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## Review Article

# A Review on Nanoparticles Loaded Mouth Dissolving Films A Novel Approach for Delivery of Poorly Water-Soluble Drug

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## ABSTRACT

Oral drug delivery is considered the most preferred route for the administration of active pharmaceutical ingredients (APIs) due to its ease of administration and high level of patient compliance. However, more than 50% of APIs face significant challenges in the development of orally administered dosage forms, primarily due to poor aqueous solubility and low oral bioavailability, particularly in Biopharmaceutical Classification System (BCS) Class II and IV drugs. This review focuses on the concept of fast dissolving films (FDFs) incorporated with nanoparticles as an innovative drug delivery system to enhance patient compliance. In this approach, a variety of polymers are utilized to improve therapeutic efficacy while minimizing toxic and adverse effects. Nanoparticles, typically in the nanometre size range, protect APIs from both in vitro and in vivo degradation and improve pharmacokinetic and pharmacodynamic properties. Although conventional dosage forms such as tablets, capsules, suspensions, and emulsions are widely available, they may not be suitable for all patient groups, especially paediatric and geriatric populations. Fast dissolving films loaded with nanoparticles (NPs) offer a promising strategy to overcome solubility limitations and achieve rapid onset of action. Additionally, these systems help address swallowing difficulties (dysphagia), improving convenience of administration, safety, and overall therapeutic efficacy. This innovative dosage form holds significant potential in the pharmaceutical market and offers a targeted and efficient drug delivery approach.

## INTRODUCTION

Orally Ingested is one of the best ways to administer an active agent because of it

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convenient, highly appropriate non-invasive patient adherence, the cheapest economic conditions, the least sterility limitations and versatility in the nature of dosage forms among the various other route of drug-delivery systems. In the design of orally delivered dosage forms, more than 40–50 percent of APIs meet the major challenges of their low oral bioavailability, due to aqueous solubility, permeation of drug, rate of dissolution, pre-systemic metabolism, and effluence susceptibility. Low oral bioavailability has the key explanation for patients being given less plasma concentration and drug action. Based on the literatures, aqueous solubility in high level, which provides the desired characteristic for therapeutic efficacy of the drug molecules and low aqueous solubility. [1]

The present pharmaceutical delivery system contains over 90% of drugs, the majority of which have low water solubility. In a similar way, 60% of drugs now being studied fall under Biopharmaceutical Classification System (BCS) Class II & IV, where the bioavailability is constrained by the rate of dissolution. New therapeutic compounds with these features of limited solubility were discovered in recent developments in combinatorial chemistry. Telmisartan is commonly used in the management of hypertension but suffer from poor aqueous solubility, leading to low and variable bioavailability. To address this issue, nanoparticles-based formulation has been explored. Drug-loaded nanoparticles disperse in the oral film have certain advantages over the normal film like a higher rate of absorption in mucosal membrane and higher mucoadhesive properties. these nanoparticles were characterized in terms of size, charge, morphology, drug loading and drug release. Their properties are optimized in term of weight, thickness, folding endurance, surface pH. Rapidly dissolving or quick dissolving

dosage forms have acquired great importance in the pharmaceutical industry due to their unique properties and advantages. They undergo disintegration in the salivary fluids of the oral cavity within a minute, where they release the active pharmaceutical ingredient. The major amount of the active pharmaceutical ingredient is swallowed orally with the saliva where subsequent absorption takes place in the gastrointestinal tract. The rapidly dissolving dosage forms are referred by various names by researchers like quick disintegrating, orally disintegrating, mouth dissolve or melt in mouth dosage forms. These dosage forms possess certain specific advantages like no need of water for disintegration, accurate dosing, rapid onset of action, ease of transportability, ease of handling, pleasant taste and improved patient compliance. [5]

Telmisartan (TLM) is an antihypertensive agent which is a nonpeptide angiotensin receptor II antagonist, that cause inhibition of the action of angiotensin II on vascular smooth muscle in the symptomatic treatment of hypertension. The major drawback of this drug is its low aqueous solubility. It is insoluble in water and hence the drug may be slowly or incompletely dissolved in the gastro intestinal tract. The bioavailability of TLM is poor about 45%, which is due to extensive first pass hepatic metabolism. The available formulation of TLM in market is an immediate release tablet. Conventional TLM tablets are not suitable where quick onset of action is required. To provide the patients with the most convenient mode of administration, there is a need to develop rapidly dissolving dosage form, particularly one that disintegrates and dissolves/disperses in saliva and can be administered without need of water. Fast dissolving films are useful in patients such as paediatric, geriatric, bedridden, or developmentally disable who may face difficulty in swallowing conventional tablets. So, the

