RESEARCH PAPER

Oral solid dosage forms, their characteristics and the role of pregelatinized starch in oral solid dosage forms

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ABSTRACT
Background
Oral solid dosage forms represent the most widely used and preferred route of drug administration due to their ease of administration, accurate dosing, stability, and cost-effectiveness. This review provides a comprehensive overview of various oral solid dosage forms including tablets, capsules, powders, and granules, discussing their characteristics, advantages, and limitations.
Objective
To examine the role and significance of pregelatinized starch as a multifunctional excipient in the formulation of oral solid dosage forms, highlighting its physicochemical properties and functional applications.
Materials and Methods
A comprehensive literature review was conducted using databases including PubMed, Scopus, and Google Scholar to gather relevant information on oral solid dosage forms and the application of pregelatinized starch in pharmaceutical formulations.
Results
Pregelatinized starch is a modified starch derivative obtained by physical or chemical processing of native starch. It exhibits excellent binding, disintegrating, and flow-enhancing properties, making it an ideal excipient for tablet and capsule formulations. Its multifunctional nature allows it to serve as a binder, disintegrant, diluent, and glidant, thereby simplifying formulation development and improving manufacturing efficiency.
Conclusion
Pregelatinized starch plays a critical role in the formulation of oral solid dosage forms due to its versatile functional properties. Its use enhances tablet hardness, reduces friability, improves drug release profiles, and facilitates manufacturing processes. Ongoing research continues to explore novel applications and modifications of pregelatinized starch to further optimize pharmaceutical formulations.
Keywords: Oral solid dosage forms, Pregelatinized starch, Tablets, Excipients, Binder, Disintegrant, Pharmaceutical formulation.
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1. Types of Pharmaceutical Dosage Forms

Pharmaceutical dosage forms are diverse delivery systems designed to deliver active pharmaceutical ingredients (APIs) to patients via various administration routes. The pharmaceutical industry encompasses a wide range of formulation types, each with specific advantages and applications [1]. The primary categories include conventional systems such as tablets, capsules, syrups, ointments, suspensions, and solutions, as well as more advanced delivery systems like nanoparticles, liposomes, and microcapsules [1]. Among these, oral solid dosage forms represent the most commonly utilized administration route due to their non-invasiveness, patient compliance, and convenience of administration [2]. Solid oral formulations, particularly tablets and capsules, constitute the most economically viable and widely accepted dosage forms in global pharmaceutical practice. The selection of a particular dosage form depends on multiple factors, including the physicochemical properties of the active ingredient, the desired therapeutic effect, patient demographics, manufacturing considerations, and regulatory requirements [3]. Patient-centric medicine design has emerged as a critical consideration, with formulation characteristics impacting three key stages of medication use: medication identification and memorability, medication handling, and swallowability [4]. For instance, the size and shape of tablets significantly influence patient acceptance, with smaller round tablets presenting challenges for elderly populations, while bright, two-colored preparations with interesting shapes improve identification and memorability [4]. Furthermore, pediatric and geriatric populations present unique challenges in formulation design, driving innovation in mini-tablets, orally disintegrating tablets, and other specialized dosage forms [5].

2. Oral Solid Dosage Forms: Historical Development and Characteristics

2.1 Historical Evolution

The development of oral solid dosage forms represents one of the most significant achievements in

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pharmaceutical manufacturing. Tablets and capsules have been the foundation of pharmaceutical delivery for centuries, with their evolution reflecting advancements in manufacturing technology, materials science, and understanding of drug delivery principles [6]. The industrial revolution marked a transition from custom-made formulations to mass production systems, with the nineteenth and twentieth centuries witnessing dramatic innovations in tablet and capsule manufacturing technologies [7]. Direct compression technology, one of the most critical developments in tablet manufacturing, emerged as an alternative to wet granulation, significantly reducing processing time and manufacturing complexity [8]. This technique involves tableting a blend of ingredients without preliminary granulation, enabling the production of robust tablets with improved cost-effectiveness [8]. The development of new excipients specifically designed for direct compression has revolutionized pharmaceutical manufacturing, allowing formulators to achieve desired tablet properties while maintaining manufacturing efficiency [9].

