

Immediate release tablet formulations: formulation strategies, superdisintegrants, and evaluation parameters with special reference to antihypertensive drugs

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Abstract

Immediate-release (IR) tablets represent the most widely utilized solid oral dosage forms owing to their simplicity, cost-effectiveness, and ability to provide rapid therapeutic action. In the management of cardiovascular disorders such as hypertension, prompt drug availability is often essential to achieve effective clinical outcomes. Antihypertensive agents, particularly β -adrenergic blockers, are commonly formulated as immediate-release dosage forms to ensure quick onset of action. Esmolol hydrochloride, a cardioselective β_1 -blocker with rapid onset and short duration of action, serves as an ideal model drug for studying immediate-release formulation strategies. This review discusses the principles of immediate-release tablet formulation, selection of excipients with emphasis on superdisintegrants, manufacturing techniques, and evaluation parameters. The role of formulation variables in influencing disintegration and dissolution behavior is highlighted, along with recent advances in immediate-release tablet technology. The review aims to provide a comprehensive overview of formulation approaches for immediate-release tablets of antihypertensive drugs, supporting the development of effective and reliable oral dosage forms.

Keywords: Immediate release tablets, antihypertensive drugs, superdisintegrants, direct compression, dissolution, esmolol hydrochloride.

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1. Introduction

Oral drug delivery remains the most preferred and widely accepted route of administration due to its convenience, patient compliance, safety, and cost-effectiveness [1]. Among the various oral solid dosage forms, tablets constitute the largest segment of pharmaceutical products because of their stability, ease of handling, accurate dosing, and large-scale manufacturability [2]. Depending on the therapeutic requirement, tablets may be designed as immediate-release, delayed-release, or controlled-release systems [3]. Among these, immediate-release (IR) tablets are intended to disintegrate and release the drug rapidly after administration, providing prompt onset of pharmacological action [4].

Hypertension is a chronic cardiovascular disorder and a leading risk factor for stroke, myocardial infarction, and heart failure. Rapid reduction of elevated blood pressure is often required in acute clinical conditions such as perioperative hypertension, supraventricular tachycardia, and emergency cardiovascular events [5]. In such situations, immediate drug availability is essential for effective management. Consequently, antihypertensive agents are frequently formulated as immediate-release dosage forms to ensure fast disintegration, rapid dissolution, and timely systemic absorption [6].

β -Adrenergic blockers play a significant role in the management of hypertension and other cardiovascular disorders [7]. Esmolol hydrochloride is a cardioselective β_1 -adrenergic receptor antagonist characterized by a rapid onset of action and a very short elimination half-life due to

metabolism by plasma esterases [8]. Although esmolol is primarily administered intravenously for acute cardiovascular control, the development and understanding of immediate-release oral formulations are valuable for short-term therapy, dose titration, and transition from parenteral to oral treatment [9].

The performance of immediate-release tablets is highly dependent on formulation components and manufacturing processes [10]. In particular, the selection and concentration of superdisintegrants play a crucial role in achieving rapid tablet disintegration and drug release [11]. Commonly used superdisintegrants such as croscarmellose sodium, sodium starch glycolate, and crospovidone act through mechanisms including swelling, wicking, and deformation recovery [12]. In addition, manufacturing techniques such as direct compression are widely employed for IR tablets due to their simplicity, low cost, and suitability for heat- and moisture-sensitive drugs [13].

In this context, the present review focuses on the formulation strategies, excipient selection, manufacturing approaches, and evaluation parameters associated with immediate-release tablets, with special emphasis on antihypertensive drugs such as esmolol hydrochloride [14]. The review also highlights recent advancements and future perspectives in immediate-release tablet technology, aiming to support the rational development of effective oral dosage forms for rapid therapeutic action.

2. Concept of immediate release tablets

Immediate-release (IR) tablets are conventional oral solid dosage forms designed to disintegrate and release the active pharmaceutical ingredient rapidly after administration, without any intentional delay or modification of drug release [15]. The primary objective of IR tablets is to ensure quick availability of the drug for absorption, thereby producing a rapid onset of therapeutic action. These dosage forms are particularly suitable for drugs that require fast pharmacological response or for conditions where immediate symptom relief is desired [16].