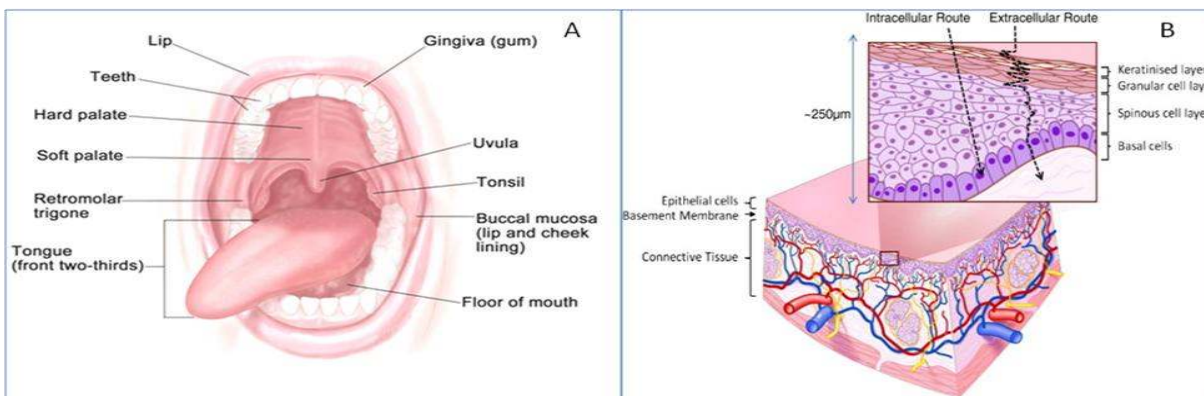


patients would be benefited from acute treatment by using proposed drug delivery system. Thus, a fast dissolving film is a unique solid oral dosage form and has valuable advantages. [3]

Initial investigations were focused on the development of placebo fast dissolving films with good peel ability, appearance and a quick disintegration time. After choosing the components for the placebo film, TLM loaded

films were formulated. Although, fast dissolving film is an attractive dosage form for the delivery of TLM, its poor water solubility is a real challenge in the development of fast dissolving films. Finally, fast dissolving films using hydroxypropyl methylcellulose (HPMC) and polyvinyl alcohol (PVA) were formulated and evaluated.

### Oral drug delivery



#### Advantages:

- Improves oral bioavailability of drugs with poor aqueous solubility.
- Enables effective taste masking of bitter drugs using suitable techniques.
- Enhances patient compliance due to ease of administration and provides rapid onset of action.
- Offers potential for targeted drug delivery and may help reduce the required dose.
- Bypasses hepatic first-pass metabolism through absorption via the oral mucosa.
- Improves overall stability and bioavailability of the formulation.

#### Hypertension

Hypertension is one of the most common chronic cardiovascular disorders worldwide and is a major contributor to both morbidity and mortality. Long-term pharmacological treatment is often required for its management. However, conventional oral

dosage forms may present several limitations, including variable gastrointestinal absorption, extensive hepatic first-pass metabolism, and fluctuations in plasma drug concentration.

These challenges have led to the development of alternative drug delivery systems that can maintain consistent therapeutic drug levels over extended periods and improve treatment outcomes. [2]

#### Telmisartan as a Candidate for oral drug delivery

Telmisartan is a selective angiotensin II receptor antagonist widely used in the treatment of hypertension. It exhibits strong antihypertensive activity and is generally effective when administered orally. However, its bioavailability can be limited due to poor solubility and absorption-related factors. It is primarily indicated for the management of hypertension and reduction of cardiovascular risk. To overcome its limitations, researchers have explored alternative delivery

approaches, including transdermal and novel oral systems, to enhance systemic availability and maintain sustained therapeutic concentrations. (3)

### Drug Profile of Telmisartan

Telmisartan is an angiotensin II receptor blocker commonly prescribed for the treatment of hypertension and cardiovascular disorders. It selectively blocks the binding of angiotensin II to AT1 receptors, resulting in vasodilation and reduction of blood pressure.

