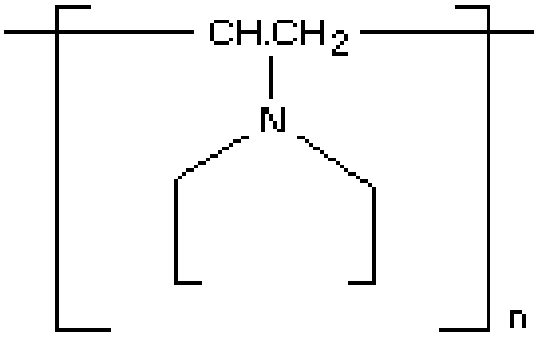

Fig 4. Structure of crospovidone

- **Functional Characteristics:**
- Acts as a superdisintegrant in fast dissolving tablets
- Promotes tablet breakup by wicking and rapid swelling
- Enhances drug release and dissolution rate
- Compatible with a wide range of active pharmaceutical ingredients

2.3.2. Sodium Starch Glycolate (SSG):

- **Name:** Sodium Starch Glycolate
- **Synonym:** Carboxymethyl starch sodium salt
- **Chemical Class:** Modified starch (cross-linked carboxymethylated starch)
- **Function:** Superdisintegrant in pharmaceutical formulations
- **CAS Number:** 9063-38-1

- **Appearance**: White to off-white, fine, free-flowing powder
- **Odor:** Odorless
- **Taste:** Tasteless
- **Nature:** Hydrophilic polymer with high swelling capacity
- **Solubility:** Practically insoluble in water, but swells rapidly in contact with water
- **pH (1% dispersion):** Approximately neutral (5.5–7.5)
- **Swelling Capacity:** Very high (forms a viscous gel upon hydration)
- **Moisture Content:** Slightly hygroscopic in nature
- **Structure:**

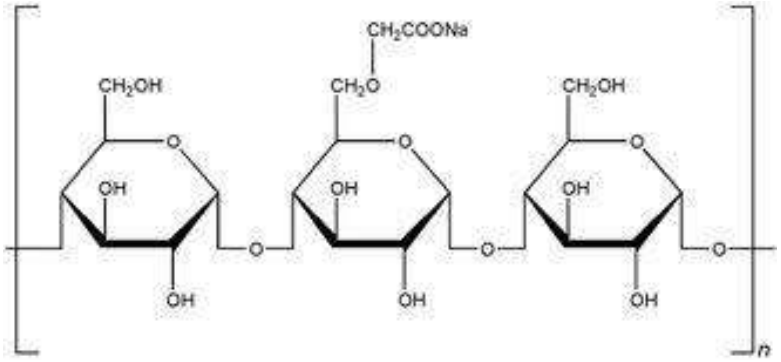

Fig 5. Structure of sodium starch glycolate

- **Functional Characteristics**
- Acts as a **superdisintegrant** in tablets and capsules
- Promotes disintegration through **rapid water uptake and swelling mechanism**
- Enhances **drug dissolution and bioavailability**
- Commonly used in **fast dissolving and immediate release formulations**
- Compatible with a wide range of active pharmaceutical ingredients

2.3.3. Microcrystalline Cellulose (MCC):

- **Name**: Microcrystalline Cellulose
- **Chemical Class:** Purified, partially depolymerized cellulose
- **Function:** Diluent, binder, and dry binder in solid dosage forms
- **CAS Number:** 9004-34-6
- **Appearance**: White, odorless, fine or granular crystalline powder
- **Taste**: Neutral / bland
- **Nature:** Insoluble, non-reactive excipient
- **Solubility:** Insoluble in water, dilute acids, and most organic solvents
- **Moisture Content:** Slightly hygroscopic
- **Compressibility**: Excellent (high compactibility and plastic deformation)
- **Flow Properties:** Good flow depending on grade (e.g., Avicel PH grades)
- **Structure:**