According to pharmacopoeial standards, immediate-release tablets are expected to disintegrate within a short period and release a substantial amount of the drug in a relatively brief time. Typically, IR tablets should release more than 80–85% of the labeled drug content within 30 minutes in an appropriate dissolution medium, although the exact criteria may vary depending on regulatory guidelines and the nature of the drug. The rapid drug release from IR tablets is achieved primarily through the use of suitable excipients and optimized formulation techniques [17].

The performance of immediate-release tablets is governed by several factors, including physicochemical properties of the drug, choice of excipients, manufacturing process, and tablet characteristics such as hardness and porosity. Among formulation components, superdisintegrants play a pivotal role in promoting rapid tablet disintegration upon contact with gastrointestinal fluids [18]. These materials facilitate the breakup of the tablet matrix through mechanisms such as swelling, capillary action (wicking), and deformation recovery, leading to faster drug dissolution [19].

Immediate-release tablets offer several advantages, including simplicity of formulation, ease of manufacturing, cost-effectiveness, and high patient compliance. However, they are not suitable for drugs requiring prolonged or controlled plasma concentrations, as rapid drug release may necessitate frequent dosing. Despite these limitations, IR tablets remain the dosage form of choice for many therapeutic agents, including antihypertensive drugs, where prompt onset of action is clinically beneficial [20].

In the context of cardiovascular therapy, immediate-release tablets play a critical role in the management of acute or episodic conditions requiring rapid blood pressure control. Therefore, understanding the fundamental concept and design principles of immediate-release tablets is essential for the rational development of effective oral formulations [21].

3. Antihypertensive drugs and need for immediate release formulations

Hypertension is a chronic and multifactorial cardiovascular disorder characterized by persistently elevated arterial blood pressure and is a major contributor to global morbidity and mortality. Uncontrolled hypertension significantly increases the risk of serious complications such as stroke, myocardial infarction, heart failure, and renal dysfunction. Pharmacological therapy remains the cornerstone of hypertension management, with several classes of antihypertensive drugs being employed to achieve and maintain optimal blood pressure control [22].

Commonly used classes of antihypertensive agents include β -adrenergic blockers, calcium channel blockers, angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs), diuretics, and vasodilators. The choice of therapy depends on the severity of hypertension, associated comorbidities, and the clinical condition of the patient. In many situations, especially during the initiation of therapy or in acute hypertensive episodes, rapid reduction of blood pressure is desirable to prevent end-organ damage [23].

Immediate-release (IR) formulations are particularly useful in such clinical scenarios where a quick onset of action is required. IR tablets rapidly disintegrate and dissolve after oral administration, allowing fast drug absorption and prompt therapeutic response. This characteristic is especially beneficial during hypertensive emergencies, perioperative hypertension, and situations requiring rapid dose titration or adjustment [24].

β -Adrenergic blockers play an important role in the management of hypertension by reducing heart rate, myocardial contractility, and cardiac output. Esmolol hydrochloride is a cardioselective β_1 -adrenergic blocker with a very short half-life due to rapid metabolism by plasma esterases. While esmolol is primarily administered intravenously for immediate cardiovascular control, understanding and developing immediate-release oral formulations is important for short-term therapy and transition from parenteral to oral dosing. Rapid drug release from IR formulations ensures timely therapeutic levels, which is critical for effective blood pressure management [25].

Moreover, immediate-release formulations offer advantages such as simplicity of design, predictable pharmacokinetics, and ease of dose modification. These features are particularly valuable in antihypertensive therapy, where individualized dosing and rapid therapeutic adjustments are often necessary. Therefore, immediate-release formulations continue to play a significant role in the treatment of hypertension, supporting effective and flexible pharmacotherapy for cardiovascular disorders [26].

