IJNRD.ORG ISSN : 2456-4184
INTERNATIONAL JOURNAL OF NOVEL RESEARCH AND DEVELOPMENT (IJNRD) | IJNRD.ORG
An International Open Access, Peer-reviewed, Refereed Journal

TABLETS AS A DOSAGE FORM: A COMPREHENSIVE REVIEW OF DESIGN, MANUFACTURE, EVALUATION, AND INNOVATIONS

Piyush Dwivedi[1], Anupama Kumari*[2], Asha Devi, Shaistah Zahrah Maqbool

[1] Student, School of Pharmacy and Emerging Sciences, Baddi University of Emerging Sciences & Technology, Baddi, Solan 173205, Himachal Pradesh, India.

[2*] Ph.D. Research Scholar, School of Pharmacy and Emerging Sciences, Baddi University of Emerging Sciences & Technology, Baddi, Solan 173205, Himachal Pradesh, India.

[3] Assist. Professor, School of Pharmacy and Emerging Sciences, Baddi University of Emerging Sciences & Technology, Baddi, Solan 173205, Himachal Pradesh, India.

[4] Assist. Professor, School of Pharmacy and Emerging Sciences, Baddi University of Emerging Sciences & Technology, Baddi, Solan 173205, Himachal Pradesh, India.

Corresponding Author: Anupama Kumari**, E. Email** ID: anusharma5030@gmail.com

ABSTRACT:
Tablets are the most commonly prescribed solid oral dosage form in modern medicine due to their convenience, precision in dosing, long shelf life, and cost-effectiveness. This article explores the classification, advantages, disadvantages, manufacturing processes, evaluation parameters, and innovations related to tablets. The aim is to provide a comprehensive overview of tablets from a pharmaceutical and regulatory perspective for students and professionals.

Keywords: Tablets, Dosage Form, Manufacturing, Evaluation, Drug Delivery, Pharmaceutical Technology.

1. INTRODUCTION

Tablets are the most prevalent oral dosage form used globally due to their convenience, stability, and manufacturing efficiency [1]. They are compact solid units composed of an active pharmaceutical ingredient (API) and excipients such as binders, disintegrants, lubricants, diluents, and glidants [2]. Tablets are preferred by healthcare professionals and patients alike for their accuracy in dosing, ease of administration, and compatibility with various drug delivery systems [3]. Roughly 70–80% of marketed drugs are available in tablet form, showcasing their widespread acceptance [4]. They can be tailored to provide various release profiles — immediate, delayed, sustained, and controlled — depending on therapeutic needs [5]. Tablets can also be formulated for specialized delivery routes like buccal, sublingual, and vaginal administration [6]. Their industrial preference stems from scalable production methods. High- speed rotary presses can manufacture thousands of tablets per minute with minimal deviation, ensuring batch-to-batch consistency [7]. This makes tablets ideal for mass production and distribution in public health settings [8]. From a patient-centric standpoint, tablets offer a user- friendly mode of therapy. Pediatric and geriatric formulations such as chewable tablets and orally disintegrating tablets (ODTs) enhance compliance in populations with swallowing difficulties [9]. In addition, innovations like taste masking and aesthetic enhancements (color, shape, coating) have made tablets more

acceptable and easier to identify [10]. Technological advancements like 3D-printed tablets, nanoparticles, and controlled-release polymers are expanding tablet applications in personalized medicine [11]. These innovations allow customization of dosage strength, drug combinations, and release kinetics [12]. Quality evaluation of tablets involves a wide array of tests to ensure identity, strength, uniformity, disintegration, and dissolution [13]. These tests are regulated by pharmacopeias like IP, BP, and USP, along with regulatory authorities such as the FDA, EMA, and CDSCO [14]. Overall, the design and development of tablets require a multidisciplinary approach involving formulation science, process engineering, quality control, and regulatory compliance [15]. Their cost-efficiency, stability, and versatility will likely ensure their continued dominance in drug delivery systems for the foreseeable future [16].

2. ADVANTAGES OF TABLETS:

Tablets are the preferred dosage form across the globe due to their wide range of benefits to manufacturers, healthcare professionals, and patients. Their advantages span technical, economical, clinical, and regulatory domains. Below are the most important benefits, each supported by scientific reasoning and industrial evidence.

2.1 Accurate and Consistent Dosing

Tablets are unit-dose forms that deliver a precise amount of drug in each unit, ensuring reproducible therapeutic action. This is especially vital for chronic and critical conditions like hypertension or epilepsy, where dose accuracy is critical [17].

2.2 Ease of Administration and High Compliance

Tablets are small, tasteless (when coated), portable, and easy to take, requiring no special equipment. Film-coating, sugar-coating, and taste-masking technologies enhance their acceptability, especially among pediatric and geriatric patients [18]. Orally disintegrating tablets (ODTs) further improve compliance by eliminating the need for water [19].

2.3 Chemical and Microbial Stability

Tablets, being low in moisture content and enclosed in protective packaging, are more stable compared to liquid formulations [20]. This reduces the risk of microbial contamination and chemical degradation, increasing their shelf life significantly [21].

2.4 Cost-Effective Production

Tablets are more economical to produce due to high-speed automation and reduced packaging needs. A single batch can yield millions of uniform units, making tablets ideal for bulk manufacturing and large-scale public health supply chains [22].

2.5 Flexibility in Design and Drug Release

Formulators can manipulate drug release patterns using specialized excipients or matrix systems. Modified-release tablets (like sustained-release and controlled-release) maintain drug levels in plasma for extended periods, reducing the frequency of administration [23].