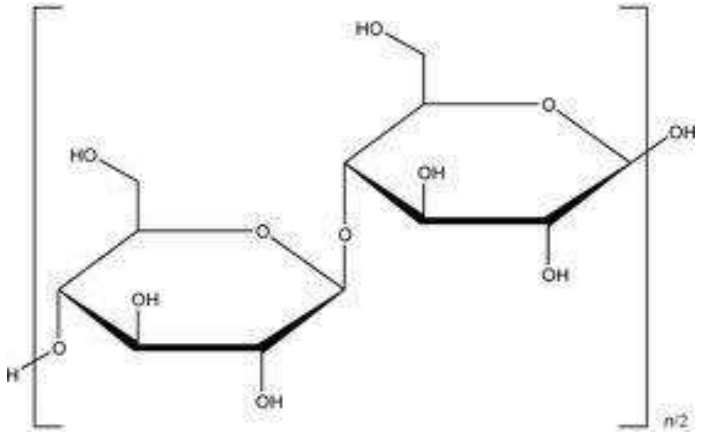

Fig.6. Structure of Microcrystalline cellulose.

Functional Characteristics

- Acts as a diluent (filler) in tablets and capsules
- Functions as a dry binder in direct compression

- Improves tablet hardness and mechanical strength
- Provides good compressibility and stability in formulations
- Commonly used in mouth dissolving tablets, fast disintegrating tablets, and conventional tablets

3. PREFORMULATION STUDIES:

Preformulation studies constitute a fundamental phase in pharmaceutical development, performed prior to formulation design. These investigations are essential for understanding the physicochemical characteristics of the drug substances and their compatibility with selected excipients. A well-executed preformulation study ensures the development of stable, effective, and reproducible pharmaceutical dosage forms with optimal therapeutic performance.

3.1.Determination of λmax

The determination of the wavelength of maximum absorption (λmax) is a critical parameter in UV–visible spectrophotometric analysis, as it represents the wavelength at which the drug exhibits maximum absorbance. Standard solutions of Tolperisone and Celecoxib (10 µg/mL) were prepared and scanned in the range of 200–400 nm using a UV–visible spectrophotometer.

The λmax values were found to be:

- **Tolperisone:** 260 nm
- **Celecoxib:** 252 nm

These wavelengths were subsequently selected for all further quantitative analytical estimations.

3.2.Preparation of Calibration Curve

Calibration curves were developed to establish the relationship between drug concentration and absorbance, thereby confirming adherence to Beer–Lambert's law.

Accurately weighed quantities of Tolperisone and Celecoxib (100 mg each) were dissolved separately in suitable solvents and the volume was adjusted to 100 mL to obtain stock solutions. Serial dilutions in the range of 1–10 µg/mL were prepared, and absorbance was measured at their respective λmax values.

The calibration curves were plotted by taking:

- **X-axis:** Concentration
- **Y-axis:** Absorbance

The resulting plots demonstrated linearity within the studied concentration range, confirming compliance with Beer–Lambert's law.

3.3.Drug–Excipient Compatibility Study (FTIR Analysis)

Drug–excipient compatibility was evaluated using Fourier Transform Infrared (FTIR) spectroscopy to detect any potential physicochemical interactions.

Principle:

FTIR spectroscopy identifies characteristic functional groups of the drug. Any interaction with excipients may lead to changes such as peak shifting, disappearance, or the appearance of new peaks.

Procedure:

Drug–excipient mixtures were triturated with potassium bromide (KBr) and analyzed over a spectral range of 4000–400 cm^{-1} using an FTIR spectrophotometer. The spectra of the physical mixtures were compared with that of the pure drug. The absence of significant changes in characteristic peaks indicated compatibility between the drug and excipients used in the formulation.

3.4.Solubility Analysis

Solubility studies were conducted to assess the solubility profile of the drugs in different solvents, as solubility plays a crucial role in dissolution, absorption, and overall bioavailability.

A small quantity of each drug was introduced into various solvents and agitated thoroughly. The solubility behavior was observed in:

- Water
- Methanol
- Ethanol
- Phosphate buffer

The extent of dissolution and presence of undissolved particles were recorded to evaluate the solubility characteristics of the drug substances.