4. Recent advances in immediate release tablet technology

The field of immediate-release (IR) tablet technology has seen significant advancements in recent years, driven by innovations in excipient design, formulation strategies, manufacturing processes, and quality control approaches. While IR tablets have been well established, modern research continues to refine their performance to achieve faster disintegration, more reliable dissolution, improved manufacturability, and enhanced patient compliance. The following sections summarize key recent developments relevant to IR tablet formulations, including those for antihypertensive drugs such as esmolol hydrochloride [27].

4.1 Development of Novel Superdisintegrants

Traditional superdisintegrants such as croscarmellose sodium (CCS), sodium starch glycolate (SSG), and crospovidone have been widely used to promote rapid tablet disintegration. Recent research has focused on:

- **Co-processed Superdisintegrants:** Combining two or more functional excipients (e.g., CCS with microcrystalline cellulose or crospovidone with sodium alginate) to enhance swelling and wicking without compromising flowability.
- **Nanotechnology-based Disintegrants:** Use of nano-sized disintegrant particles to increase surface area and promote faster water uptake.
- **Natural and Bio-based Superdisintegrants:** Exploration of plant-derived polymers such as **guar gum, locust bean gum, and modified starches** as sustainable alternatives with efficient disintegration properties.

These novel disintegrants often exhibit improved efficiency at lower concentrations, leading to more robust IR tablets with shorter disintegration times [28].

4.2 Advanced Manufacturing Techniques

4.2.1 Direct Compression with Engineered Excipients

Direct compression remains the technique of choice for immediate-release tablets due to its simplicity. Recent advances include:

- **Co-processed excipients** specifically engineered for IR applications, providing enhanced compressibility, flow, and disintegration in one material.
- **Multifunctional excipients** that combine diluent, binder, and disintegrant properties, reducing the number of excipients needed in a formulation.

4.2.2 3D Printing (Additive Manufacturing)

Emerging studies demonstrate the feasibility of 3D-printed immediate-release tablets with customized release profiles. 3D printing allows:

- Tailored geometries to optimize surface area for faster disintegration.
- Personalized dosing and rapid prototyping during formulation development.

Though not yet mainstream for large-scale IR tablet manufacturing, 3D printing represents a flexible tool for personalized medicine.

4.3 Formulation Design Using Quality by Design (QbD)

Quality by Design (QbD) has been increasingly incorporated into IR tablet development to ensure robust performance and regulatory compliance. Key QbD elements include:

- **Risk assessment** to identify critical formulation and process parameters.
- **Design of Experiments (DoE)** to systematically optimize disintegrant type/level, compression force, and excipient ratios.
- **Design space definition** to establish operational limits that ensure desired performance (e.g., disintegration time and dissolution rate).

The QbD approach improves product understanding and reduces batch-to-batch variability.

4.4 Enhanced Dissolution Technologies

Strategies to improve drug dissolution and bioavailability in IR tablets include:

- **Solid dispersions** with hydrophilic carriers to enhance wetting and dissolution of poorly water-soluble drugs.
- **Amorphous solid dispersions** to increase apparent solubility.
- **Use of surfactants and solubilizing agents** to promote rapid wettability.

These approaches can be especially beneficial for antihypertensive drugs that present solubility challenges.

4.5 In Vitro–In Vivo Correlation (IVIVC) Models

While IR tablets are generally expected to release drug rapidly, establishing a reliable in vitro–in vivo correlation helps predict clinical performance and streamline formulation adjustments. Recent advances in modeling dissolution data to match pharmacokinetic profiles enhance confidence in formulation decisions and reduce reliance on extensive in vivo testing.

4.6 Regulatory and Quality Control Advances

Regulatory science has evolved alongside IR tablet technology. Recent developments include:

- **Real-Time Release Testing (RTRT)** using process analytical technology (PAT) tools, enabling in-process monitoring of disintegration and dissolution surrogates.
- **Enhanced dissolution specifications and accelerated testing protocols** to ensure consistent product performance across batches.

These quality control enhancements improve product reliability and reduce time-to-market.