2.2 Key Characteristics of Oral Solid Dosage Forms

Oral solid dosage forms possess several defining characteristics that contribute to their widespread acceptance and utility. These formulations are designed to undergo specific transformations following oral administration, including disintegration in the gastrointestinal tract, dissolution of the active ingredient, and subsequent absorption through the intestinal mucosa [10]. The gastrointestinal transit of pharmaceutical dosage forms is influenced by multiple factors, including the physical form (solutions, pellets, or single units), stomach contents, and fed versus fasted states [10]. Conventional solid dosage forms, while widely utilized, often suffer from limitations including poor bioavailability, plasma concentration fluctuations, and challenges in swallowability for certain patient populations [1]. These limitations have driven the development of specialized oral dosage forms such as orally disintegrating tablets (ODTs), which rapidly disintegrate or dissolve in the oral cavity without requiring water, thereby improving patient compliance and therapeutic efficacy [11]. The immediate release property of ODTs makes them particularly valuable for patients with swallowing difficulties, pediatric patients, and those requiring rapid onset of action [11]. The mechanical properties of tablets represent critical quality attributes that must be carefully controlled during development and manufacturing. Parameters such as hardness, friability, disintegration time, and drug release profiles are essential indicators of tablet quality and therapeutic performance [12]. Tablets must withstand mechanical stresses during manufacturing, transportation, and distribution, as well as rough handling by end users, necessitating comprehensive quality control evaluation [13].

3. Excipients in Oral Solid Dosage Forms

3.1 Role and Classification of Excipients

Pharmaceutical excipients have evolved from being considered merely inert, cost-effective substances to being recognized as essential functional components of drug formulations [14]. Excipients typically constitute 80-90% of the final pharmaceutical product and play critical roles in ensuring formulation stability, bioavailability, and manufacturing feasibility [14]. The International Pharmaceutical Excipient Council (IPEC) has established comprehensive guidelines for excipient categorization and safety evaluation, reflecting the increasingly sophisticated understanding of excipient functionality [14].

The impact of excipients extends beyond simple formulation inertness; they directly interact with gut microbiota and can significantly influence drug pharmacokinetics and host metabolic health [15]. Excipients typically represent over 90% of the final dosage form, yet their interactions with the gastrointestinal environment are frequently overlooked during formulation development [15]. Known excipient-gut microbiota interactions exist for various classes of inactive pharmaceutical ingredients, including solubilizing agents, binders, fillers, sweeteners, and color additives, requiring careful consideration during formulation design [15].

3.2 Major Classes of Excipients Used in Oral Solid Dosage Forms

Fillers and Binders: Fillers and binders represent essential excipients in tablet formulations, providing bulk and facilitating tablet bonding during compression [16]. These materials must possess adequate flow properties, compressibility, and binding capacity while maintaining chemical stability and compatibility with the active ingredient [16]. Common fillers include microcrystalline cellulose, lactose, and various starches, each offering distinct physicochemical properties suited to different formulation requirements.

Disintegrants: Disintegrants are crucial excipients that facilitate tablet breakdown into smaller particles, enabling rapid drug dissolution and absorption [17]. These materials function through various mechanisms including swelling, wicking, and particle repulsion [18]. Superdisintegrants, characterized by their enhanced swelling capacity and rapid disintegration efficiency, have become increasingly important in formulating fast-disintegrating tablets and improving bioavailability of poorly soluble drugs [19].

Polymeric Excipients: Natural polymeric plant-derived excipients have received considerable attention due to their non-toxicity, stability, renewability, and versatility [20]. Polysaccharides such as cellulose and its derivatives (including hydroxypropylcellulose and carboxymethyl cellulose), chitosan, and various plant gums demonstrate remarkable potential as matrix formers, binders, disintegrants, and controlled-release agents [20]. These materials can be chemically modified to suit specific formulation needs while maintaining their natural and renewable origins [21].

Solubilizing Agents and Alkalinizing Agents: For poorly soluble drugs, specialized excipients can be incorporated to enhance dissolution and bioavailability [16]. Alkalinizing agents such as calcium carbonate can be strategically used to improve dissolution rates of pH-dependent drugs [22]. Surfactants and cyclodextrins serve as complexing excipients that enhance the apparent solubility of water-insoluble drugs through formation of inclusion complexes or micelles [23].

Lubricants: Magnesium stearate represents the most commonly used lubricant in oral solid dosage forms, reducing friction during tablet compression and facilitating ejection from tablet dies [24]. However, magnesium stearate can adversely impact tablet hardness and drug dissolution if used improperly, necessitating careful optimization of concentration and blending techniques [24].