3.5.Determination of Melting Point

Melting point determination was carried out as an indicator of drug purity.

Principle:

Pure substances exhibit a sharp and characteristic melting point range, whereas impurities generally cause depression and broadening of the melting range.

Procedure:

Drug samples were filled into sealed capillary tubes and placed in a melting point apparatus.

The temperature at which complete melting occurred was recorded and compared with standard reference values.

4. PREPARATION OF MOUTH DISSOLVING TABLET:

4.1.Procedure:

1. All formulation ingredients were accurately weighed according to the composition specified for each batch.
2. The active pharmaceutical ingredients and excipients were blended thoroughly using a mortar and pestle to

ensure uniform distribution of the components within the powder mixture.

3. The resulting powder blend was passed through sieve number 60 to achieve uniform particle size distribution and improve flow characteristics.

4. Lubricants and glidants were subsequently incorporated into the sieved blend and mixed uniformly to facilitate the compression process and minimize friction during tablet manufacture.

5. The final lubricated blend was compressed into tablets using a tablet compression machine fitted with flat-faced punches under appropriate compression force.

6.

4.2.Formulation Tables:

Table 1. Formulation of mouth dissolving Tolperisone tablets

Ingredients	**T1**	**T2**	**T3**	**T4**	**T5**	**T6**	**T7**	**T8**
Crospovidone	8	8	8	8	10	10	10	10
Tolperisone	150	150	150	150	150	150	150	150
Sodium Starch Glycolate	7	9	11	13	7	9	11	13
Microcrystalline Cellulose	20	20	20	20	20	20	20	20
Mannitol	114	112	110	108	112	110	108	106
Magnesium Stearate	3	3	3	3	3	3	3	3
Talc	1	1	1	1	1	1	1	1
Aspartame	2	2	2	2	2	2	2	2
Total Weight	305	305	305	305	305	305	305	305

Table 2. Formulation of mouth dissolving Celecoxib tablets

Ingredients	**C1**	**C2**	**C3**	**C4**	**C5**	**C6**	**C7**	**C8**
Celecoxib	100	100	100	100	100	100	100	100
Crospovidone	4	4	4	4	6	6	6	6
Sodium Starch Glycolate	4	6	8	10	4	6	8	10
Microcrystalline Cellulose	15	15	15	15	15	15	15	15
Mannitol	90	88	86	84	88	86	84	82
Magnesium Stearate	2	2	2	2	2	2	2	2
Talc	1	1	1	1	1	1	1	1
Aspartame	2	2	2	2	2	2	2	2
Total Weight	218	218	218	218	218	218	218	218

5. RESULT:

5.1.Post compression evaluation of Tolperisone mouth dissolving tablets:

The post-compression parameters of Tolperisone tablets were found within acceptable limits.

- The tablet weight variation was found within pharmacopeial limits indicating uniform die filling.
- Thickness of tablets indicated uniform compression.
- Friability values below 1% confirmed good mechanical strength.
- Hardness values suggested adequate tablet integrity.

Table 3. Evaluation of Tolperisone mouth dissolving tablets

Paramet ers	T1	T2	T3	T4	T5	T6	T7	T8
Uniformi ty weight (mg)	305.18±1.15	304.92±1.04	305.31±1.27	304.87±1.18	305.44±1.36	304.96±1.25	305.22±1.14	305.08±1.19
Thicknes s (mm)	3.18±0.02	3.26±0.03	3.32±0.01	3.40±0.02	3.28±0.03	3.35±0.02	3.48±0.01	3.56±0.03
Friability (%)	0.31±0.01	0.28±0.03	0.25±0.01	0.23±0.02	0.27±0.01	0.24±0.02	0.19±0.01	0.18±0.01
Hardness (kg/cm²)	3.12±0.04	3.24±0.02	3.31±0.03	3.42±0.04	3.35±0.03	3.48±0.02	3.65±0.01	3.58±0.02
Drug content (%)	98.14±0.15	98.72±0.18	99.08±0.12	99.24±0.14	98.83±0.16	99.15±0.11	99.62±0.09	99.38±0.13

The results showed that all the formulations possessed acceptable hardness and friability, confirming adequate mechanical resistance. Drug content uniformity indicated homogeneous mixing of ingredients. Among all formulations, T7 and T8 exhibited superior post-compression characteristics due to optimized concentration of superdisintegrants.

