International Journal of Scientific Research and Engineering Development-– Volume 8 Issue 5, Sep-Oct 2025
Available at www.ijsred.com

RESEARCH ARTICLE OPEN ACCESS

A REVIEW ON PHARMACEUTICALS DOSAGE FORMS CONCEPTS THEIR PROPERTIES AND STANDARDS

[1]Shaik Nayab Rasool, [2]Cherukuri Sunitha,[3]G Jayasyamala,[4]Averineni Ravi Kumar,[5]Y Ratna Kumari, [6]M Vinod Kumar,[7]G Rajesh Kumar

1Department of Pharmaceutics, MRR College of Pharmacy, Nandigama 521185 AP INDIA
2Department of Pharmaceutics, Browns College of Pharmacy Khammam 507305 TG INDIA
3Department of Pharmaceutical Analysis, NRI College of Pharmacy,Agiripalli Vijayawada 521212 AP INDIA
4Department of Pharmacognosy, Nimra College of Pharmacy Vijayawada 521456 AP INDIA
5Department of Pharmacognosy, Narayana Pharmacy College Chintareddypalem Nellore 524002 AP INDIA
6Department of Pharmaceutical Analysis,Narayana Pharamacy College Chintareddypalem Nellore 524002 AP INDIA
7Department of Pharmaceutics, VRC Gowtham Eductional Society's Vijaya College of Pharmacy Mudinepalli 521325 AP INDIA
karavi315@gmail.com

ABSTRACT

Pharmaceutical dosage forms play a vital role in ensuring that medications are delivered to the body in a manner that is safe, effective, and convenient for the patient. These formulations are carefully designed to improve drug stability**,** absorption**,** therapeutic action**,** and patient adherence**.**Whether it's solids like tablets and capsules**,** liquids**,** semi-solids**,** injectables**,** inhalation therapies, or transdermal systems, each type of dosage form is selected based on the specific characteristics of the drug and the intended route of administration.Having a thorough understanding of these various dosage forms allows healthcare professionals to:Select the most suitable formulation for the patient,Enhance the effectiveness of treatment,Reduce the risk of adverse effects,And ensure correct and consistent usage.With ongoing advancements in pharmaceutical technology, more sophisticated systems—such as controlled-release and targeted delivery forms—are being introduced to further improve treatment outcomes and patient quality of life.In the choice of dosage form is a crucial step in the development of any drug, serving as the link between the medication's potential benefits and its actual performance in clinical use.

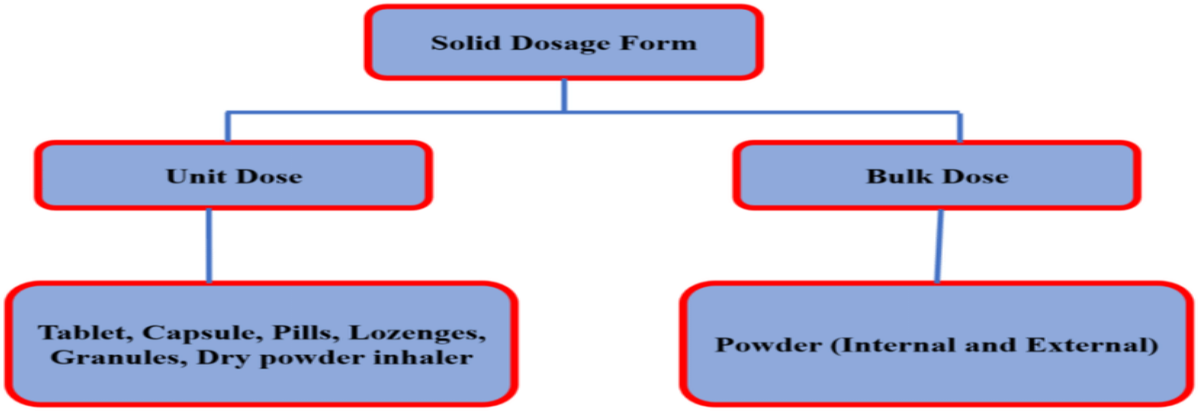
Keywords: Pharmaceutical Dosage Forms. Solid, Liquid. Advance Dosage Forms

INTRODUCTION

Pharmaceutical dosage forms refer to the physical form in which a drug is produced and administered. These forms ensure the **safe**, **effective**, and **convenient** delivery of medications, often classified by **route of administration**, **physical state**, and **release profile**.