#### Physicochemical Properties

Molecular Formula: C<sub>33</sub>H<sub>30</sub>N<sub>4</sub>O<sub>2</sub>

Molecular Weight: 514.62 g/mol

Category: Antihypertensive Agent

Mechanism: Angiotensin II Receptor Antagonist

### Nanoparticles in Drug Delivery:

Nanoparticles are submicron-sized carriers that improve drug solubility, stability, and bioavailability. Techniques such as solvent evaporation, nanoprecipitation, and high-pressure homogenization are commonly used for nanoparticle preparation. Polymers like poloxamer, PLGA, and chitosan are widely employed to stabilize nanoparticles and control drug release.

### Fast Dissolving Films (FDFs):

Fast dissolving films are thin polymeric strips designed to disintegrate quickly upon contact with saliva. Common film-forming polymers include HPMC, PVA, and pullulan. Plasticizers such as PEG 400 enhance flexibility, while sweeteners and flavouring agents improve palatability.

### Formulation Strategy:

The formulation of nanoparticles loaded FDFs typically involves two steps:

Preparation of drug-loaded nanoparticles.

Incorporation of nanoparticles into film-forming polymer matrix via solvent casting method.

Critical formulation parameters include polymer concentration, plasticizer ratio, drug loading efficiency, and film thickness.

### Ideal Properties of Oral Film:

- It should have an acceptable taste.
- Pleasant mouth feels.
- Rapid disintegration <30 sec when placed on the tongue.
- It should be less friable and have good mechanical strength.
- It should have stable in environmental conditions.
- Film quickly dissolve to release a drug in the mouth.

### Reason for Selection of ofdf

The drug therapy and the target population are the two critical issues for the design of an oral dosage forms. Based on the pediatric, 8–10 years old and geriatric people group.

The dosage form sizes have also been a challenge, particularly due to swallowing difficulties. Typically, the swallowing function is underlying an aging process and then few malfunctions may be age-related, generally called as presbyopia, but due to pathological conditions is referred as dysphagia. For this reason, the ofdf appeared as suitable to patients with swallowing difficulties



and comfortable dosage form compared with other conventional oral dosage forms.

### **Poorly Aqueous soluble drug (BCS II and BCS IV)**

**Drug with nanoparticles:** Increases solubility, increase bioavailability and prevent drug from degradation.

**Nanoparticles incorporated films:** Avoid pre-systemic action, avoid dysphagia, no need of water and better patient compliances.

### **Benefits of Nanoparticle loaded in the oral film:**

- Increased bioavailability
- Rapid onset of action.
- Better drug stability.
- Improved patient compliances
- Reduced drug dose requirement.
- Uniform drug distribution in the film
- Improved mechanical properties of film.
- Suitable for paediatric and geriatric population.

### **Limitations:**

- Stability issues
- Moisture sensitivity
- Limited drug loading capacity
- Manufacturing challenges
- Taste masking difficulties
- Drug polymer or drug nanoparticles interaction.
- Requirement for specialized equipment.

### **Formulation Strategy of Poorly Water-Soluble Drugs via Nanotechnology**

Poor aqueous solubility remains a major barrier in the development of orally, parentally and trans dermally delivered therapeutics with nearly 40-60% of new chemical entities falling under BCS

class second or fourth. Nanotechnology-based drug delivery system NDDS have emerged as a versatile platform to enhance solubility, dissolution rate, permeability, and bioavailability. These nanotechnology approaches exploit particle size reduction, surface engineering, and Nano-scale carriers to improve physicochemical and biopharmaceuticals properties.

### **NP AS CARRIER FOR DELIVERY OF DRUG THROUGH ORAL FAST-DISSOLVING FILMS (OFDFS)**

Further these NPs are processed for solid dosage forms like capsule filling or compressed into tablets. This indicates that conversion of NPs in patients friendly and acceptable dosage form involves several stages which are complicated and time consuming. Approximately 60% of all dosage forms are available in tablet and capsule forms in pharmacy but those are not suitable for all age groups and patients. Regarding children, elderly people or patients with swallowing problems, the oral dosage form must be adjusted. For the reason of less bioavailability and the longer onset action for patients with dysphasia, the manufacturers turned to parenteral and liquid oral dosing forms. The parenteral medication is painful and the liquid oral formulations such as syrup, suspension and emulsion have a problem with accurate dosing. Based on literature survey, the formulation of an OFDF with drug NPs is one of the best strategies for enhancing the poorly soluble drugs. This approach is becoming more important as an alternative, modern method of API delivery to meet current industry and consumer needs in terms of patient acceptance. The rationale of NPs incorporated OFDFs formulations Cryoprotectants must be utilized.