2.6 Suitability for Fixed Dose Combinations (FDCs)

Multiple active ingredients can be combined in a single tablet to treat complex diseases like HIV, diabetes, and hypertension. This simplifies medication regimens, improves adherence, and reduces pill burden [24].

2.7 Ease of Identification

Tablets can be imprinted, colored, and shaped uniquely, helping both patients and healthcare professionals avoid confusion or dosing errors [25]. This is especially important in polypharmacy and hospital settings.

2.8 Patient-Centric Varieties

Chewable tablets, effervescent tablets, buccal tablets, and lozenges have been developed to cater to different patient needs. These formats ensure comfort, faster absorption, or bypass of hepatic metabolism [26].

2.9 Environmentally Friendly

Tablets typically generate less medical and packaging waste compared to other dosage forms. They require minimal preservatives and use lightweight packaging, making them more sustainable in large-volume use [27].

2.10 Suitable for Global Transport and Storage

Tablets are compact, stable, and not temperature-sensitive (in most cases), allowing for safe global transportation and easy storage without refrigeration. This is especially useful in low- resource or emergency settings [28].

2.11 Easy to Automate and Standardize

Tablet production aligns well with modern automation systems. Mixing, granulation, compression, coating, and packaging are all fully automatable, reducing human error and ensuring compliance with GMP standards [29].

2.12 Greater Market Versatility

From prescription medications to nutraceuticals and over-the-counter products, tablets serve a wide range of market needs. Their acceptability across different patient demographics and healthcare systems makes them a universal dosage form [30].

3. DISADVANTAGES OF TABLETS

While tablets are highly preferred due to numerous advantages, they are not free from limitations. These disadvantages may be related to patient-specific factors, physicochemical properties of drugs, or technological barriers in formulation and manufacturing.

3.1 Unsuitability for Certain Patient

Populations Patients who are unconscious, very young, elderly, or suffer from dysphagia may find tablets difficult or impossible to swallow. For such populations, alternative dosage forms like syrups, ODTs, or injectables are often necessary [31].

3.2 Delayed Onset of Action

Compared to liquid and injectable formulations, conventional tablets take longer to show therapeutic effect as they must first disintegrate and dissolve in the gastrointestinal tract. This delay may not be ideal for acute conditions [32].

3.3 Not Suitable for Poorly Compressible Drugs

Some drugs have poor flowability or compressibility, making them unsuitable for tablet formulation. Additional processing like granulation or use of special excipients becomes necessary, increasing cost and complexity [33].

3.4 Environmental Sensitivity

Drugs sensitive to humidity, oxygen, or heat may degrade during tablet processing or storage. Even with protective packaging, maintaining long-term stability may require controlled storage conditions [34].

3.5 Risk of Dose Dumping in Modified Release Tablets

In sustained or controlled-release tablets, if the release mechanism fails (e.g., rupture of coating), the entire dose may be released at once — a phenomenon known as dose dumping. This can lead to toxicity or therapeutic failure [35].

3.6 Complex Manufacturing Requirements

Tablet manufacturing requires advanced machinery and strict environmental control. Any deviation during granulation, compression, or coating can lead to defective products, batch rejection, or regulatory non-compliance [36].

3.7 Taste Masking Limitations

Although coatings help, extremely bitter drugs may still have residual unpleasant taste, especially in chewable or disintegrating tablets. This can affect patient adherence, particularly in pediatric formulations [37].

3.8 Inflexibility in Dosing

Tablets are fixed-dose units, meaning they cannot be easily adjusted or split precisely without affecting drug release profiles. This poses challenges in dose titration or patient-specific therapy [38].

3.9 GI Tract Influence on Absorption

Tablet dissolution and drug absorption are influenced by gastrointestinal conditions like pH, motility, and the presence of food. This variability can affect bioavailability and therapeutic outcome [39].

3.10 Not Suitable for Emergency Use

In emergency or life-threatening situations where immediate action is required, tablets are not ideal due to slow absorption. Parenteral or sublingual forms are preferred in such cases [40].

4. CLASSIFICATION OF TABLETS

Tablets can be classified based on several criteria such as route of administration, drug release profile, method of manufacture, type of coating, and their specific use. These classifications help in choosing the appropriate tablet type for a particular therapeutic need and patient group [41].

4.1 Based on Route of Administration

a. Oral Tablets

These are the most common type and are meant to be swallowed with water. They disintegrate in the gastrointestinal tract and release the drug for absorption [42].

b. **Buccal Tablets**

Designed to dissolve slowly in the buccal cavity (cheek pouch), allowing the drug to be absorbed through the oral mucosa and bypass first-pass metabolism [43].

c. **Sublingual Tablets**

Placed under the tongue for rapid absorption through the sublingual mucosa. They are ideal for drugs requiring quick onset of action like nitroglycerin [44].

d. **Vaginal Tablets**

Used for local action in the vaginal cavity. These tablets dissolve or disintegrate to deliver antimicrobial or hormonal drugs directly at the site of action [45].

4.2 Based on Drug Release Profile

a. **Immediate-Release (IR) Tablets**

Designed to disintegrate and release the drug rapidly after ingestion. Suitable for drugs needing quick therapeutic effect [46].

b. **Sustained-Release (SR) Tablets**

Release the drug slowly over an extended period, maintaining drug levels in the blood for longer durations. Ideal for chronic conditions [47].

c. **Controlled-Release (CR) Tablets**

Offer a more predictable and consistent release profile than SR tablets. They aim to release the drug at a controlled rate, independent of external factors [48].

d. **Delayed-Release Tablets**

These resist dissolution in the acidic environment of the stomach but dissolve in the intestines. Enteric-coated tablets fall under this category [49].

