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OVERVIEW ON EMERGING TRENDS IN IMMEDIATE RELEASE TABLET TECHNOLOGY

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ABSTRACT

Immediate release tablets are the most widely used dosage form due to their simple manufacturing, patient compliance, and rapid therapeutic effect. Growing demand for faster onset of action and improved bioavailability has led to innovative technologies that enhance disintegration and dissolution. This review highlights advances such as superdisintegrants, effervescent systems, solid dispersions, hot melt extrusion, and emerging approaches like 3D printing. These technologies improve drug release profiles and overcome challenges of poor solubility and variable absorption. The paper also outlines pre formulation study, Preparation methods and evaluation parameters, industrial applications, limitations, and future prospects. Understanding these advances will support the development of effective, stable, and patient-friendly formulations, making the topic highly relevant to pharmaceutical industry practice.

KEYWORDS: Immediate release tablets, superdisintegrants,

effervescent systems, solid dispersion, hot melt extrusion, 3D printing.

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INTRODUCTION

The most popular dose form tablets are used to administer three-fourths of all drugs.^[1] A tablet is a solid unit dosage form that can be round, oval, or square in shape and is made via compression and wet/dry granulation. Binders, lubricants, and glidants are frequently included as excipients for effective tableting. Disintegrants are added to pills to facilitate their simple breakdown in the digestive tract. In addition to making the tablet smoother and simpler to swallow, the coating of pigments, sweeteners, and flavoring agents serves to cover up the taste of other contents. Additionally, tablet coating increases shelf life and provides environmental protection.^[2]

The term "immediate release" refers to tablets that breakdown quickly and release the medication. Designing a dosage form for instant release tablets is important for medications that need to be delivered more quickly for a greater therapeutic impact. When at least 85% of the prescribed dosage dissolves in 30 minutes, the dosage form is considered immediate release. For items containing high solubility pharmaceuticals to be classified as an IR dosage form, the Food and Drug Administration (FDA) states that at least 80% of the drug must be released in 30 minutes. In certain situations, immediate release (IR) dosage forms—also referred to as conventional release dosage forms—are made as dispersible dosage forms that will dissolve or disintegrate prior to oral intake, allowing for the rapid absorption of medications following oral administration. In majority of patients need quick therapeutic effects from their medications, which causes them to not comply with traditional drug therapy, which reduces the efficacy of treatment. The advantages of simplicity of dosage and convenience of dosing are combined in a novel method called instant release. The purpose of these pills is to release the medications at a faster rate.

Immediate release tablets have just begun to acquire acceptance and appeal as a medication delivery method, mostly due to their convenience of administration, rapid beginning of action, affordability, and improved patient compliance. They are also an instrument for creating opportunities, prolonging product life cycles, and opening up new markets.^[7]

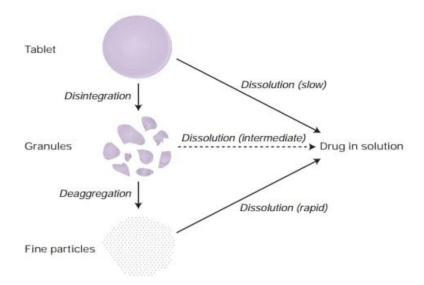


Fig.1: Immediate release tablet drug delivery system.

Advantages

- 1. Long shelf life and a unit dosage system.
- 2. Immediate release increases stability and bioavailability.
- 3. Tablet to reduce issues with bioavailability.
- 4. It is possible to load drugs as much as feasible.
- 5. Efficient at reduced concentrations.

Disadvantages

- 1. Regular dosage is necessary for medications with a short half-life. successful swallowing issues in both children and elderly people.
- 2. Drugs that have an unpleasant taste, a strong odor, or are oxygen-sensitive may need to be coated or encapsulated to reduce bioavailability issues.
- 3. GI irritation risk associated with excessive dosages of medications.
- 4. Ineffective at lower concentrations A sudden release of a drug may result in a high plasma concentration, which can be harmful.^[8-12]

TYPES OF IMMEDIATE RELEASE TABLET

Immediate release (IR) tablets are designed to disintegrate and dissolve rapidly after administration to ensure prompt therapeutic action. They are the most common oral solid dosage form because of their convenience, ease of manufacture, and patient acceptability.^[13] Depending on formulation design and mechanism of disintegration, IR tablets can be broadly classified into several types.