4. Pregelatinized Starch: Physicochemical Properties and Characterization

4.1 Definition and Preparation of Pregelatinized Starch

Pregelatinized starch (PGS), also known as partially pregelatinized starch or instant starch, is a physically modified starch prepared by partial gelatinization of native starch under controlled conditions [25]. This modification involves heating starch granules in the presence of limited water, causing swelling and partial rupturing of granule structure without complete gelatinization [26]. The degree of pregelatinization can be precisely controlled by manipulating processing parameters including temperature, moisture content, mechanical action, and treatment duration [26]. Pregelatinized starch has received FDA approval as an isolated excipient in various pharmaceutical applications, including use in granules, capsules, tablets, suppositories, implants, stents, transdermal systems, and ophthalmic formulations [25]. The versatility of pregelatinized starch across multiple dosage forms reflects its unique physicochemical properties and multi-functional capabilities.

4.2 Physicochemical Properties

Structural Characteristics: Native starch granules possess a semicrystalline structure composed of amylose (linear glucose polymer) and amylopectin (branched glucose polymer) [27]. The ratio of amylose to amylopectin varies significantly among different starch sources, profoundly influencing the functional properties of the resulting pregelatinized starch [27]. Pregelatinization induces structural changes including partial granule swelling, disruption of the crystalline structure, and exposure of previously inaccessible reactive sites [27].

Particle Size and Morphology: Pregelatinized starch obtained from different botanical sources (yucca, corn, rice) demonstrates considerable variation in particle size, morphology, and porosity [28]. Corn-derived pregelatinized starch (Starch 1500) exhibits the smallest particle size, highest density, and superior flow properties compared to alternative sources [28]. Scanning electron microscopy studies reveal that pregelatinization induces alterations in granular morphology, with irregular structures observed in some sources and more regular patterns in others [29].

Water Absorption and Swelling Characteristics: One of the most significant properties of pregelatinized starch is its enhanced water absorption and swelling capacity compared to native starch [29]. The swelling power of pregelatinized starch is substantially reduced compared to native starch due to the disruption of granule structure during processing; however, the cold-water solubility is significantly increased [29]. This unique combination of reduced swelling combined with increased cold-water solubility makes pregelatinized starch particularly valuable for direct compression tableting applications.

Solubility and Viscosity: Native starch exhibits poor solubility in water at room temperature, limiting its pharmaceutical applications [27]. Pregelatinization dramatically improves starch solubility in cold water, while also modifying viscosity characteristics [29]. The increased soluble starch content of modified starches such as hydroxypropylated versions can reach 69-70% compared to 17-18% for native starch, reflecting the substantial structural modifications achieved through chemical or physical treatment [30].

Rheological Properties: The rheological behavior of pregelatinized starch suspensions differs substantially from native starch, with improved flowability and modified viscosity profiles [29]. These improved flow properties make pregelatinized starch particularly suitable for direct compression and other manufacturing processes requiring uniform powder flow [28].

4.3 Comparative Analysis of Pregelatinized Starch from Different Sources

Starch Source	Particle Size	Density	Flow Properties	Compressibility	Key Characteristics
Corn (Starch 1500)	Small	High	Excellent	Good	Most widely used, lowest porosity
Yucca	Irregular	Variable	Moderate	Better than corn	Irregular granule morphology
Rice	Moderate	Low	Good	Moderate	Lower density, good flow
Cassava/Tapioca	Variable	Moderate	Moderate to Good	Depends on modification	Versatile, amenable to modification
Sweet Potato	Moderate	Variable	Moderate	Better compactibility than native	Moderate

Source: Data compiled from [28], [29], [31]

5. Uses of Pregelatinized Starch in Oral Solid Dosage Forms

5.1 Direct Compression Filler-Binder Applications

Pregelatinized starch serves as an excellent filler-binder in direct compression formulations, demonstrating superior performance compared to native starch [28]. The improved flow properties and compressibility of pregelatinized starch make it particularly suitable for high-speed tablet presses, enabling cost-effective manufacturing without preliminary granulation [28]. Unlike native starch, which is essentially uncompressible and exhibits poor flow, pregelatinized starch achieves good binding capacity and tablet hardness while maintaining acceptable friability [28].

The multi-functional role of pregelatinized starch in direct compression formulations is reflected in its ability to simultaneously serve as filler, binder, and disintegrant, reducing the number of excipients required and simplifying formulation design [25]. The onset of plastic deformation in pregelatinized starch occurs at lower pressures compared to some alternative excipients, contributing to its excellent compactibility [28].

5.2 Disintegrant Functionality

The disintegrant properties of pregelatinized starch are significantly enhanced compared to native starch due to the partial disruption of granule structure and increased water absorption capacity [32]. Acid-modified starches, including those derived from yam species, demonstrate improved disintegrant efficiency when incorporated both intra- and extragranularly in tablet formulations [32]. The mode of incorporation (intra- versus extra-granular) significantly influences disintegrant efficacy, with extragranular incorporation generally producing faster disintegration times [32]. Modified tapioca starches, including pregelatinized variants, have demonstrated excellent potential as tablet disintegrants with superior performance characteristics [31]. The wicking mechanism of pregelatinized starch, combined with its swelling capacity, enables rapid tablet breakdown in aqueous environments, facilitating drug dissolution and absorption [18].