5.2.Evaluation of Wetting Time of Tolperisone Mouth Dissolving Tablets

Wetting time is considered an important evaluation parameter for mouth dissolving tablets, as it reflects the time required for saliva or dissolution medium to penetrate the tablet matrix and initiate the disintegration process. A shorter wetting time is indicative of rapid hydration of the tablet, which subsequently facilitates faster disintegration and drug release within the oral cavity.

In the present study, the wetting time of Tolperisone mouth dissolving tablets decreased progressively with increasing concentrations of the superdisintegrants, Crospovidone and Sodium Starch Glycolate. This reduction in wetting time can be attributed to the enhanced water uptake and swelling properties of these excipients, which promote rapid penetration of the dissolution medium into the tablet matrix and accelerate tablet disintegration.

Table.4. Wetting Time of Tolperisone Mouth Dissolving Tablets

Formulati on	Wetting Time (sec)
T1	34.62±0.04
T2	31.48±0.06
T3	28.94±0.08
T4	25.36±0.12
T5	27.82±0.05
T6	23.17±0.11
T7	19.84±0.07
T8	16.28±0.09

The observed reduction in wetting time was attributed to the enhanced capillary action and superior water uptake capacity of the superdisintegrants employed in the formulation. Crospovidone facilitated rapid water penetration through its pronounced wicking mechanism, whereas Sodium Starch Glycolate contributed through extensive swelling upon hydration. Consequently, formulations T7 and T8 exhibited significantly shorter wetting times, indicating rapid tablet hydration and efficient disintegration due to the optimized concentration of superdisintegrants incorporated in these formulations.

5.3.Evaluation of Water Absorption Ratio:

The water absorption ratio is an important parameter that reflects the ability of a tablet to rapidly absorb water, thereby facilitating faster hydration of the tablet matrix and promoting rapid disintegration.

Table 5. Water Absorption Ratio of Tolperisone Mouth Dissolving tablets

Formulation	Water Absorption Ratio
T1	41.26±1.05
T2	48.37±1.14
T3	55.28±1.21
T4	66.45±1.17
T5	53.84±1.08
T6	63.72±1.16
T7	71.34±1.12
T8	78.52±1.24

The water absorption ratio increased progressively with increasing concentrations of the superdisintegrants incorporated in the formulations. The enhanced water uptake capacity promoted rapid swelling of the disintegrant particles, resulting in efficient disruption and disintegration of the tablet matrix. Among all the formulations evaluated, formulation T8
exhibited the highest water absorption ratio, indicating superior hydration characteristics and enhanced disintegration performance.

5.4.Evaluation of In-vitro Disintegration Time:

Disintegration time is one of the most critical quality attributes of mouth dissolving tablets, as it directly influences the rate of drug release and onset of therapeutic action. Rapid
disintegration within the oral cavity is essential to ensure patient convenience, improved compliance, and enhanced bioavailability of the drug.

Table 6. In-vitro Disintegration Time of Tolperisone Mouth Dissolving Tablets

Formulation	Disintegration Time (sec)
T1	37.12±0.06
T2	34.48±0.08
T3	31.76±0.12
T4	28.52±0.07
T5	30.18±0.11
T6	26.47±0.08
T7	23.84±0.05
T8	19.42±0.04

The disintegration time decreased significantly with increasing concentrations of Crospovidone and Sodium Starch Glycolate in the formulations. This reduction in disintegration time can be attributed to the rapid swelling behavior of Sodium Starch Glycolate and the efficient wicking action of Crospovidone, which facilitated the penetration of

the dissolution medium into the tablet matrix and promoted rapid tablet disintegration. Among the formulations evaluated, T7 and T8 demonstrated superior disintegration characteristics, exhibiting considerably shorter disintegration times compared to the other batches. However, formulation T7 provided a more favorable balance between mechanical strength and rapid disintegration, indicating its suitability as the optimized formulation for mouth dissolving tablet development.