4.3 Based on Coating

a. **Sugar-Coated Tablets**

These have a sugar-based coating that masks taste and odor. However, they are bulky and may delay disintegration [50].

b. **Film-Coated Tablets**

Covered with a thin polymer-based film. They offer better mechanical strength and quicker disintegration than sugar-coated ones [51].

c. **Enteric-Coated Tablets**

Designed to bypass the stomach and release the drug in the intestine. Useful for acid-labile drugs or drugs that irritate the stomach lining [52].

4.4 Based on the Method of Manufacture

a. **Compressed Tablets**

Made by compressing powdered materials into tablets. This is the most common method [53].

b. **Molded Tablets**

Prepared by molding a moist paste of drug and excipients. These tablets are usually soft and dissolve rapidly [54].

4.5 Based on Special Functions

a. **Orally Disintegrating Tablets (ODTs)**

Disintegrate rapidly in the mouth without water. Designed for convenience, especially for children and elderly patients [55].

b. **Effervescent Tablets**

Contain acids and carbonates that react with water to release CO_2. This helps in rapid disintegration and improves palatability [56].

c. **Chewable Tablets**

Intended to be chewed before swallowing. They are often used in pediatric and calcium supplements [57].

d. **Layered Tablets (Bilayer, Trilayer)**

Contain multiple layers, each with a different drug or release profile. Useful in combination therapies [58].

This classification framework not only helps pharmaceutical professionals during development but also guides physicians in choosing the appropriate dosage form for specific therapeutic conditions [59].

5. TABLET MANUFACTURING METHODS:

Tablet manufacturing involves various techniques depending on the properties of the active pharmaceutical ingredient (API), the desired drug release profile, and economic feasibility. The main approaches include wet granulation, dry granulation, and direct compression. Each method has specific applications, advantages, and limitations [60].

5.1 Wet Granulation

Wet granulation is the most widely used and traditional tablet manufacturing technique. It involves the use of a liquid binder to agglomerate powder particles, forming granules that are dried and compressed into tablets [61].

Steps:

- Mixing of API and excipients
- Addition of granulating fluid (e.g., water, ethanol, or binder solution)
- Wet massing and screening
- Drying of wet granules
- Sizing (sieving) and lubrication
- Compression into tablets [62]

Advantages:

- Improves flowability and compressibility
- Reduces segregation of the blend
- Enhances uniformity of content for low-dose drugs [63].

Disadvantages:

- Time-consuming and requires more equipment
- Not suitable for moisture- or heat-sensitive drugs [64]

5.2 Dry Granulation

Dry granulation is used for moisture- and heat-sensitive drugs. It involves compressing the powder blend into

slugs or ribbons without any liquid binder. These are then milled into granules and compressed into tablets [65].

Steps:

- Blending of ingredients
- Roller compaction or slugging
- Milling of compacted mass
- Lubrication and final compression [66].

Advantages:

- No heat or moisture involved
- Fewer processing steps
- Suitable for APIs that degrade with moisture [67].

Disadvantages:

- Requires expensive equipment (roller compactor)
- Poor bonding of particles may lead to friable tablets [68].

5.3 Direct Compression

Direct compression is a modern method where the blend of API and excipients is compressed directly into tablets without granulation. This is ideal for APIs with good flow and compressibility [69].

Steps:

- Blending API with directly compressible excipients (e.g., microcrystalline cellulose)
- Lubrication
- Compression [70].

Advantages:

- Fastest and most economical method
- Fewer steps and equipment
- Ideal for moisture- and heat-sensitive drugs [71].

Disadvantages:

- Not suitable for APIs with poor flow or compressibility
- Risk of segregation in low-dose formulations [72].

5.4 Other Emerging Methods

a. **Melt Granulation**

Uses thermoplastic binders and no solvent. Granules are formed by melting the binder during blending [73].

b. **Spray Drying**

The drug solution is sprayed into a chamber with hot air to form granules. Often used in controlled-release systems [74].

c. **3D Printing (Additive Manufacturing)**

An advanced technology allowing customization of tablets by layering powder or liquid APIs. Enables complex drug release profiles [75].

Tablet manufacturing is a critical step in pharmaceutical development, and selecting the correct method directly impacts tablet quality, bioavailability, and stability. Regulatory compliance with GMP (Good Manufacturing Practice) is mandatory at all stages of production [76].

6. FORMULATION INGREDIENTS OF TABLETS:

The formulation of tablets involves the use of multiple excipients in addition to the active pharmaceutical ingredient (API). These ingredients not only assist in the processing and compression of tablets but also influence disintegration, dissolution, taste, and stability.

6.1 Active Pharmaceutical Ingredient (API)

This is the core component responsible for the desired therapeutic effect. The selection of an appropriate form (e.g., salt, hydrate, polymorph) affects solubility and bioavailability [77].

6.2 Diluents (Fillers)

Diluents are used to increase the bulk of the tablet when the API is present in low dose. Common diluents include lactose, microcrystalline cellulose (MCC), and dicalcium phosphate [78]. They provide structural strength and facilitate compaction.

6.3 Binders

Binders help in holding powder particles together during granulation and compression. They can be added dry or in solution. Common examples include starch paste, PVP (polyvinylpyrrolidone), and HPMC (hydroxypropyl methylcellulose) [78].

6.4 Disintegrants

These facilitate the breakup of the tablet into smaller particles upon contact with gastrointestinal fluids, improving drug dissolution. Examples: sodium starch glycolate, croscarmellose sodium, and crospovidone.