1. Conventional Immediate Release Tablets

These are the traditional compressed tablets that disintegrate within a few minutes after ingestion, releasing the drug for absorption in the gastrointestinal tract. They are generally prepared using conventional excipients and manufacturing techniques like direct compression or wet granulation.^[14] The onset of action depends on the disintegration time and drug solubility.^[15] (e.g., Paracetamol 500 mg, Ciprofloxacin tablets).

2. Fast Dissolving or Orally Disintegrating Tablets (ODTs)

Fast dissolving tablets are designed to disintegrate or dissolve rapidly in the mouth without the need for water, usually within 30 seconds. These formulations enhance patient compliance, especially for pediatric, geriatric, and dysphagic patients.^[16] The use of super disintegrants like cross povidone, croscarmellose sodium, and sodium starch glycolate facilitates rapid disintegration.^[17] ODTs may be prepared by direct compression, freezedrying, or sublimation techniques.^[18] (e.g., Ondansetron ODT, Levocetrizine MD).

3. Effervescent Tablets

Effervescent tablets contain a mixture of acids (such as citric or tartaric acid) and carbonates or bicarbonates that react in the presence of water to release carbon dioxide. The generated gas causes tablet breakup and promotes rapid dissolution of the drug.^[19] These tablets provide fast onset of action and mask unpleasant tastes of drugs by effervescence.^[20] (e.g., Vitamin C effervescent tablet, ORS effervescent tablet).

4. Dispersible Tablets

Dispersible tablets are designed to disperse rapidly in water to form a uniform suspension or solution before administration. They are especially useful for pediatric and geriatric patients where swallowing tablets is difficult. The dispersion process increases the surface area of the drug, leading to faster absorption and improved bioavailability.^[21] (e.g., Amoxicillin DT, Ofloxacin DT).

5. Sublingual Tablets

Sublingual tablets are placed under the tongue, where they dissolve quickly and allow direct absorption of the drug into the systemic circulation through the mucous membrane. This avoids first-pass metabolism and ensures a faster onset of action. They are ideal for emergency drugs like nitroglycerin and clonidine. (e.g., Nitroglycerin SL tablet, Buprenorphine SL tablet).

6. Buccal Tablets

Buccal tablets are designed to dissolve slowly when placed between the gum and cheek. Although they are not as rapid as sublingual tablets, they provide a balance between immediate and sustained drug release, maintaining therapeutic levels for longer durations.^[20] (e.g., Nicotine buccal tablet, Progesterone buccal tablet).

Table 1: Emerging Technologies in Immediate Release Tablets. [24-32]

Technology	Examples	Advantage	Limitation
Superdisintergants	Crospovidone, Sodium Starch Glycolate, Croscarmellose Sodium	Help tablet break and dissolve quickly → faster onset of action	Limited effect on very poorly soluble drugs
Effervescent System	Dispirin (Aspirin + citric acid + sodium bicarbonate)	disintegration due to CO ₂ release, pleasant taste	Moisture sensitive and needs special packaging
Fast dissolving / ODT technology	Ondansetron ODT, Paracetamol ODT	Dissolves in mouth without water, ideal for pediatric & geriatric use	Limited drug dose can be incorporated
Solid dispersion	Ibuprofen, Nifedipine formulations	Enhances solubility and uniform dispersion of drug in polymer	High processing temperature may degrade drug
3D Printing	Spritam® (Levetiracetam)	Personalized dose, complex shapes, rapid disintegration	Expensive equipment, limited large-scale use

APPLICATIONS OF IMMEDIATE RELEASE TABLETS

- **1. Pain Management and Inflammation Control** IR formulations of ibuprofen, diclofenac sodium, and ketoprofen are used for rapid relief in conditions such as headache, arthritis, and postoperative pain. The fast disintegration ensures early absorption and prompt therapeutic action. [33, 18]
- **2. Antimicrobial Therapy** Antibiotics such as ciprofloxacin, clarithromycin, and amoxicillin are formulated as IR tablets to achieve fast plasma concentration and effective infection control.^[34]
- **3. Cardiovascular Disorders** Drugs like amlodipine, nifedipine, and atenolol in IR form are preferred for managing hypertension and angina, providing immediate symptom relief.^[35]
- **4. Diabetes Mellitus** IR formulations of glibenclamide and glipizide are used for quick glycemic control, helping prevent postprandial glucose spikes.^[36]
- **5. CNS Disorders** Drugs such as diazepam, alprazolam, and paracetamol-caffeine combinations in IR dosage are effective for anxiety, insomnia, and tension-related headaches due to their rapid onset of action. [37]