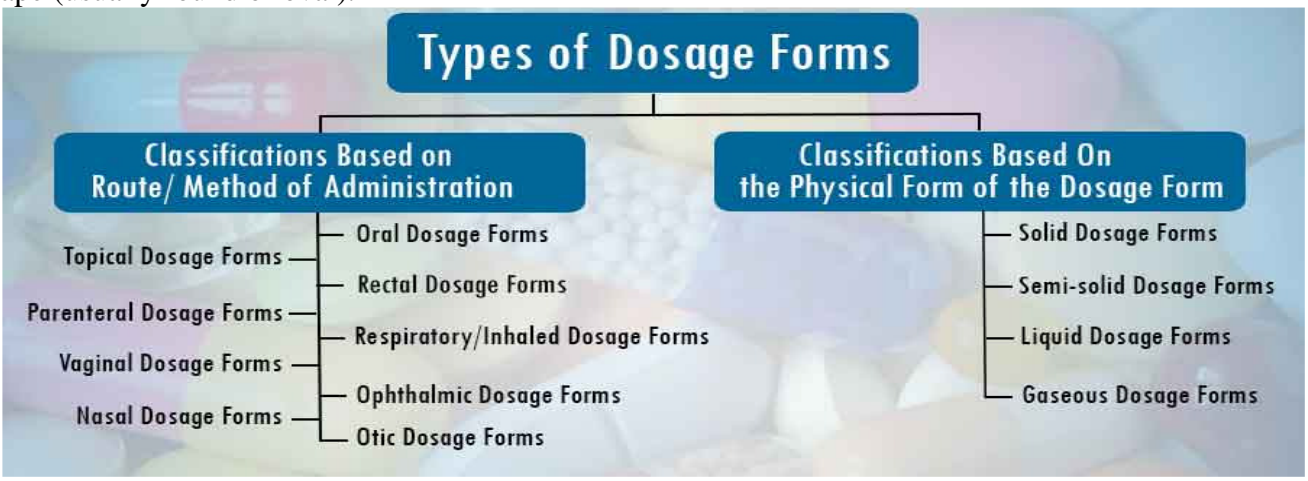
1. Solid Dosage Forms

Solid dosage forms are the **most frequently used** pharmaceutical products because of their **long shelf life**, **ease of use**, **accurate dosing**, and **cost-effectiveness**. They are primarily administered **orally**, though some may be used **sublingually, buccally**, or **rectally**, depending on the formulation and therapeutic need.



1. Tablets

Tablets are **compressed solid units** containing an active drug and excipients, formed into a definite shape (usually round or oval).



Types of Tablets:

Type	Description	Purpose
Uncoated Tablets	Simple, compressed tablets without outer coatings	Immediate release
Film-Coated Tablets	Coated with a thin, protective polymer layer	Taste masking and moisture protection
Enteric-Coated Tablets	Have acid-resistant coating	Bypass stomach, release in intestines
Effervescent Tablets	Contain acids and carbonates, release CO_2 in water	Rapid dispersion in water
Chewable Tablets	Intended to be chewed before swallowing	Ideal for children or difficulty swallowing
Sublingual Tablets	Placed under the tongue	Rapid absorption into bloodstream
Buccal Tablets	Placed between gum and cheek	Avoid first-pass metabolism
Orally Disintegrating Tablets (ODT)	Dissolve quickly on the tongue	Convenient for on-the-go use
Controlled-Release Tablets	Designed for extended drug release over time	Reduced dosing frequency

Advantages:

- Accurate and consistent dosing
- Easy to store and transport
- Cost-efficient manufacturing
- Long-term stability

Disadvantages:

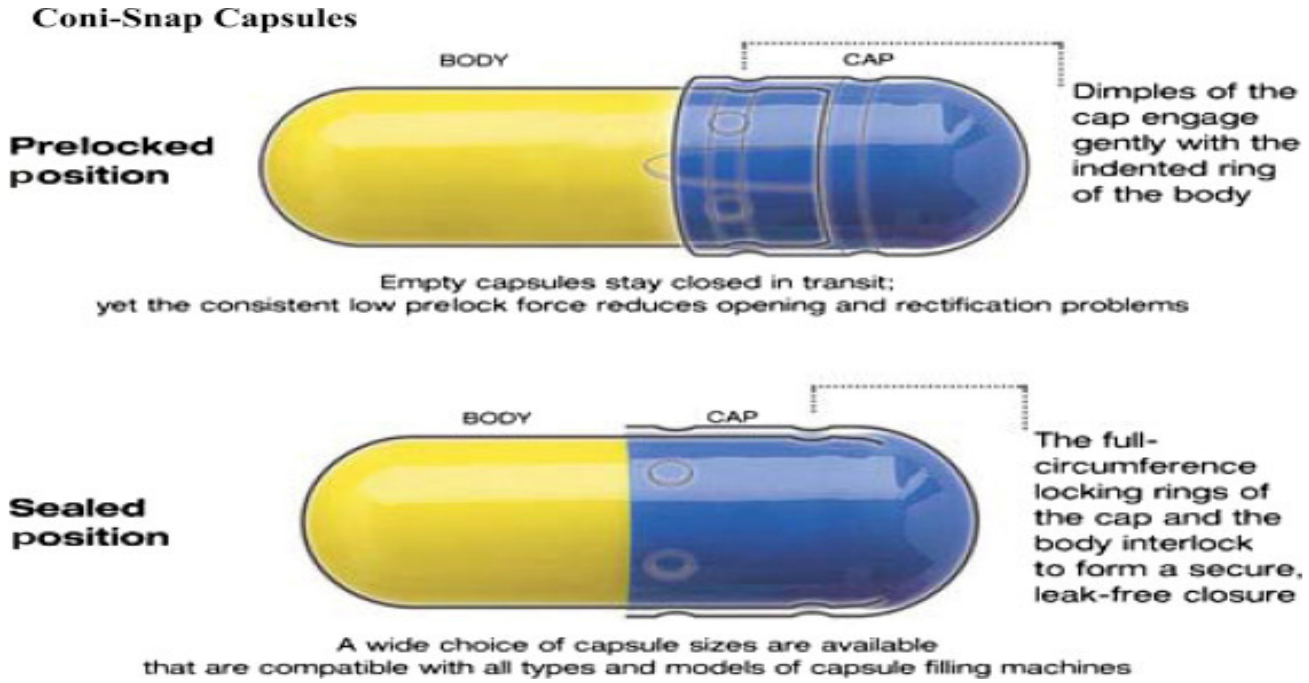
- Unsuitable for patients with swallowing difficulties
- Cannot be used in unconscious or vomiting patients
- Some drugs may degrade in the stomach

2. Capsules

Capsules are **solid enclosures**, usually made from gelatin, that contain drug substances in powder, granule, or liquid form.

Types:

Type	Description
Hard Gelatin Capsules	Made of two parts, filled with dry powders or granules
Soft Gelatin Capsules	One-piece, flexible shell filled with liquid or semi-solid formulations



Advantages:

- Easier to swallow than tablets
- Can mask unpleasant taste or odor
- Suitable for both solid and liquid drugs

Disadvantages:

- Sensitive to heat and humidity
- May not be acceptable to vegetarians or due to religious reasons
- Typically more expensive than tablets

3. Powders

Powders are **finely ground solid substances**, which may be administered directly, mixed with food or liquids, or reconstituted before use.

Categories	Function	Excipients	Source
Diluents/fillers	Make up the bulk of solid unit	Lactose	Animal
Binders and adhesives	Provide cohesive qualities to powdered material	Gelatine	Animal (Bovine)
Lubricant	Reduce inter-particular friction, and improve the rate of flow tablet granulation	Magnesium stearate	Synthetic
Glidant	Improve flow characteristics of powder mixture	Corn starch	Plant
Colouring agent	Impart aesthetic appearance to dosage form	Titanium dioxide	Mineral
Plasticizers	Produce elasticity and flexibility to the coating materials in case of tablets	Polyethylene glycol (PEG)	Synthetic
Alkylating agent	Sources off carbon dioxide in effervescent tablets and granules	Sodium bicarbonate	Synthetic

Types:

- **Bulk powders:** Supplied in large containers, not pre-measured (e.g., laxatives).
- **Divided powders:** Individually pre-measured doses in sachets or packets.