4.7 Patient-Centric Formulation Trends

To improve overall patient experience, especially among elderly or pediatric populations:

- **Smaller tablet sizes** with rapid disintegration.
- **Taste-masked IR tablets** for drugs with unpleasant taste (e.g., bitter antihypertensives).
- **Orally disintegrating tablets (ODTs)** as a subcategory of IR that dissolves without water.

Although ODTs are beyond strict IR tablets, the design principles intersect with IR formulation goals.

Recent advances in immediate-release tablet technology emphasize functional excipient innovations, design optimization using QbD, improved manufacturing processes, and enhanced dissolution strategies, all contributing to better therapeutic performance and patient compliance. These developments are particularly relevant for antihypertensive drugs where rapid onset of action is clinically desirable.

5. Future perspectives

Immediate-release (IR) tablet technology continues to evolve in response to the growing demand for faster therapeutic action, improved product quality, and enhanced patient compliance. Although IR tablets are well-established dosage forms, several emerging trends and research directions offer opportunities for further improvement, particularly in the context of antihypertensive drug therapy [29].

One important future direction is the integration of Quality by Design (QbD) and Process Analytical Technology (PAT) in IR tablet development. These approaches enable a deeper understanding of critical formulation and process variables affecting disintegration and dissolution, leading to more robust products with reduced batch-to-batch variability and improved regulatory compliance [30].

The development of novel and multifunctional excipients is another promising area. Co-processed and engineered excipients with combined diluent, binder, and disintegrant properties can simplify formulations and improve manufacturing efficiency. Additionally, the exploration of natural and biodegradable superdisintegrants aligns with the increasing emphasis on sustainability and safety in pharmaceutical development [31].

Advances in personalized medicine and additive manufacturing technologies, such as 3D printing, may further influence immediate-release tablet design. These technologies offer the potential for patient-specific dose customization, rapid prototyping, and tailored tablet geometries to optimize disintegration and dissolution behavior, which could be particularly beneficial in antihypertensive therapy requiring individualized dosing [32].

Another key area of future research is the establishment of more reliable in vitro–in vivo correlations (IVIVC) for immediate-release formulations. Improved predictive models can reduce reliance on extensive in vivo studies, accelerate product development, and support regulatory submissions [33].

Finally, increased focus on patient-centric formulation design—including smaller tablet sizes, improved taste masking, and enhanced swallowability—will continue to drive innovation in IR tablet technology. For antihypertensive drugs, where long-term adherence is critical, such improvements may significantly enhance therapeutic outcomes [34].

In summary, future advancements in immediate-release tablet technology are expected to combine innovative excipient design, advanced manufacturing methods, regulatory science, and patient-focused strategies,

ensuring continued relevance and effectiveness of IR formulations in modern pharmacotherapy [35].

6. Conclusion

Immediate-release tablets continue to represent a cornerstone of oral drug delivery systems due to their simplicity, rapid onset of action, and high patient acceptability [36]. In the management of hypertension and other cardiovascular disorders, immediate drug availability is often critical for achieving prompt therapeutic effects, making immediate-release formulations particularly valuable [37]. Antihypertensive drugs, including β -adrenergic blockers such as esmolol hydrochloride, benefit significantly from well-designed IR dosage forms that ensure rapid disintegration and dissolution [38].

The effectiveness of immediate-release tablets is largely dependent on rational formulation design, appropriate selection of excipients—especially superdisintegrants—and the use of suitable manufacturing techniques such as direct compression [39]. Advances in excipient technology, formulation optimization through Quality by Design approaches, and improved evaluation methodologies have significantly enhanced the performance and reliability of IR tablets.

Recent developments in immediate-release tablet technology, including co-processed excipients, novel superdisintegrants, and patient-centric formulation strategies, have further expanded the potential of these dosage forms. Looking ahead, integration of advanced manufacturing technologies, predictive modeling, and personalized medicine concepts is expected to drive continued innovation in IR tablet development [40].

In conclusion, immediate-release tablets remain an indispensable dosage form in antihypertensive therapy. Ongoing research and technological advancements will continue to refine their design and performance, supporting the development of safe, effective, and patient-friendly oral formulations that meet evolving clinical and regulatory requirements.

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