The NPs preparation is simple and also suitable for water insoluble drugs. In that several formulation parameters such as aqueous solubility, humidity,



stability at ambient temperature, photo stability, compatibility with solvent system and additives performs a crucial role in the successful formulation of drugs. Based on literature NP formulation can be suitable to drugs with BCS classes II, III and IV to increasing their solubility and thus partition into the gastrointestinal barrier.

## List of different excipients used in formulation of nanoparticles

### 1. Stabilizers

Stabilizers are added to maintain the stability of nanosuspensions, polymeric nanoparticles, and lipid-based carriers. The particle size and overall stability depend on the type and concentration of the stabilizer used. Common examples include non-ionic surfactants such as poloxamer 188, poloxamer 407, Tween 20, Tween 40, Tween 80, and polyethylene glycol (PEG) derivatives.

### 2. Co-surfactants

Co-surfactants assist in the formation and stabilization of nanosuspension. They improve interfacial fluidity and enhance drug solubilization. Frequently used co-surfactants include ethanol, propylene glycol, PEG 400, glycerol, and polyglycol ethers.

### 3. Organic Solvents

Selection of an appropriate organic solvent is critical for nanoparticle preparation. The solvent should possess suitable physicochemical properties and a high capacity to dissolve both the drug and polymer. It significantly influences particle size, drug entrapment efficiency, and overall formulation performance. Commonly used solvents include methanol, ethanol, chloroform, isopropanol, and ethyl acetate.

### 4. Other Additives

Additional excipients may be incorporated depending on the route of administration and physicochemical properties of the drug.

**Buffers:** Used to maintain and control the pH of the formulation, thereby enhancing stability. However, interactions with environmental conditions may sometimes affect system performance.

**Polyols:** Polyhydric alcohols that act as solvents and mild reducing agents. They also assist in stabilizing nanoparticle systems.

**Osmogenes:** Utilized in double emulsion (W/O/W) solvent evaporation techniques to produce porous nanoparticles and improve formulation characteristics.

## Types of nanoparticles used in FDFs

- **Polymeric nanoparticles:** Made of PLGA, PCL, chitosan, eudragit.
  - Suitable for sustained or controlled release fast release.
  - can encapsulate hydrophilic and hydrophobic drug.
- **Lipid based nanoparticles:** Solid lipid nanoparticles (SLN),
  - Nanostructured lipid carrier (NLC)
  - Improve solubility of poorly water-soluble drugs
  - Provide protection against degradation.
- **Nano emulsion:** Excellent for lipophilic drugs.
  - Offer rapid absorption due to small droplet size.

## Methods of preparation of Nanoparticles



**1. Solvent Evaporation:** In solvent evaporation method, the polymer dissolved in suitable organic solvent like dichloromethane, ethyl acetate or ethyl acetate chloroform which is also used as the solvent for dissolving the hydrophobic drug. Drug is dispersed into this solution. Then the polymer and drug solution mixture emulsified in an aqueous phase containing surfactant or emulsifying agent (such as polysorbates, poloxamer, sodium dodecyl sulphates, poloxamer, polyvinyl alcohol, gelatine) to prepare oil in water (o/w) type of emulsion by using mechanical stirring, sonication, or micro fluidization (high-pressure homogenization through narrow channels). After the emulsion formation, the added organic solvent is evaporated by the increased temperature and the reduced pressure when continuous stirring. In this, based on the type and concentrations of stabilizer the particle size can be influenced.

**2. Solvent Diffusion:** This is a redesigned version of the process of solvent evaporation. In this case, the polymer is dissolved in an aqueous solution which contains stabilizing agents. This dissolves the polymer in the water miscible solvent, such as propylene, benzyl alcohol etc. According to the ratio between oil and polymer, that above solvent diffuses to the external phase and the nanospheres or Nano capsules are formed. Because of the spontaneous diffusion of solvents, the small particles are formed between two phases because of interfacial turbulence. Whereas the water concentration may increase miscible solvent, the reduction in particle size may be achieved. Hydrophilic or hydrophobic drugs can be used both in the solvent evaporation process and in the solvent diffusion process. In the case of hydrophilic drug, the drug dissolved in the internal aqueous phase must form a multiple emulsion w/o/w.