- **6. Gastrointestinal Disorders** Drugs like omeprazole, loperamide, and cimetidine are used in IR form for rapid acid suppression and symptomatic relief in ulcers and diarrhea. [38]
- **7. Allergic Reactions and Motion Sickness** Cinnarizine, cyclizine, and cyproheptadine in IR dosage provide quick antihistaminic and antiemetic action. [39]

MATERIALS AND METHODS

The formulation of immediate release (IR) tablets involves the careful selection of suitable excipients, followed by the application of appropriate processing techniques to achieve rapid drug disintegration and dissolution. Generally, an IR tablet contains an active pharmaceutical ingredient (API), diluents, binders, super disintegrants, lubricants, and glidants. Each component contributes to the physical stability, mechanical strength, and disintegration behavior of the formulation.^[13]

PRE FORMULATION STUDIES

1. Physical Appearance and Organoleptic Evaluation

Evaluation of colour, odour, and physical form of the drug is the first step in preformulation. For IR tablets, uniform particle appearance and absence of aggregates ensure homogeneous mixing with superdisintegrants and diluents, which directly affects disintegration time and content uniformity.^[40]

2. Solubility Studies

Solubility screening in different solvents and pH conditions is crucial. For IR tablets, drugs should ideally have high aqueous solubility (>1 mg/mL) to achieve rapid dissolution in gastric fluids. Poorly soluble drugs may require salt formation, co-solvents, or micronization to meet IR dissolution targets.^[41]

3. pKa Determination and Ionization Behaviour

Knowledge of pKa helps determine the drug's ionization at gastrointestinal pH. IR formulations often rely on ionized forms for faster dissolution, and pKa guides selection of appropriate pH modifiers or buffering agents to ensure rapid onset.^[42]

4. Particle Size and Surface Area Analysis

Smaller particle size increases dissolution rate (Noyes–Whitney principle). For IR tablets, particle size $<100 \mu m$ is often targeted to accelerate drug release, while avoiding excessive fine particles that may compromise flow.^[43]

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5. Flow Properties (Angle of Repose, Carr's Index, Hausner Ratio)

Good flowability ensures uniform die filling. IR tablets require angle of repose <30°, Carr's index 10–15%, and low Hausner ratio to maintain weight uniformity, crucial for fast-disintegrating tablets.^[44]

6. Compressibility and Compactibility Studies

Compressibility is critical for IR tablets manufactured by direct compression. Optimal compressibility ensures tablets have adequate hardness (3–5 kg/cm²) for handling, yet low enough to disintegrate rapidly (Shangraw, 1994).^[45]

7. Drug-Excipient Compatibility Studies

Drug excipients compatibility Study include various techniques likes, DSC (Differential Scanning Calorimetry), FTIR (Fourier Transform Infrared Spectroscopy). Compatibility studies ensure that excipients like superdisintegrants, fillers, and lubricants do not inhibit rapid tablet disintegration or reduce solubility. Selection of compatible excipients ensures IR tablets meet disintegration time <15 min. [46]

8. Bulk Density and Tapped Density

These influences die fill and compression. For IR tablets, bulk density 0.4–0.6 g/mL with consistent tapped density ensures uniformity, reduces capping, and supports rapid disintegration and dissolution.^[47]

9. Stability Studies (Accelerated & Short-Term)

Stability under temperature and humidity ensures the IR tablet maintains disintegration time, hardness, and dissolution profile throughout shelf-life. Accelerated conditions (40°C/75% RH) help predict long-term performance.^[48]

METHODS FOR PREPARATION

1. Direct Compression Method

This is the most commonly employed and economical technique for IR tablet manufacturing. In this method, all excipients and API are blended uniformly and directly compressed into tablets without prior granulation. It is especially suitable for moisture- and heat-sensitive drugs, as it eliminates wetting and drying steps.^[13] The success of this method largely depends on the flowability and compressibility of the powder blend.