5.3 Controlled Release and Matrix Forming Applications

Pregelatinized starch can be utilized in controlled-release matrix formulations, where the starch matrix gradually erodes upon exposure to gastrointestinal fluids, thereby modulating drug release rates [25]. Carboxymethyl pregelatinized starch (CMPGS) demonstrates particular utility as a sustained-release excipient, with in vitro dissolution studies showing controlled drug release over extended periods [33]. The degree of chemical substitution in modified pregelatinized starches directly influences drug release kinetics, allowing formulators to tailor release profiles to specific therapeutic requirements [33].

5.4 Hydrogel and Advanced Formulation Applications

Recent innovations have demonstrated the utility of pregelatinized starch in advanced delivery systems. The incorporation of pregelatinized starch into alginate-based 3D hydrogel patches for topical delivery has shown remarkable effects on physicochemical properties including porosity, gelation time, and release rates [34]. The synergistic incorporation of pregelatinized starch with other natural polysaccharides improves the mechanical properties and functionality of drug delivery systems while maintaining biocompatibility and biodegradability [34].

The viscoelastic properties, printing accuracy, gelation time, microstructure, and release rates of starch-containing hydrogel patches can be precisely modulated by varying the amount of pregelatinized starch added to the formulation [34]. This level of control over formulation properties enables the rational design of personalized drug delivery systems tailored to individual patient needs.

6. Synthesis and Chemical Modification of Pregelatinized Starch

The chemical modification of pregelatinized starch through carboxymethylation and other reactions enables the preparation of new excipients with enhanced functionality [33]. The degree of substitution achieved during carboxymethylation can be precisely controlled through manipulation of reaction parameters including sodium hydroxide concentration, reaction time, temperature, and the molar ratio of reagents [33]. Higher degrees of substitution (0.55) with optimal reaction efficiency (55%) are achievable under carefully controlled conditions [33].

Scanning electron microscopy reveals that carboxymethylation induces significant structural rearrangements, causing granular disintegration and increasing the specific surface area available for drug interaction [33]. X-ray diffraction analysis demonstrates that the crystallinity of starch is substantially altered following chemical modification, with changes in the degree of crystallinity correlating with modifications in functional properties [33]. Partially pregelatinized cassava starch prepared by mechanical activation demonstrates that controlled mechanical treatment can achieve varying degrees of gelatinization [26]. Mechanical activation significantly increases cold-water solubility and flowability while decreasing the gelatinization temperature and modifying viscosity characteristics [26]. These properties can be systematically controlled by adjusting milling time, enabling the preparation of partially pregelatinized starch with tailored characteristics suited to specific pharmaceutical applications [26].

7. Physicochemical Characterization Techniques

The comprehensive characterization of pregelatinized starch and its derivatives requires multiple analytical techniques. Fourier-transform infrared spectroscopy

(FTIR) reveals characteristic functional groups and chemical modifications, with carboxymethyl-substituted starches showing new absorption bands at 1417 and 1603 cm^{-1} indicating carboxymethyl group presence [33]. X-ray diffraction (XRD) provides insights into the crystalline structure and degree of crystallinity, with the diffraction patterns revealing the extent of structural disruption achieved during pregelatinization [29]. Scanning electron microscopy (SEM) enables direct visualization of granule morphology and surface characteristics, revealing the structural changes induced by pregelatinization and chemical modification [29]. Rheological analysis, including determination of viscosity and viscoelastic properties, characterizes the flow behavior and processing characteristics of pregelatinized starch formulations [29]. Particle size analysis using laser diffraction provides quantitative data on particle size distribution, a critical parameter influencing powder flow and tablet properties [28].

8. Comparative Performance in Tablet Formulations

Pregelatinized starch demonstrates superior performance compared to native starch in direct compression tablet formulations [28]. Tablets formulated with pregelatinized starch exhibit acceptable hardness, lower friability, and improved disintegration characteristics compared to those containing native starch [28]. The onset and rate of plastic deformation during compression are more favorable for pregelatinized starch, contributing to superior tablet bonding and mechanical strength [28]. Co-processing techniques that combine pregelatinized starch with other excipients can further enhance tablet properties. The addition of pregelatinized starch to formulations containing microcrystalline cellulose or other fillers synergistically improves flow properties, compressibility, and disintegration characteristics [35]. Content uniformity analysis demonstrates that pregelatinized starch, compared to native starch, produces more homogeneous powder blends, particularly when using novel dry powder hybrid mixing devices [35].