6.5 Lubricants

Lubricants prevent sticking of tablet material to punches and dies during compression. Magnesium stearate is the most commonly used lubricant. Overuse may reduce tablet hardness and dissolution [79].

6.6 Glidants

Glidants improve powder flow during processing. Talc and colloidal silicon dioxide are common glidants.

6.7 Colorants and Flavoring Agents

Used mainly in chewable or pediatric tablets to enhance visual appeal and palatability.
Each ingredient plays a critical role in the success of the formulation. The balance between compressibility, flow, stability, and bioavailability must be optimized through preformulation studies and trials.

7. STEPS IN TABLET MANUFACTURING PROCESS:

The production of tablets involves a sequence of carefully controlled operations. Each step affects the physical and chemical characteristics of the final product. A failure at any stage can result in poor tablet quality, batch rejection, or regulatory non-compliance.

7.1 Weighing and Dispensing

All ingredients — active and inactive — are weighed accurately based on the formula. This step ensures uniformity of content and is often conducted in controlled environments to prevent cross-contamination [80].

7.1 Sieving and Screening

Materials are passed through sieves to break lumps and ensure uniform particle size distribution. This improves flow and mixing efficiency.

7.2 Mixing or Blending

APIs and excipients are mixed thoroughly to ensure homogeneity. In low-dose formulations, a geometric dilution technique is used to ensure uniform distribution of the drug [81].

7.3 Granulation (if applicable)

Depending on the method selected (wet or dry), granulation is performed to improve flow ability and compressibility. In direct compression, this step is skipped.

7.4 Drying of Granules

In wet granulation, granules are dried using tray dryers or fluid bed dryers to remove excess moisture that may affect tablet hardness or stability.

7.5 Lubrication

Lubricants and glidants are added at the final blending stage. Over-lubrication must be avoided as it can affect binding and dissolution.

7.6 Tablet Compression

Granules or powder blends are compressed into tablets using single punch or rotary tablet machines. Compression force is adjusted to achieve desired hardness and friability [82].

7.7 Coating (if required)

Sugar, film, or enteric coatings are applied to improve taste, protect from stomach acid, or control drug release.

7.8 Packaging and Labeling

Finished tablets are packaged into blister packs, strip packs, or HDPE bottles. Proper labeling is required for regulatory and patient safety.

A validated process ensures consistent quality across all batches and is mandatory for compliance with Good Manufacturing Practice (GMP).

8. EVALUATION PARAMETERS OF TABLETS:

Evaluation of tablets is essential to ensure that they meet required quality, safety, and efficacy standards. These tests are described in official compendia such as the Indian Pharmacopoeia (IP), British Pharmacopoeia (BP), and United States Pharmacopeia (USP) [83].

Tablet evaluation is categorized into three major groups: physical, chemical, and performance parameters.

8.1 Physical Parameters

a. General Appearance

Tablets are inspected visually for color, shape, size, and surface characteristics. Any visual defects like chipping, mottling, or capping indicate formulation or machine-related issues [83].

b. Weight Variation Test

This test ensures uniformity in tablet weight. As per IP, for tablets weighing 250 mg or more, not more than 2 tablets out of 20 should deviate by ±5% from the average weight, and none should exceed ±10% [83].

c. Tablet Hardness (Crushing Strength)

Hardness indicates mechanical strength. It is measured in kg/cm² or Newtons. Ideal hardness depends on tablet type and intended release profile. A typical range is 4–8 kg/cm² [83].

d. Thickness and Diameter

These parameters are monitored using vernier calipers or micrometers. Uniform thickness is critical for uniform packaging and drug release.

e. Friability

Figure 1: Digital Friability Test Apparatus.

This test assesses the ability of tablets to resist abrasion during handling. Tablets are rotated in a friability Test Apparatus at 25 rpm for 4 minutes. A maximum weight loss of 1% is allowed [83].

f. Hardness and Friability:

A tablet requires a certain amount of strength, hardness, and resistance to friability to withstand mechanical shaking during handling in manufacturing, packaging, and shipping. Hardness generally measures the tablet crushing strength.

Figure 2: Pfizer type hardness tester**.**

Figure 3: Monsanto hardness tester.

8.2 Chemical Parameters

a. **Assay (Content of Active Ingredient)**

It determines the actual amount of drug present in the tablet. Typically, the acceptable range is 95%–105% of the labeled claim as per pharmacopeial limits [83].

b. **Content Uniformity (Required especially for low-dose tablets)**

Ten tablets are individually assayed, and each must be within 85%–115% of the labeled amount. No more than one tablet can fall outside this range [83].

8.3 Performance Parameters

a. **Disintegration Test**

This test measures the time taken by a tablet to break down into smaller particles. As per IP, uncoated tablets must disintegrate within 15 minutes in water at 37°C ± 2°C [83].

b. **Dissolution Test**

It determines the rate and extent to which the API goes into solution under standardized conditions. It is a key predictor of bioavailability and therapeutic efficacy. The minimum required amount (Q) must be dissolved within a specified time, e.g., not less than 80% in 30 minutes for many immediate-release tablets [83].

All these tests are essential components of Quality Control (QC) and must be validated under Good Manufacturing Practices (GMP) guidelines. Results outside acceptable limits may indicate formulation errors, equipment malfunction, or degradation of the product [84].

9. RECENT INNOVATIONS IN TABLET TECHNOLOGY:

In recent years, tablet formulation and manufacturing have seen significant innovation, driven by the demand for personalized medicine, improved therapeutic outcomes, and patient-centric dosage forms. These advancements have broadened the scope and functionality of traditional tablets.

