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Design, optimization and characterization of a prebiotic-integrated Albendazole mouth dissolving film utilizing mixed Hydrotropy for enhanced drug solubility and gastrointestinal absorption

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Abstract
Albendazole is a broad-spectrum anthelmintic drug widely used for the treatment of parasitic infections. However, its therapeutic effectiveness is limited by poor aqueous solubility and low gastrointestinal absorption, resulting in reduced bioavailability. The present review focuses on the development of a prebiotic-integrated albendazole mouth dissolving film using mixed hydrotropy to enhance drug solubility and gastrointestinal absorption. Mixed hydrotropic solubilization offers a safe and efficient approach for improving solubility without the use of toxic organic solvents. The integration of prebiotic polymers such as inulin and fructooligo saccharides improves intestinal microflora balance and enhances drug absorption. Mouth dissolving film technology provides rapid drug release, improved patient compliance, and avoidance of first-pass metabolism. Various formulation parameters, optimization techniques, and characterization methods such as drug content, folding endurance, disintegration time, and dissolution studies are discussed. The review highlights the potential of combining hydrotropic solubilization and prebiotic integration as an innovative strategy for improving albendazole bioavailability.

Keywords: Albendazole, oral films, prebiotics, helminthiasis, drug delivery systems, bioavailability

Introduction

Albendazole is a benzimidazole derivative widely used as a broad-spectrum anthelmintic agent for the treatment of intestinal helminthic infections. Despite its therapeutic importance, albendazole belongs to Biopharmaceutical Classification System (BCS) Class II, characterized by low aqueous solubility and high permeability. Poor solubility results in limited dissolution in gastrointestinal fluids, leading to reduced oral bioavailability.

Conventional tablet formulations of albendazole exhibit delayed onset of action and inconsistent absorption. Therefore, novel drug delivery systems are required to improve dissolution and absorption characteristics.

Mouth dissolving films (MDFs) are thin polymeric strips that rapidly disintegrate in the oral cavity without the need for water. These films improve patient compliance, particularly in pediatric and geriatric populations.

Mixed hydrotropy is an emerging solubility enhancement technique that utilizes combinations of hydrotropic agents such as sodium benzoate, urea, and sodium citrate to enhance drug solubility. This method reduces the need for organic solvents and surfactants.

Prebiotics such as inulin and fructooligosaccharides improve gastrointestinal microflora and enhance nutrient and drug absorption. Incorporation of prebiotics into mouth dissolving films may improve gastrointestinal uptake of albendazole.

This review discusses formulation strategies, optimization techniques, and characterization methods for developing prebiotic-integrated albendazole mouth dissolving films using mixed Hydrotropy.

Fig 1: Albendazole Mouth Dissolving

Rationale for Albendazole-Loaded Oral Films

1. Drug-Related Challenges of Albendazole

Albendazole is a broad-spectrum anthelmintic widely used for the treatment of helminthic infections. Despite its therapeutic effectiveness, Albendazole presents significant formulation challenges due to:

- Poor aqueous solubility (Biopharmaceutics Classification System – Class II drug)
- Low and variable oral bioavailability
- Extensive first-pass metabolism
- Dissolution rate–limited absorption in the gastrointestinal tract

Because its absorption is dissolution-dependent, improving solubility is critical for enhancing systemic availability and therapeutic efficacy.