2. Wet Granulation Method

This technique involves mixing the API with diluents and binders, adding a suitable granulating agent (commonly water or hydroalcoholic solution), followed by wet massing, sieving, drying, and compression. Wet granulation improves compressibility, reduces segregation, and ensures uniform drug distribution. [14] However, this method is not suitable for drugs sensitive to moisture or heat. [17]

3. Dry Granulation Method

Dry granulation is applied when the drug or excipients are moisture- or heat-sensitive. The powder blend is first compacted into slugs or ribbons using a roller compactor, which is then milled and compressed into tablets. This process improves flow and density without using liquid binders. [15,49] Although it reduces processing time, it requires high compression force and may lead to non-uniform density.

After compression, the tablets undergo evaluation tests such as hardness, friability, weight variation, disintegration, and dissolution to ensure product quality as per pharmacopoeial standards.[50]

EVALUATION PARAMETERS OF IMMEDIATE RELEASE TABLETS

Evaluation of immediate release (IR) tablets is a critical step to ensure their quality, performance, and therapeutic effectiveness. Several physical, mechanical, and chemical parameters are assessed as per pharmacopoeial standards (IP, BP, and USP). The following parameters are commonly evaluated.

1. General Appearance

The physical appearance of tablets provides an overall indication of their quality. Tablets should possess a uniform shape, color, and surface texture, free from cracks, chips, or surface irregularities. A smooth and consistent surface ensures proper coating and consumer acceptability.[51]

2. Weight Variation Test

This test determines the uniformity of weight among tablets in a batch. Twenty tablets are randomly selected, weighed individually, and compared with the average weight. According to Indian Pharmacopoeia. [52] The deviation should not exceed ±5% for tablets weighing more than 250 mg. Consistent tablet weight ensures uniform drug content. [53]

3. Hardness Test

Tablet hardness, also known as crushing strength, measures the mechanical integrity and ability to withstand handling during manufacturing, packaging, and transport. It is typically measured using a Monsanto or Pfizer hardness tester, and the acceptable range for IR tablets is 3–5 kg/cm².^[54]

4. Friability Test

Friability evaluates a tablet's ability to resist abrasion during packaging and shipping. It is measured using a Roche Friabilator, where tablets are rotated for 4 minutes at 25 rpm. The weight loss should be less than 1% of the initial weight to meet standard specifications.^[55]

5. Disintegration Test

This test determines the time required for tablets to break down into particles small enough to pass through a 10-mesh screen. Immediate release tablets should disintegrate within 15 minutes as per IP/BP standards. The test is conducted using a disintegration apparatus with six glass tubes and a temperature-controlled bath maintained at 37 \pm 2 °C. [56]

6. Dissolution Test

The dissolution test assesses the rate and extent of drug release from the tablet into the dissolution medium. It is performed using USP Apparatus I (basket) or II (paddle) at a specified rotation speed, typically 50-75 rpm. Dissolution studies help predicts bioavailability and therapeutic efficacy. [57]

7. Drug Content Uniformity

This parameter ensures that each tablet contains the labeled amount of active ingredient within acceptable limits (±5%). Ten tablets are randomly selected, powdered, and analyzed spectrophotometrically or chromatographically (UV or HPLC method). Uniformity ensures accurate dosing and consistent therapeutic effect. [58]

8. Thickness and Diameter

Tablet thickness and diameter are measured using Vernier calipers or micrometers. These physical dimensions affect packaging, coating, and dissolution behavior. Uniformity in size reflects good control of granulation and compression parameters.^[59]

9. Stability Studies

Stability testing evaluates the physical and chemical stability of tablets under controlled conditions of temperature and humidity, as per ICH guidelines (40 °C ± 2 °C / 75% ± 5% RH). The study ensures that tablet properties such as hardness, disintegration, and assay remain within limits over time. [53]

10. Moisture Content

Excess moisture in tablets may affect their hardness, disintegration time, and microbial growth. The moisture content is determined using a Karl Fischer titrator or moisture analyzer, and should generally remain below 2%. [51]

CONCLUSION

Immediate release tablet technology continues to be a cornerstone in oral drug delivery due to its simplicity, patient compliance, and rapid therapeutic effect. With the evolution of novel formulation strategies such as superdisintegrants, solid dispersion, hot melt extrusion, and 3D printing, the limitations of conventional tablets especially poor solubility and variable bioavailability—are being effectively overcome. These advancements not only enhance the onset of drug action but also enable the formulation of drugs with challenging physicochemical properties. Moreover, the application of immediate release systems across diverse therapeutic areas such as cardiovascular, anti-infective, analgesic, and anti-diabetic therapy underscores their clinical significance.

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