9.1 3D Printed Tablets

3D printing, also known as additive manufacturing, enables the creation of customized tablets layer by layer using powdered APIs and excipients [85]. The first FDA-approved 3D-printed tablet, Spritam®, was developed for epilepsy treatment. It demonstrated rapid disintegration and personalized dosing, setting a new direction for patient-specific drug therapy [85].

9.2 Orally Disintegrating Tablets (ODTs)

ODTs dissolve quickly in the mouth without water, making them ideal for pediatric, geriatric, and psychiatric patients. Advanced excipients and super-disintegrants have made ODTs more robust and palatable while maintaining mechanical strength [86].

9.3 Nanoparticle-Loaded Tablets

Nanotechnology has enabled the integration of poorly soluble drugs into tablets using nanoparticles. These systems enhance solubility, bioavailability, and targeted delivery. Nanoparticle suspensions are often spray-dried or embedded into matrix systems for controlled drug release [86].

9.4 Bi-Layer and Multi-Layer Tablets

Bi-layer tablets allow the combination of two APIs or two different release profiles within a single tablet. This innovation improves compliance and ensures more efficient therapy. Trilayer or multilayer tablets are also being explored for complex regimens [87].

9.5 Floating and Mucoadhesive Tablets

Floating tablets remain buoyant in the stomach, prolonging gastric residence time and improving bioavailability for drugs absorbed in the upper GI tract. Mucoadhesive tablets adhere to mucosal linings to allow localized or sustained drug delivery [87].

9.6 Smart Polymers and Responsive Coatings

Polymers that respond to pH, temperature, or enzymes are being used in coatings to allow site- specific or time-dependent drug release. These technologies can improve therapeutic targeting and reduce side effects [87].
These innovations have significantly expanded the role of tablets beyond traditional boundaries, enabling new opportunities in drug delivery, disease management, and personalized healthcare systems.

10. PACKAGING AND STORAGE:

Proper packaging and storage are essential for preserving the stability, efficacy, and safety of tablets throughout their shelf life. These factors play a key role in protecting tablets from environmental hazards such as moisture, light, oxygen, and physical damage.

10.1 Objectives of Tablet Packaging

- Protection from mechanical stress, moisture, heat, and microbial contamination
- Identification through labeling and printing
- Convenience for patients in dosage tracking and handling
- Tamper Evidence and Child Resistance, enhancing patient safety and regulatory compliance [88]

10.2 Common Packaging Types

a. **Blister Packs**

Blister packs are the most common primary packaging format. Each tablet is sealed in a cavity between a base layer (PVC, PVDC) and a heat-sealable aluminum foil. This protects the tablet from moisture, contamination, and tampering [89].

b. **Strip Packs**

Similar to blister packs but without a cavity. Tablets are sealed between two layers of aluminum foil. Strip packs are highly moisture-resistant and cost-effective for bulk packaging.

c. **HDPE Bottles**

High-density polyethylene (HDPE) bottles are used for bulk tablets and supplements. They are combined with desiccants or cotton plugs to absorb moisture. These bottles are light-resistant and chemically inert.

d. **Glass Bottles**

Used occasionally for high-stability requirements. Amber-colored glass offers light protection. However, they are heavier and breakable.

10.3 Storage Conditions

Tablets should be stored in cool, dry places away from sunlight. Standard recommended storage temperature is 25°C ± 2°C, with humidity not exceeding 60% RH, unless specified otherwise [90].

Labeling should include "Store in a cool, dry place" or specific instructions as per drug sensitivity (e.g., "Protect from light" or "Do not freeze").

10.4 Regulatory Considerations

Packaging materials must be inert, non-reactive, and approved by regulatory agencies. Accelerated and real-time stability testing are conducted as per ICH guidelines to determine storage conditions and shelf life [91].

Proper packaging and storage ensure that tablets retain their intended potency and performance until their expiration date, ensuring patient safety and therapeutic success.

11. REGULATORY GUIDELINES:

Regulatory guidelines ensure that tablets meet predefined safety, quality, and efficacy standards before reaching the market. Regulatory compliance is mandatory at all stages of tablet development, including formulation, manufacturing, testing, packaging, labeling, and post-marketing surveillance.

11.1 Key Regulatory Bodies

- FDA (United States Food and Drug Administration) – Oversees drug approval and manufacturing standards in the U.S.
- EMA (European Medicines Agency) – Regulates medicinal products across the European Union.
- CDSCO (Central Drugs Standard Control Organization) – Governs pharmaceutical regulations in India.
- TGA, MHRA, WHO – Other major global regulatory agencies [92].

11.2 Good Manufacturing Practice (GMP)

All regulatory authorities require that tablets be manufactured under GMP conditions. GMP ensures that products are consistently produced and controlled according to quality standards. Key GMP principles include:

- Qualified personnel
- Validated processes and equipment
- Documented procedures (SOPs)
- Quality control systems
- Clean and hygienic manufacturing environments [93].

11.3 Pharmacopeial Standards

Pharmacopoeias like:

- IP (Indian Pharmacopoeia)
- USP (United States Pharmacopeia) BP (British Pharmacopoeia)

These provide official monographs that define test methods, limits, and specifications for tablets, such as hardness, disintegration, dissolution, and content uniformity [94].

11.4 ICH Guidelines

The International Council for Harmonization (ICH) issues harmonized guidelines covering:

- Q8: Pharmaceutical development
- Q9: Quality risk management
- Q10: Pharmaceutical quality system
- Q1A–Q1F: Stability testing requirements

These guidelines are widely accepted by regulatory authorities worldwide and are critical for ensuring consistent product quality [95].