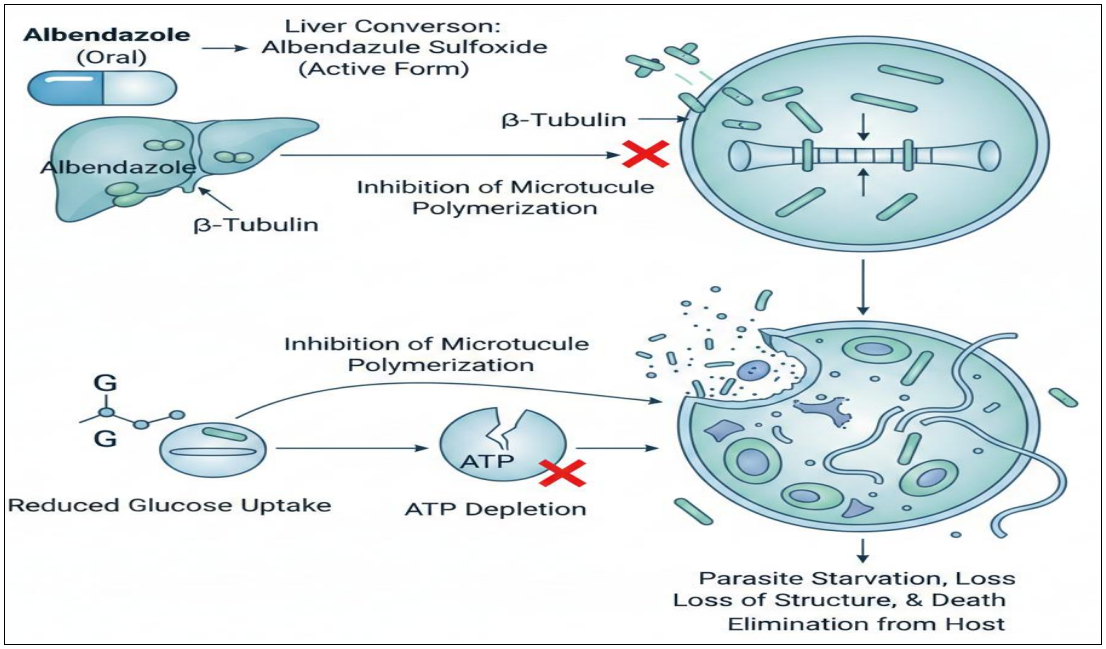

Fig 2: Mode of action of albendazole

2. Need for Solubility Enhancement

Albendazole's limited water solubility leads to

- Incomplete drug release in gastric fluids
- Variable plasma concentration profiles
- Reduced therapeutic response in some patients

Traditional approaches such as solid dispersions, micronization, and lipid-based systems have limitations in stability, scalability, or cost. Therefore, mixed hydrotropy offers a promising alternative by:

- Increasing solubility without chemical modification
- Avoiding large amounts of organic solvents
- Reducing individual hydrotrope concentration-related toxicity
- Providing a cost-effective and scalable approach

Thus, hydrotropic solubilization can significantly enhance dissolution and gastrointestinal absorption

Justification for Mouth Dissolving Films (MDFs)

Mouth dissolving films (MDFs) offer several advantages over conventional tablets and suspensions:

- Rapid disintegration in saliva (no need for water)
- Improved patient compliance (especially pediatric and geriatric populations)
- Accurate dosing
- Reduced risk of choking
- Faster onset of action
- Potential partial avoidance of first-pass metabolism (if some absorption occurs buccally)

For helminth infections, which commonly affect children, an oral film system provides superior ease of administration compared to tablets.

Formulation Strategies for Albendazole-Loaded Oral Films

1. Selection of Film-Forming Polymers

The choice of polymer is critical for achieving desirable mechanical strength, flexibility, and disintegration characteristics. Commonly used polymers include hydroxypropyl methylcellulose (HPMC), These polymers provide excellent film-forming properties and compatibility with albendazole.

2. Plasticizers and Excipients

Plasticizers such as glycerol are incorporated to enhance film flexibility and prevent brittleness. Sweeteners, flavoring agents, and saliva-stimulating agents may be added to improve palatability and patient acceptance, particularly in pediatric formulations.

3. Incorporation of Prebiotics

Prebiotics can be uniformly dispersed within the polymeric matrix to ensure consistent dosing. Their physicochemical compatibility with albendazole and film-forming polymers must be carefully evaluated to prevent phase separation or compromised film integrity.