Advantages:

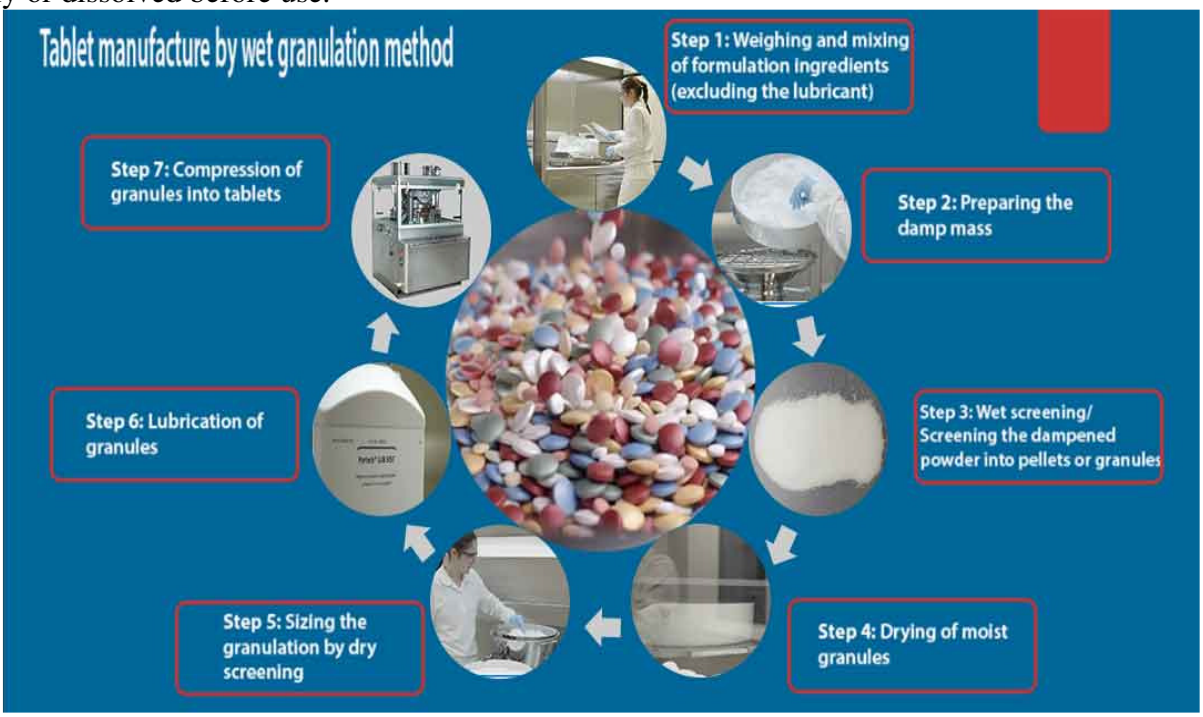
- Rapid dissolution and absorption
- Ideal for heat-sensitive drugs
- Good for children and elderly

Disadvantages:

- Less accurate dosing than tablets or capsules
- Risk of moisture contamination and spillage

4. Granules

Granules are **coarse particles** formed by binding small powder particles together. They can be consumed directly or dissolved before use.



Types:

- **Effervescent Granules:** React with water to release CO_2, improving taste and solubility.
- **Coated Granules:** Used for delayed or modified release purposes.

Advantages:

- Better stability than powders
- Reduced dustiness and improved taste
- Better flow properties for manufacturing

Disadvantages:

- Require more processing steps
- Not all drugs are suitable for granulation

◆ 5. Lozenges and Troches

These are **solid medicated preparations** designed to **dissolve slowly** in the mouth, providing local or systemic drug delivery.

Common Uses:

- Relief of sore throats
- Local antiseptics or anesthetics
- Antifungal agents for oral infections (e.g., clotrimazole)

Advantages:

- Extended drug contact with oral tissues
- Generally pleasant tasting
- Effective for localized treatment

Disadvantages:

- Not suitable for high-dose drugs
- May be accidentally swallowed before complete dissolution