**3. Solvent Displacement or Nanoprecipitation Method:** This method involves precipitation of a preformed polymer from an organic phase, and with the presence or absence of a surface-active agent, the organic phase diffuses into the aqueous phase. Polymers encapsulated, the API or lipophilic surfactant are dissolved in water, in Therapeutic Drug Carrier Systems Nanoparticle-Loaded Oral Fast-Dissolving Film by co-solvents like acetone (used in making the internal phase more homogenous) or ethanol (semi-polar water-compatible solvent). Then this solution is poured into a magnetic stabilizer-containing aqueous solution. The NPs are rapidly formed, and the solvent is separated from the mixture with reduced pressure by the action of rapid solvent diffusion. The approach is used for drugs which are poorly water soluble. The scale, release, and yield of nanospheres have been shown to be affected by changing the preparation parameters. To formulate smaller nanospheres, the modification of the polymer concentration in organic solution is found to be useful with a restricted range of polymer to drug ratios.

**4. Polymerization Method:** In this manner, monomers are polymerized in an aqueous solution as NPs. After the polymerization process, this drug is either incorporated or dissolved into the polymerization media or absorbed into the NPs. The NP suspension is then purified in an isotonic ally surfactant-free medium to extract various stabilizers and surfactants used to ultracentrifuges and re-suspend particles for polymerisation.

**5. Coacervation or Ionic Gelation Method:** The process involves the precipitation of a preformed polymer with an organic phase and the organic layer diffused with or without surface-active substances into the aqueous phase. The preparation of NPs is performed with biodegradable and hydrophilic polymers such as



chitosan, sodium alginate and gelatine, which are developed using a coacervation technique. The development of hydrophilic chitosan NPs was first developed and reported by Calvo and Janes using two aqueous phases, using the ionic gelation method. In the first phase, it includes polymers such as chitosan, co-polymer such as ethylene or propylene oxide and chitosan dissolved in analytical acetic acid with or without stabilizer. Polyanion sodium tripolyphosphate is present in the second phase. The two phases were mixed, and an electropositive loaded amino group of the chitosan interacts with the electrically negative loaded tripolyphosphate to produce nanometre level coacervates. The surface charge of particles can be adjusted depending on the chitosan and stabilizer ratio.

**6. Double Emulsification Method:** There is limited entrapment of hydrophilic drugs in emulsification and evaporation method, and therefore a double emulsification technique is used. Firstly, water in oil emulsion, prepared with continuous stirring by adding aqueous drug solution to the organic polymer solution. This produced an aqueous phase of emulsion again, with a vigorous agitation, produced w/o/w emulsion, then separated by using strong centrifugation the organic solvent.

## **CHARACTERIZATION OF NANOPARTICLES**

**1) particle size analysis:** The particle size should be less than 1000 nm in nanoparticles. It was analysed by using Malvern particle size analyser. Particles in the size range of colloids display constant random thermal motion which is known as Brownian motion. This motion causes the intensity of light scattered by the particles to vary with time. The larger the particle slower their motion and hence the smaller the variation in intensity of light scattered.

**2) zeta potential:** zeta potential of nanoparticles was measured by Malvern zeta sizer mainly consist of laser which is used to provide a light source to illuminate the particles within the sample.

**3) Entrapment efficiency:** 2ml of Telmisartan nanosuspension dispersion was centrifuged for about 30minutes. The supernatant was diluted up to 10ml and suitable concentrations were prepared with methanol to produce a concentration within beer's range and the absorbance was measured at 296nm using UV visible spectrophotometer.

$$Ee \% = \frac{W (\text{added Drug}) - W (\text{free Drug})}{W (\text{added Drug})} \times 100$$

## **COMPOSITION OF ORAL FILM**

- Active pharmaceuticals ingredients
- Film forming polymer
- Plasticizer
- Saliva stimulating agent
- Surfactant
- Flavours
- Colouring agent

**Methods used for manufacturing oral film:**  
**Following are methods used for manufacturing oral film.**

- Solvent casting method
- Semisolid casting method
- Hot melt extrusion
- Solid dispersion extrusion
- Rolling method

**1.Solvent Casting Method:** In the technique of solvent casting, the hydrophilic film forming polymers is dissolved in distilled water. The drug molecule and the remaining adjuvants, such as colouring agent, flavouring agents, and sweeteners, are dissolved in an appropriate amount of solvent system. Both solutions are mixed with a high shearing process and stirred to be homogeneous. The vacuum used to remove the air trapped and finally poured into the Petri plates then dried and cut to uniform dimensions ( $2 \times 2$  cm).