5.5.In-vitro Drug Release Study of Tolperisone Mouth Dissolving Tablets:

The in-vitro dissolution studies demonstrated rapid drug release from all prepared mouth dissolving tablet formulations of Tolperisone. The dissolution profile indicated that formulations containing higher concentrations of superdisintegrants exhibited significantly enhanced drug release characteristics. The improved dissolution behavior can be attributed to the rapid disintegration and increased surface area available for drug dissolution resulting from the efficient swelling and wicking mechanisms of the superdisintegrants. Consequently, formulations with optimized concentrations of Crospovidone and Sodium Starch Glycolate showed faster and more complete drug release compared to formulations containing lower concentrations of these excipients.

Table 7. In-vitro Drug Release Study of Tolperisone Mouth Dissolving Tablets

Time (min)	T1	T2	T3	T4	T5	T6	T7	T8
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2	24.36	25.74	27.18	29.25	28.47	30.16	33.84	36.25
4	40.52	43.18	47.36	50.27	48.92	53.18	58.74	69.42
8	58.43	63.27	68.16	72.58	69.43	74.62	81.24	88.35
12	74.16	79.35	83.52	87.18	85.74	89.26	94.18	98.54
14	82.47	88.54	91.26	94.73	92.84	96.18	99.42	-

The dissolution profiles demonstrated rapid drug release from all the prepared mouth dissolving tablet formulations of Tolperisone. The enhanced dissolution behavior was primarily attributed to the rapid disintegration of the tablet matrix and improved wettability imparted by the incorporated superdisintegrants. Among the formulations evaluated, formulation T7 exhibited an optimal drug release profile while maintaining satisfactory mechanical strength and rapid disintegration characteristics, thereby representing the most balanced formulation. Although formulation T8 showed comparatively faster drug release, a slight reduction in mechanical integrity and increased fragility were observed, which may be attributed to the higher concentration of superdisintegrants incorporated in the formulation. The mechanism of drug release from the mouth dissolving tablets was predominantly governed by the combined effects of capillary action (wicking), swelling of the superdisintegrants upon hydration, and increased porosity of the tablet matrix. These
mechanisms facilitated rapid penetration of the dissolution medium into the tablet structure, resulting in efficient tablet disintegration and enhanced drug dissolution.

5.6. Evaluation of Celecoxib Mouth Dissolving Tablets:

The prepared Celecoxib mouth dissolving tablets were evaluated for various physicochemical and performance parameters to assess their quality and suitability as a fast-dissolving oral
dosage form. The evaluation results demonstrated satisfactory tablet characteristics, including acceptable mechanical properties and uniformity parameters, along with a rapid drug release profile. These findings indicate the successful development of mouth dissolving tablets
capable of providing prompt drug dissolution and potential enhancement in therapeutic efficacy and patient compliance

Table 8. Evaluation of Celecoxib Mouth Dissolving Tablets

Param et er	C1	C2	C3	C4	C5	C6	C7	C8
Unifor mi of weight (mg)	218.26 ±1 .12	217.84 ±1 .24	218.15 ±1 .18	217.62 ±1 .32	218.44 ±1 .21	217.91 ±1 .26	218.52 ±1 .16	218.07 ±1 .28
Thickn es s (mm)	2.32±0. 0 1	2.44±0. 0 2	2.56±0. 0 3	2.68±0. 0 2	2.42±0. 0 1	2.51±0. 0 3	2.74±0. 0 2	2.82±0. 0 1

Friabili ty (%	0.24±0.02	0.21±0.01	0.18±0.03	0.16±0.02	0.19±0.01	0.17±0.02	0.15±0.01	0.14±0.01
Hardne (kg/cm^2)	3.24±0.02	3.36±0.01	3.41±0.03	3.58±0.02	3.33±0.01	3.46±0.02	3.68±0.03	3.54±0.02
Drug conte n (%)	98.42±0.08	98.86±0.11	99.12±0.14	99.24±0.09	98.94±0.15	99.31±0.12	99.64±0.10	99.38±0.13