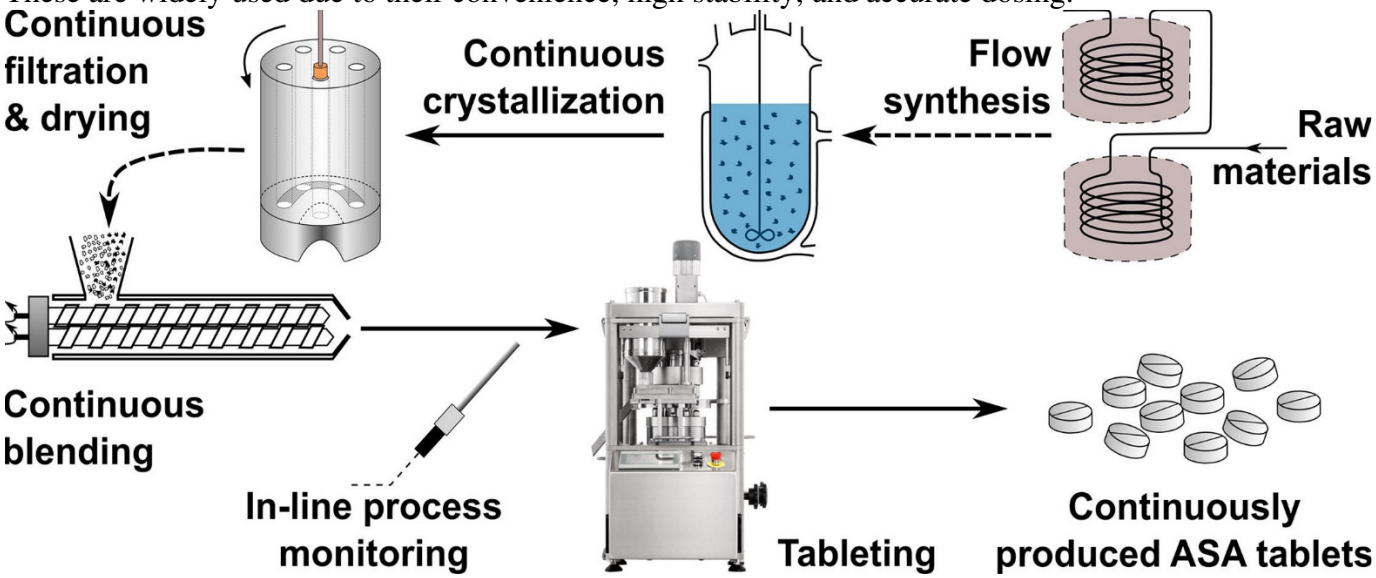
6. Pills (Historical)

Historically, pills referred to **small, round solid doses** of medicine prepared by hand. This form is now obsolete and has been largely replaced by tablets and capsules.

Comparison Table: Solid Dosage Forms

Form	Key Characteristic	Common Use
Tablets	Compressed solid units	Most widely used oral medications
Capsules	Gelatin shells with contents	Ideal for taste masking and oils
Powders	Fine dry particles	Quick dissolution in liquids
Granules	Larger, free-flowing particles	Improved stability and taste
Lozenges	Dissolve in mouth	Throat and mouth conditions

These are widely used due to their convenience, high stability, and accurate dosing.



a. Tablets

Solid units of compressed powdered drug and excipients.

Common types include:

- **Film-coated tablets:** Coated to improve taste or protect the drug from stomach acid.
- **Enteric-coated tablets:** Designed to bypass the stomach and dissolve in the intestine.
- **Effervescent tablets:** Dissolve in water, releasing carbon dioxide.
- **Orally Disintegrating Tablets (ODTs):** Disintegrate rapidly in the mouth without water.
- **Sublingual/Buccal tablets:** Placed under the tongue or in the cheek pouch for quick absorption.

b. Capsules

Encased in a gelatin shell, useful for masking taste.