Research Area	Focus of Future Study	Objective
Advanced Rheology	Molecular modeling of the polymer-hydrotrope interaction.	To predict film flexibility and prevent "blooming" (drug leaching) during long-term storage.
Microbiome Analysis	16S rRNA sequencing of gut microbiota post-administration.	To quantify the actual prebiotic "boost" and its effect on Albendazole's metabolism.
Bioavailability	Comparative Pharmacokinetic (PK) studies vs. commercial tablets.	To prove that the MDF achieves higher C_{max} and faster T_{max} due to enhanced solubility.
Taste Masking	Development of "Smart" polymers that release drug only at gastric pH.	To completely eliminate the bitter taste of Albendazole without affecting oral dissolution.
Industrial Scale-up	Feasibility of Hot-Melt Extrusion (HME).	To move away from solvent casting (w hich is slow) to a continuous, solvent-free manufacturing process.
Stability Testing	Accelerated stability studies under Zone IVb conditions (Hot/Humid).	To ensure the prebiotic component doesn't absorb moisture and degrade the film matrix.

Evaluation Parameters for Albendazole Oral Films

1. Physicochemical Characterization

Oral films are evaluated for thickness, weight variation, surface pH, folding endurance, tensile strength, and moisture content. These parameters ensure uniformity, stability, and mechanical robustness.

2. Drug Content Uniformity and Disintegration Time

Uniform drug distribution within the film matrix is essential for accurate dosing. Rapid disintegration, typically within 30–60 seconds, is a key performance attribute of oral films.

3. *In vitro* Drug Release Studies

Dissolution studies are conducted using simulated saliva or gastrointestinal fluids to assess drug release kinetics. Albendazole-loaded oral films generally demonstrate enhanced dissolution rates compared to conventional tablets due to increased surface area and improved wettability.

***In vivo* Evaluation and Therapeutic Performance**

Animal studies evaluating albendazole oral films have reported improved bioavailability and enhanced anthelmintic efficacy compared to traditional dosage forms. Pharmacokinetic parameters such as maximum plasma concentration and area under the curve are often significantly increased, reflecting improved absorption [16].

The inclusion of prebiotics may further enhance therapeutic outcomes by supporting gut health and reducing treatment-associated gastrointestinal disturbances. Safety evaluations typically demonstrate good tolerability, with no significant adverse effects observed in preclinical models [17].

Regulatory and Quality Considerations

Oral films containing albendazole and prebiotics must comply with regulatory guidelines governing pharmaceutical quality, safety, and efficacy. Critical quality attributes include content uniformity, stability under various storage conditions, and microbial limits. Regulatory agencies increasingly emphasize patient-centric drug product design, aligning well with the oral film delivery platform [18].

Challenges and Future Perspectives

Despite their advantages, challenges associated with oral film formulations include scale-up difficulties, moisture sensitivity, and ensuring long-term stability of both drug and prebiotics. Future research should focus on advanced formulation techniques, taste-masking strategies, and clinical evaluation in target populations.

The integration of nutraceutical components such as prebiotics into pharmaceutical dosage forms represents a promising direction for holistic management of helminthic infections. Well-designed clinical studies are needed to confirm the translational benefits observed in preclinical investigations.