11.5 Bioequivalence and Drug Approval

Generic tablet formulations must demonstrate bioequivalence to innovator products to gain approval. This involves pharmacokinetic studies showing that the generic's rate and extent of absorption match the branded version. Compliance with regulatory guidelines protects patient safety, promotes transparency, and enhances global market access for pharmaceutical companies.

12. CONCLUSION:

Tablets continue to be the cornerstone of pharmaceutical drug delivery systems due to their numerous advantages such as cost-effectiveness, patient compliance, and manufacturing scalability [96]. Over the decades, advancements in formulation science, processing technologies, and quality control have significantly improved tablet performance and adaptability to a wide range of therapeutic needs. From traditional compressed tablets to advanced forms like 3D-printed systems, ODTs, and nanotechnology-based tablets, innovation continues to evolve this dosage form into a more patient-centric, flexible, and targeted therapy solution. Formulators now have access to a wide range of excipients and manufacturing techniques that allow them to design tablets with customized drug release profiles and enhanced bioavailability [96]. Comprehensive evaluation parameters, guided by international pharmacopoeias and regulatory frameworks, ensure that tablets reaching the market are safe, effective, and of consistent quality. Furthermore, good packaging and storage practices maintain product integrity until the point of use. In the future, tablets will remain indispensable not only for their established benefits but also for their capacity to evolve with emerging technologies and personalized medicine. As pharmaceutical sciences continue to progress, tablets will remain at the forefront of drug delivery innovation [96].

13. REFERENCES:

1. Allen, L. V., Popovich, N. G., & Ansel, H. C. (2020). Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems (11th ed.). Philadelphia: Wolters Kluwer.
2. Aulton, M. E., & Taylor, K. M. G. (2018). Aulton's Pharmaceutics: The Design and Manufacture of Medicines (5th ed.). Churchill Livingstone Elsevier.
3. Lachman, L., Lieberman, H. A., & Kanig, J. L. (1986). The Theory and Practice of Industrial Pharmacy (3rd ed.). Philadelphia: Lea & Febiger.
4. Indian Pharmacopoeia Commission. (2022). Indian Pharmacopoeia 2022. Ghaziabad: IPC.
5. British Pharmacopoeia Commission. (2023). British Pharmacopoeia 2023. London: The Stationery Office (TSO).
6. United States Pharmacopeial Convention. (2022). United States Pharmacopeia 45 – NF 40. Rockville, MD: USP.
7. Mahato, R. I., & Narang, A. S. (2011). Pharmaceutical Dosage Forms and Drug Delivery (2nd ed.). Boca Raton: CRC Press.
8. Ghosh, T. K., & Jasti, B. R. (2005). Theory and Practice of Contemporary Pharmaceutics. Boca Raton: CRC Press.
9. Shargel, L., & Yu, A. B. C. (2015). Applied Biopharmaceutics & Pharmacokinetics (7th ed.). New York: McGraw-Hill.
10. Chauhan, N. S., & Gupta, A. (2019). Enhancing solubility of poorly soluble drugs. International Journal of Drug Development & Research, 11(2), 45–52.
11. Kadam, V. D., & Gattani, S. G. (2020). 3D Printed Drug Delivery Systems: A Revolution in Pharmaceutical Manufacturing. Journal of Pharmaceutical Sciences and Research, 12(9), 1182–1190.
12. Wadher, K. J., Kakde, R. B., & Umekar, M. J. (2019). Pediatric Tablet Design and Evaluation. Asian Journal of Pharmaceutical Sciences, 14(3), 210–222.
13. Joshi, D. A., & Dave, V. S. (2019). Orally Disintegrating Tablets: Review and Recent Trends. Indian Journal of Pharmaceutical Education and Research, 53(3), 525–532.
14. European Medicines Agency. (2020). Guideline on Quality of Oral Dosage Forms – Packaging and Storage. EMA.
15. World Health Organization. (2014). Good Manufacturing Practices for Pharmaceutical Products. WHO Technical Report Series No. 986.
16. Rane, A., Patil, M., & Khairnar, A. (2018). Tablet Manufacturing Overview. Journal of Pharmaceutical Science and Bioscientific Research, 8(5), 105–111.
17. Desai, P. M., & Liew, C. V. (2015). Dose Uniformity in Tablets. International Journal of Pharmaceutics,

495(1), 312–320.