5.7.Wetting Time of Celecoxib Mouth Dissolving Tablets

Table 9. Wetting Time of Celecoxib Mouth Dissolving Tablets

Formulati on	**Wetting Time (sec)**
C1	26.42±0.08
C2	24.37±0.11
C3	21.18±0.07
C4	18.54±0.06
C5	21.92±0.09
C6	18.36±0.05
C7	15.18±0.04
C8	12.46±0.03

5.8.Water Absorption Ratio of Celecoxib Mouth Dissolving Tablets:

Table 10. Water Absorption Ratio of Celecoxib Mouth Dissolving Tablets

Formulati on	**Water Absorption Ratio**
C1	42.36±1.04
C2	50.18±1.15
C3	61.42±1.24
C4	72.38±1.42
C5	58.16±1.18
C6	68.52±1.33
C7	76.84±1.27
C8	86.48±1.36

5.9.In-vitro Disintegration Time of Celecoxib Mouth Dissolving Tablets

Table 11. In-vitro Disintegration Time of Celecoxib Mouth Dissolving Tablets

Formulati on	Disintegration Time (sec)
C1	30.46±0.09
C2	28.17±0.08
C3	24.82±0.06
C4	19.36±0.04
C5	24.54±0.07
C6	23.68±0.05
C7	20.12±0.03
C8	16.82±0.02

5.10 In-vitro Drug Release Study of Celecoxib Mouth Dissolving Tablets

Table : In-vitro Drug Release Study of Celecoxib Mouth Dissolving Tablets

Time (min)	C1	C2	C3	C4	C5	C6	C7	C8
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
2	22.84	24.35	26.48	28.16	27.25	29.74	32.16	35.28
4	38.52	41.84	46.35	49.82	47.26	51.74	57.28	67.36
8	56.43	61.28	67.84	72.48	69.37	74.28	80.46	87.18
12	72.64	77.46	82.35	86.54	84.16	88.42	93.16	97.52
14	80.26	86.18	90.52	94.36	91.28	95.14	99.28	-

6. CONCLUSION:

The prepared formulations exhibited satisfactory physicochemical characteristics with respect to weight variation, thickness, hardness, friability, and drug content, indicating acceptable tablet quality and uniformity. The incorporation of Crospovidone and Sodium Starch Glycolate as superdisintegrants significantly influenced the performance of the mouth dissolving tablets by reducing wetting time and disintegration time while increasing the water absorption ratio and dissolution rate. For Tolperisone formulations, increasing concentrations of superdisintegrants resulted in improved tablet hydration, rapid disintegration, and enhanced drug release. Among the formulations evaluated, formulation T7 demonstrated the most favorable balance between mechanical strength, rapid disintegration, and dissolution performance, and was therefore identified as the optimized formulation. Although formulation T8 exhibited slightly faster drug release, it showed comparatively lower mechanical integrity due to the higher concentration of superdisintegrants.

Similarly, Celecoxib mouth dissolving tablets exhibited satisfactory post-compression characteristics and rapid dissolution behavior. Formulations containing higher concentrations of superdisintegrants demonstrated improved wetting, faster disintegration, and enhanced drug release profiles. Among the Celecoxib formulations, C7 provided an optimum combination of tablet strength and rapid dissolution characteristics, whereas C8 showed the fastest drug release but exhibited relatively higher fragility. The enhanced drug release observed in both drug formulations was

primarily attributed to the combined effects of capillary action, swelling of superdisintegrants, and increased porosity of the tablet matrix. These mechanisms facilitated rapid penetration of the dissolution medium into the tablet structure, resulting in efficient disintegration and accelerated drug dissolution.

Overall, the developed mouth dissolving tablets of Tolperisone and Celecoxib demonstrated excellent pharmaceutical performance and represent promising patient-friendly dosage forms capable of providing rapid onset of action, improved bioavailability, enhanced therapeutic efficacy, and better patient compliance, particularly among pediatric, geriatric, dysphagic, and bedridden patients.

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