**2.Semi-Solid Casting Method:** This approach is favoured in the formulation of OFDFs using acid-insoluble polymers. This has two stages; the aqueous soluble polymer has been dissolved in distilled water in the first step. The insoluble polymer in acid is dissolved in an effective solvent solution in the second step. Then the two phases are combined, and the above mixture is supplied with an appropriate quantity of the plasticizer for the creation of a gel mask. Finally, by using heat control drums, it is cast in ribbons or films. The thickness of the film should be within 0.015–0.05 inches. For this process, a ratio of 4:1 should be used for film formation and acid-insoluble polymers.

**3.Hot Melt Extrusion Method:** This technique first requires the combination of a drug molecule with a solid carrier to form granular material. Those granules are then dried and put into the extruder where the granules are melted by heaters. The velocity of the screw will vary between 4 and 15 minutes, and the granules will remain within the extruder. Application temperature would be  $100^{\circ}\text{C}$ , extruded into a cylindrical tube to acquire an OFDF.

**4.Rolling Method:** During this method, the API, polymer filming and other additives are combined and form a homogeneous mixture or suspension, which is then rolled. Relevant rheological studies

should be carried out on the blend or suspending. Water and alcohol combinations are the main solvent in this process. The strip or OFDF are finished with dehydration on rollers and cut into patient-acceptable sizes and forms.

**5.Solid Dispersion Method:** The technique involves the solid dispersion of API integrated in a melted hydrophilic polymer solution for loading of the API. The API is dissolved in the appropriate liquid Critical Reviews™ in Therapeutic Drug Carrier Systems Nanoparticle-Loaded Oral Fast-Dissolving Film 19 solvent system and obtained that solution is added to the melt of the appropriate hydrophilic polymeric agent, which can be reached below  $70^{\circ}\text{C}$  without removing the liquid solvent to achieve solid dispersion. To the end, using dyes, the solid dispersion developed is cut into strip or film.

#### Evaluation parameter for film

**1)Visual appearance:** Evaluate the formulated film for their visual characteristics. film should be visually inspected for their appearance.

**2) Thickness:** An electronic Vernier calliper is utilized to measure each films thickness at five location, including the centre and four corners. The weight of the acceptable film should not deviate substantially from the weighted average.

**3) Folding Endurance:** Folding endurance demonstrated the films flexibility. the measurement was taken manually by pressing the two sides of the film between the thumb and index finger. The film was frequently folded in the centre until it broke. The number of times the film was folded before breaking was recorded as folding endurance. The average of the triplicate observations is provided.



**4) pH:** The pH of a film is measured by placing it in a Petri dish dissolving the film with 2ml of distilled water and then determining the pH by containing the film surface with a Ph meter electrode. It is essential to determine surface pH because acidic or basic pH might lead to oral mucous irritation.

**5) Drug content uniformity:** The film was dissolved in 100 ml of phosphate buffer solution with a Ph of 6.8 and 1% SLS was added. The mixture was stirred for 30 minutes using a magnetic stirrer. Sample are taken from the solution and filtered using a syringe filter with a pore size of 0.45um. The sample were analysed for absorbance at a wavelength of 239 nm using a UV spectrophotometer. The amount was calculated using an equation developed from the calibration curve of telmisartan.

## CONCLUSION:

Nanoparticle-loaded fast dissolving films represent a next-generation oral delivery platform that unites the speed of dissolving films with the precision and performance of nanotechnology. By embedding nanoparticles within thin polymeric matrices, these systems overcome solubility limitations, improve drug stability, and offer rapid therapeutic onset without compromising patient convenience. Despite formulation challenges such as nanoparticle aggregation and film mechanical balance, advancements in polymer science and nanofabrication are steadily resolving these limitations. Overall, nanoparticle-integrated FDFs hold strong potential to transform the delivery of both conventional and sensitive biomolecules, paving the way for more effective, patient-friendly, and personalized therapies.

## FUTURE SCOPE:

Nanoparticle-loaded fast dissolving films represent a next-generation oral delivery platform that unites the speed of dissolving films with the precision and performance of nanotechnology. By embedding nanoparticles within thin polymeric matrices, these systems overcome solubility limitations, improve drug stability, and offer rapid therapeutic onset without compromising patient convenience. Despite formulation challenges such as nanoparticle aggregation and film mechanical balance, advancements in polymer science and nanofabrication are steadily resolving these limitations. Overall, nanoparticle-integrated FDFs hold strong potential to transform the delivery of both conventional and sensitive biomolecules, paving the way for more effective, patient-friendly.

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