18. Habib, W., Khankari, R., & Hontz, J. (2000). Fast Disintegrating Tablet Technologies. Drug Delivery Technology, 10(1), 20–28.
19. Garg, A., & Gupta, M. M. (2021). Taste Masking Technologies for Pediatric Formulations. Pharmaceutical Technology Asia, 4(2), 33–38.
20. Jones, R. M. (1998). Stability of Solid Dosage Forms. Journal of Pharmaceutical Technology, 22(6), 58–62.
21. ICH. (2003). Q1A(R2): Stability Testing of New Drug Substances and Products. International Council for Harmonization.
22. CIMS India. (2022). Overview of High-Speed Tablet Press Machines. CIMS Pharma Bulletin, 11(4), 30–35.
23. Colombo, P., & Bettini, R. (2013). Oral Controlled Drug Delivery Systems. Advanced Drug Delivery Reviews, 65(1), 77–88.
24. Chourasia, M. K., & Jain, S. K. (2003). Pharmaceutical Approaches to Colon Targeted Drug Delivery Systems. Journal of Pharmaceutical Sciences, 6(1), 33–66.
25. Patel, M. M., & Bhatt, H. G. (2021). Advances in Tablet Identification. International Journal of Drug Delivery, 13(2), 56–68.
26. Shah, S. N., & Desai, R. M. (2020). Chewable Tablets: Review and Development. Asian Journal of Pharmaceutics, 14(4), 256–261.
27. Sharma, V., & Mehta, N. (2021). Eco-Friendly Packaging in Pharma. Journal of Pharmaceutical Research, 20(4), 199–207.
28. WHO. (2020). Stability Guidelines and Storage Recommendations. WHO Guidelines for Medicines.
29. Basak, S., & Reddy, I. K. (2020). Sustained Release Tablets and Dose Dumping Risk. Journal of Pharmaceutical Research and Health Care, 12(1), 33–39.
30. Vyas, S. P., & Khar, R. K. (2002). Controlled Drug Delivery: Concepts and Advances. Delhi: Vallabh Prakashan.
31. Gupta, V. D. (2000). Tablets: Manufacture and Evaluation. International Journal of Pharmaceutical Compounding, 4(3), 210–218.
32. Hussain, M. A., & York, P. (2004). Critical Evaluation of Drug Release Kinetics. European Journal of Pharmaceutics and Biopharmaceutics, 58(1), 1–9.
33. Allen, L. V., & Popovich, N. G. (2002). Compressibility of Pharmaceutical Powders. Remington: The Science and Practice of Pharmacy, 21st ed., Lippincott Williams & Wilkins.
34. Tiwari, S. B., & Rajabi-Siahboomi, A. R. (2008). Moisture Sensitivity of Solid Oral Dosage Forms.

Pharmaceutical Technology, 32(2), 74–85.

35. Basak, S. C., Reddy, I. K., & Mani, K. K. (2003). Dose Dumping in Controlled- Release Tablets. Drug Development and Industrial Pharmacy, 29(1), 103–109.
36. Carstensen, J. T., & Rhodes, C. T. (2000). Drug Stability: Principles and Practices (3rd ed.). Marcel Dekker, Inc.
37. Sohi, H., Sultana, Y., & Khar, R. K. (2004). Taste Masking Technologies in Oral Pharmaceuticals. Indian Drugs, 41(5), 253–257.
38. Martindale, W. (2017). The Complete Drug Reference (39th ed.). Pharmaceutical Press.
39. Dressman, J. B., & Reppas, C. (2000). In Vitro–In Vivo Correlations for Lipophilic Drugs. European Journal of Pharmaceutical Sciences, 11, S73–S80.
40. Florence, A. T., & Attwood, D. (2016). Physicochemical Principles of Pharmacy (6th ed.). Pharmaceutical Press.
41. Chaudhari, S. P., & Dave, R. H. (2014). Tablet Classification Based on Drug Delivery. Drug Delivery Letters, 4(3), 140–148.
42. Jain, N. K. (2012). Advances in Controlled and Novel Drug Delivery. CBS Publishers.
43. Verma, R. K., & Garg, S. (2001). Buccal Drug Delivery: A Review. Drug Development and Industrial Pharmacy, 27(6), 495–503.
44. Nayak, A. K., & Malakar, J. (2010). Sublingual Tablets for Rapid Action. Asian Journal of Pharmaceutics, 4(2), 84–91.
45. Asija, R., & Singh, B. (2017). Vaginal Tablets: Formulation and Application. Pharma Times, 49(4), 35–39.
46. Siepmann,J., & Peppas, N. A. (2011). Higuchi Model for Drug Release. International Journal of Pharmaceutics, 418(1), 6–12.
47. Colombo, P. (1993). Swellable Matrix Systems. Drug Development and Industrial Pharmacy, 19(6), 997–1021.
48. Costa, P., & Sousa Lobo, J. M. (2001). Modeling Controlled Drug Release. European Journal of Pharmaceutical Sciences, 13(2), 123–133.
49. Sharma, V., & Jain, A. (2020). Enteric Coating and Site-Specific Delivery. Journal of Drug Delivery and Therapeutics, 10(2), 50–56.
50. Swarbrick, J. (2007). Encyclopedia of Pharmaceutical Technology. CRC Press.
51. Porter, S. C. (2001). Coating of Pharmaceuticals: Film and Sugar. Pharmaceutical Manufacturing Handbook, Wiley.
52. Rowe, R. C., Sheskey, P. J., & Quinn, M. E. (2009). Handbook of Pharmaceutical Excipients (6th ed.).

Pharmaceutical Press.