Category	Current Challenges	Future Perspectives
Solubility & Loading	Albendazole is highly hydrophobic (BCS Class II/IV); maintaining high drug loading without recrystallization in a thin film is difficult.	Exploration of nanocrystal technology or solid dispersions integrated into the hydrotropic film matrix.
Palatability	Many hydrotropic agents and Albendazole itself have a bitter or chemical aftertaste, which is problematic for mouth-dissolving films (MDF).	Utilization of electronic tongues (e-tongues) for precise taste masking and microencapsulation of the drug.
Stability	Prebiotics (like Inulin or FOS) can be hygroscopic, potentially making the film sticky or reducing its mechanical strength over time.	Development of advanced moisture-barrier packaging and use of non-hygroscopic prebiotic derivatives.
Manufacturing	Scaling up "solvent casting" leads to thickness variations; hydrotropic blends may alter the viscosity of the casting polymer.	Transitioning to Hot-Melt Extrusion (HME) or 3D printing for more uniform, continuous production.
Synergy	Quantifying the exact "prebiotic effect" on Albendazole absorption in the gut is complex and varies by individual microbiome.	In-vivo microbiome mapping to tailor the prebiotic type to specific patient populations (personalized medicine).
Regulatory	Mixed hydrotropic blends require rigorous safety profiles (GRAS status) for the specific ratios used in the film.	Development of a standardized safety database for synergistic hydrotropic combinations.

Conclusion

Albendazole continues to be a cornerstone therapy for helminthic infections; however, its therapeutic performance is significantly hindered by poor aqueous solubility and dissolution rate–limited gastrointestinal absorption. These limitations necessitate advanced formulation strategies to enhance its bioavailability and clinical efficacy.

The present review highlights the scientific relevance of integrating mixed hydrotropy with mouth dissolving film (MDF) technology to overcome solubility-related barriers. Mixed hydrotropy offers a synergistic solubilization mechanism without chemical modification of the drug, reducing the need for organic solvents and minimizing toxicity associated with high concentrations of single hydrotropic agents. This approach directly enhances drug dissolution, thereby improving the potential for gastrointestinal absorption.

The incorporation of Albendazole into a mouth dissolving film provides additional therapeutic and patient-centric advantages, including rapid disintegration, improved compliance, ease of administration without water, and suitability for pediatric and geriatric populations. Furthermore, the integration of a prebiotic component introduces a novel multifunctional dimension to the dosage form, supporting gut microbiota balance and potentially improving intestinal health during anthelmintic therapy.

Collectively, the convergence of solubility enhancement, innovative thin-film delivery, and microbiome-supportive excipients represents a promising translational strategy. This integrated system holds strong potential to improve bioavailability, therapeutic outcomes, and patient acceptability. Future investigations should focus on *in vivo* pharmacokinetic evaluation, stability assessment, and large-scale manufacturing feasibility to facilitate clinical translation.

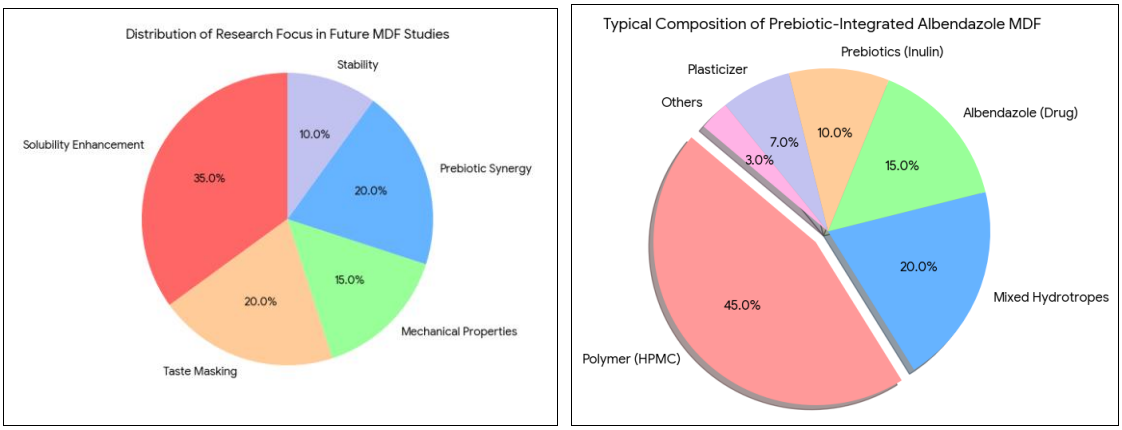

Fig 3: MDF Composition & Future Studies

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