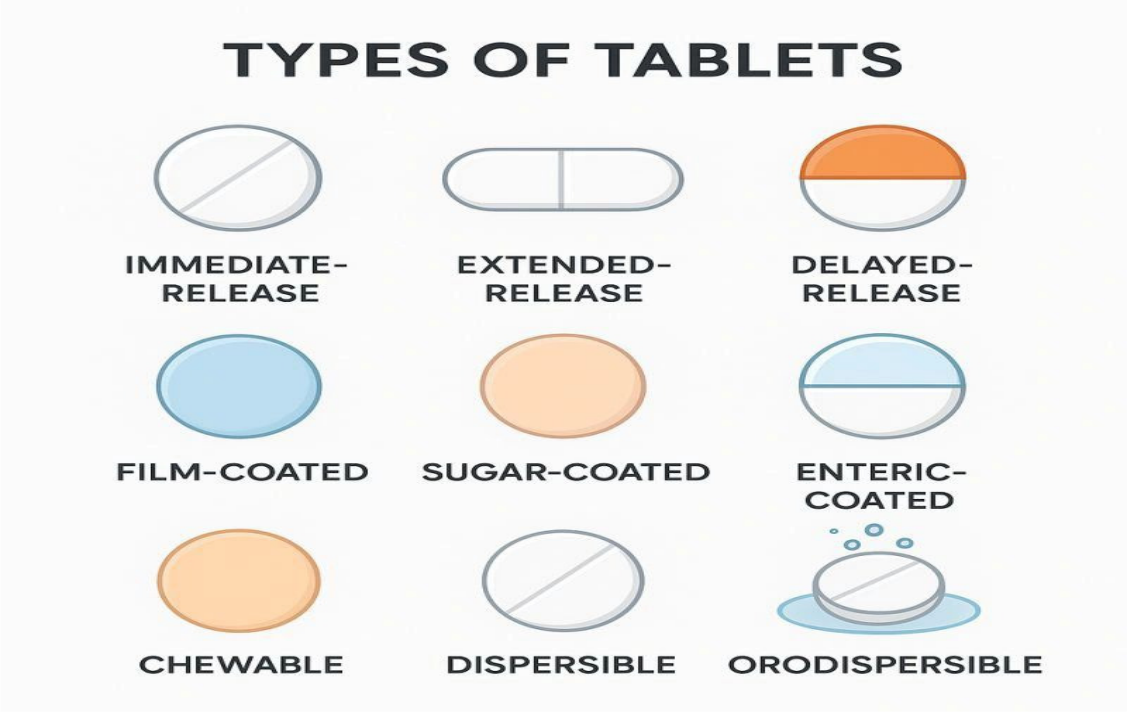
- **Hard Gelatin Capsules:** Hold dry powders or granules.
- **Soft Gelatin Capsules:** Contain oils or liquid-based medications.

c. Powders and Granules

Dry, free-flowing forms that may be dissolved in liquids or taken directly.

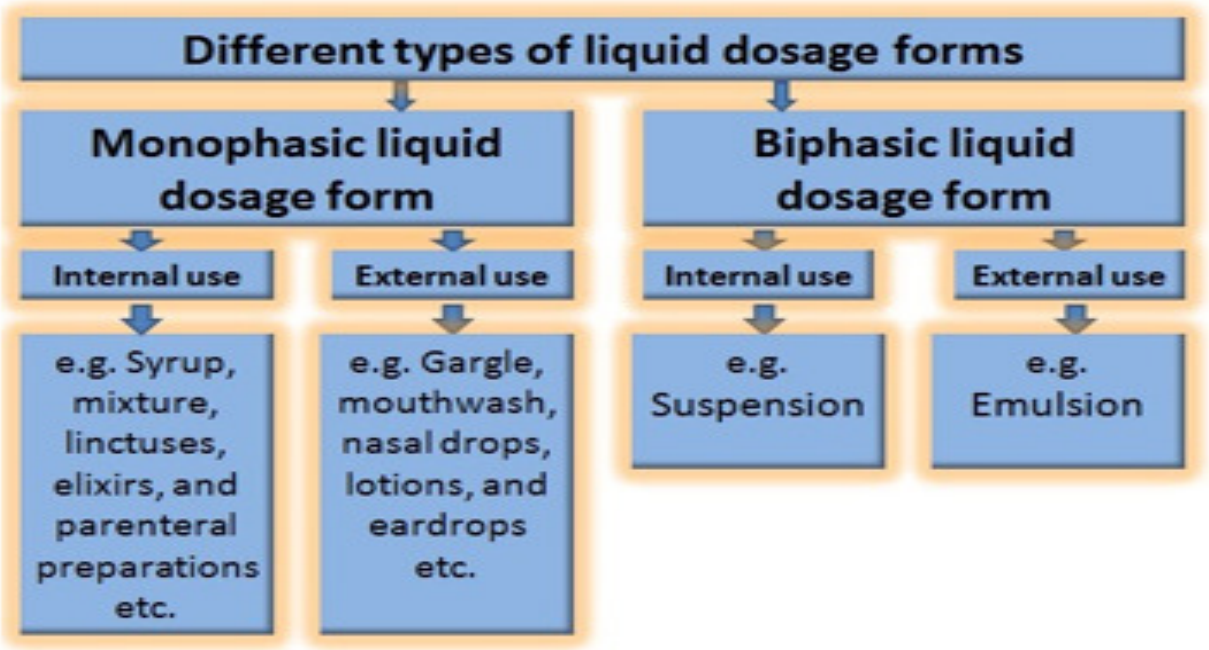
- **Powders:** Finely ground drugs.
- **Granules:** Larger particles with improved stability and taste.
- **Effervescent granules:** Fizz when mixed with water due to CO_2 release.