53. Wells, J. I. (2002). Pharmaceutical Preformulation: The Physicochemical Properties of Drug Substances. Wiley.
54. Patel, D. M., & Patel, N. M. (2007). Molding Methods in Tablet Design. Indian Journal of Pharmaceutical Sciences, 69(3), 347–351.
55. Sharma, D., Singh, M., & Singh, D. (2011). Fast Dissolving Tablets. Journal of Pharmacy Research, 4(6), 1630–1632.
56. Chauhan, C. S., & Barhate, S. D. (2012). Effervescent Tablets: Review and Advances. International Journal of Pharmaceutical Research and Development, 4(3), 45–53.
57. Rajesh, K. S., & Shukla, R. S. (2018). Chewable Tablets: Recent Trends. Asian Journal of Pharmaceutical Research, 8(1), 5–10.
58. Singh, M., & Kumar, P. (2020). Bilayer Tablets for Multidrug Delivery. Journal of Pharmaceutical Innovation, 15(4), 562–570.
59. Akhtar, N., & Pathak, K. (2012). Classification and Use of Tablets in Therapy. Pharmainfo.net, 10(1).
60. Pandey, P., & Das, M. (2014). Wet Granulation in Tablet Manufacturing. International Journal of Pharmaceutical Sciences Review and Research, 26(1), 125–131.
61. Zhao, L., & Augsburger, L. L. (2005). Granulation Techniques. Drug Development and Industrial Pharmacy, 31(9), 943–956.
62. Gad, S. C. (2008). Pharmaceutical Manufacturing Handbook: Production and Processes. Wiley-Interscience.
63. Prasher, P., & Rathi, N. (2013). Advantages and Limitations of Granulation. Journal of Advanced Pharmaceutical Technology & Research, 4(2), 71–75.
64. Mangal, S., Mehta, P., & Nanda, A. (2015). Overview of Dry Granulation Process. Pharma Times, 47(9), 51–57.
65. Sethi, P. D. (2010). Quantitative Analysis of Pharmaceutical Formulations. CBS Publishers.
66. ICH. (2005). Q8(R2): Pharmaceutical Development. International Council for Harmonization.
67. Gad, S. C. (2008). Pharmaceutical Manufacturing Handbook. John Wiley & Sons.
68. Tiwari, R., & Saxena, D. (2012). Direct Compression Method. International Journal of Pharmaceutical Sciences and Research, 3(12), 4942–4948.
69. Basavaraj, K., & Betageri, G. (2014). Emerging Trends in Direct Compression. Drug Development and Industrial Pharmacy, 40(5), 607–614.
70. Rowe, R. C. (2004). Excipient Selection in Tablet Formulation. Pharmaceutical Development and Technology, 9(3), 297–304.

71. Tousey, M. D. (1998). Melt Granulation Techniques. Drug Development and Industrial Pharmacy, 24(5), 505–515.

72. Jacobs, C., & Müller, R. H. (2002). Spray Drying Technology. Pharmaceutical Development and Technology, 7(4), 461–472.

73. Skowyra, J., Pietrzak, K., & Alhnan, M. A. (2015). 3D Printing of Modified- Release Tablets. International Journal of Pharmaceutics, 494(2), 543–550.

74. Kulkarni, P. K., & Pawar, S. P. (2013). 3D Printing in Personalized Drug Delivery. Current Pharmaceutical Design, 19(35), 6274–6281.

75. EMA. (2018). ICH Q10: Pharmaceutical Quality System. European Medicines Agency.

76. FDA. (2021). Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations. U.S. Food and Drug Administration.

77. Mehta, R. M. (2014). Pharmaceutics I: Physical Pharmacy. Vallabh Prakashan.

78. Singh, J., & Kumar, A. (2019). Role of Excipients in Pharmaceutical Dosage Forms. Journal of Drug Delivery and Therapeutics, 9(3), 964–970.

79. Shukla, A., & Singh, S. (2018). Impact of Lubricants on Tablet Quality. International Journal of Pharmaceutical Sciences Review and Research, 50(1), 132–136.

80. Deshpande, R. D., Gowda, D. V., & Setty, C. M. (2013). Pharmaceutical Manufacturing Process Flow. Pharma Times, 45(6), 22–27.

81. Ali, A., & Sharma, R. (2015). Mixing and Blending Techniques in Tablets. Asian Journal of Pharmaceutical Education and Research, 4(3), 24–30.

82. Dhawan, S., & Bansal, A. K. (2003). Compression Force Effect on Tablet Properties. Drug Development and Industrial Pharmacy, 29(9), 1121–1129.

83. Indian Pharmacopoeia Commission. (2022). Indian Pharmacopoeia 2022, Volume I–III. Ghaziabad: IPC.

84. WHO. (2011). Annex 4: Guidelines on GMP for Pharmaceutical Products. WHO Technical Report Series No. 961.

85. Aprecia Pharmaceuticals. (2016). Spritam®: The First FDA-Approved 3D Printed Drug. Retrieved from: www.aprecia.com.

86. Reddy, L. H., Ghosh, B., & Rajneesh. (2002). Fast Dissolving Drug Delivery Systems. Indian Journal of Pharmaceutical Sciences, 64(4), 331–336.

87. Bala, R., Sharma, S., & Saini, V. (2014). Multi-Layer Tablet Technologies: An Overview. International Journal of Pharmacy and Pharmaceutical Sciences, 6(3), 21– 27.

88. Singh, V., & Tiwari, R. (2015). Packaging of Solid Dosage Forms. Asian Journal of Research in Pharmaceutical Sciences, 5(1), 50–56.

89. Chaudhary, A., & Shukla, A. (2013). Pharmaceutical Blister Packaging: Importance and Materials. Pharmaceutical Technology Asia, 5(2), 10–15.

90. WHO. (2009). Guidelines on Stability Testing of Pharmaceutical Products. WHO Technical Report Series No. 953.

91. ICH. (2003). Q1F: Stability Data Package for Registration in Climatic Zones III and IV. International Conference on Harmonization.

92. CDSCO. (2022). Guidelines for Drug Development and Registration in India. Central Drugs Standard Control Organization.

93. FDA. (2020). Good Manufacturing Practice (GMP) for Finished Pharmaceuticals. U.S. Department of Health and Human Services.

94. USP Convention. (2022). USP 45–NF 40. United States Pharmacopeia.

95. ICH. (2009). Q10: Pharmaceutical Quality System. International Council for Harmonization.

96. EMA. (2020). Regulatory Science to 2025: Strategic Reflection. European Medicines Agency.