9. Safety and Biocompatibility Considerations

Pregelatinized starch derived from various botanical sources has been extensively evaluated for safety and biocompatibility. Hydroxypropyl banana starch and other modified starches meet FDA-approved specifications and demonstrate no evidence of toxicity at doses up to 1,000 mg/kg body weight in animal studies [30]. The degree of substitution and hydroxypropyl group percentage in modified starches remain within FDA-acceptable limits, confirming their suitability for pharmaceutical use [30].

The interaction of excipients including pregelatinized starch with gut microbiota represents an emerging area of pharmaceutical science [15]. While pregelatinized starch is generally recognized as safe, understanding its potential interactions with the gastrointestinal microbiota is important for optimizing formulation safety and efficacy [15].

10. Future Perspectives and Emerging Applications

The pharmaceutical applications of pregelatinized starch continue to expand with emerging technologies. Three-dimensional printing techniques enable the incorporation of pregelatinized starch into customized dosage forms with precisely controlled release profiles and mechanical properties [13]. The viscoelastic and printability characteristics of pregelatinized starch make it suitable for advanced additive manufacturing approaches [34].

Nanotechnology approaches offer opportunities for further modification and enhancement of pregelatinized starch properties. Nanoparticles and nanocomposites incorporating starch demonstrate enhanced functionality for controlled release and targeted delivery applications [36]. The development of starch-based nanoparticles represents a promising direction for improving drug bioavailability and reducing therapeutic doses while maintaining tolerability [36].

Co-processing strategies combining pregelatinized starch with other excipients continue to generate new multi-functional materials with superior properties [37]. These advanced excipient blends enable the formulation of drugs with challenging physicochemical properties, including poorly soluble compounds and high-potency drugs requiring enhanced content uniformity [37].

11. Regulatory Status and Pharmacopeial Standards

Pregelatinized starch is recognized and approved as a pharmaceutical excipient by major regulatory agencies including the United States Food and Drug Administration (FDA) and is described in major pharmacopeias including the United States Pharmacopeia (USP) and European Pharmacopoeia (EP) [25]. These regulatory approvals confirm the safety, efficacy, and consistent quality of pregelatinized starch for use in pharmaceutical formulations [25].

The regulatory acceptance of pregelatinized starch as a direct compression excipient has facilitated its widespread adoption in the pharmaceutical industry, enabling manufacturers to develop efficient and cost-effective tablet formulations without regulatory concerns [9]. Continued research and development of pregelatinized starch derivatives with enhanced functionality will likely support expanded regulatory acceptance and broader pharmaceutical applications [33].

12. Conclusions

Oral solid dosage forms represent the most widely used pharmaceutical delivery systems, with tablets and capsules constituting the primary administration routes for the majority of oral medications. The development and optimization of these formulations depend critically on the appropriate selection and application of pharmaceutical excipients, with pregelatinized starch emerging as one of the most versatile and functionally important excipients in modern pharmaceutical manufacturing.

Pregelatinized starch, prepared through controlled physical modification of native starch, offers unique physicochemical properties including improved water solubility, enhanced flow characteristics, superior compressibility, and multifunctional capability. These properties make pregelatinized starch particularly valuable for direct compression tablet formulations, where it simultaneously serves as filler, binder, and disintegrant, thereby reducing formulation complexity and manufacturing costs.

The physicochemical characteristics of pregelatinized starch vary significantly based on botanical source and processing conditions, enabling formulators to select sources best suited to specific formulation requirements. Chemical modification through carboxymethylation and hydroxypropylation further extends the functionality of pregelatinized starch, enabling applications in controlled-release formulations, advanced delivery systems, and specialized dosage forms.

Emerging technologies including 3D printing, nanotechnology, and co-processing techniques promise to further expand the pharmaceutical applications of pregelatinized starch. Continued investigation of pregelatinized starch properties and development of novel derivatives will support the formulation of increasingly sophisticated drug delivery systems capable of addressing the challenges posed by poorly soluble, poorly permeable, and high-potency drugs.

The regulatory approval and pharmacopeial recognition of pregelatinized starch as a pharmaceutical excipient, combined with its demonstrated safety and biocompatibility, position it as an essential component of the modern pharmaceutical formulator's armamentarium. As the pharmaceutical industry continues to evolve toward personalized medicine and advanced manufacturing technologies, pregelatinized starch will likely play an increasingly important role in enabling the development of innovative, patient-centric therapeutic formulations.

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