d. Lozenges/Troches



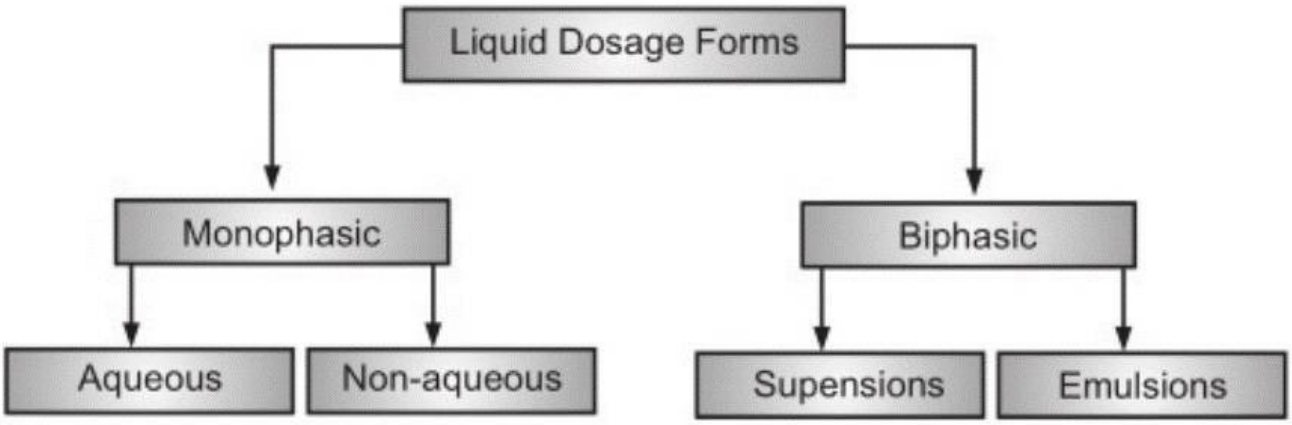
Slow-dissolving forms for use in the mouth; suitable for local effects in the oral cavity.

2. Liquid Dosage Forms



Liquid dosage forms refer to pharmaceutical preparations where the **active pharmaceutical ingredient (API)** is either **dissolved or dispersed** in a liquid medium. These formulations are used in **oral, injectable, topical, mucosal, and other administration routes**.

They are particularly beneficial for **pediatric, geriatric, and dysphagic (difficulty swallowing) patients**, offering ease of administration and flexible dosing.



◆ **Classification of Liquid Dosage Forms**

Liquid formulations are classified based on:

- **Physical nature** (solutions, suspensions, emulsions),
- **Route of administration** (oral, parenteral, topical, etc.),
- **Therapeutic use** (systemic vs. local effect).

1. Solutions

A solution is a **clear, homogeneous liquid** in which the drug is **completely dissolved** in a solvent (like water or alcohol).

Common Types:

Type	Description	Examples
Aqueous Solutions	Water-based; most frequently used	Oral rehydration solution
Syrups	Thick, sweetened liquids often containing sugar	Paracetamol syrup
Elixirs	Transparent, flavored liquids containing water and alcohol	Diphenhydramine elixir
Tinctures	Alcoholic extracts of plant or chemical substances	Iodine tincture
Spirits	Concentrated alcohol-based volatile solutions	Peppermint spirit
Aromatic Waters	Flavored aqueous solutions of volatile substances	Rose water

Advantages:

- Quick drug action due to immediate dissolution
- Easy swallowing for all age groups
- Dose can be easily adjusted

Disadvantages:

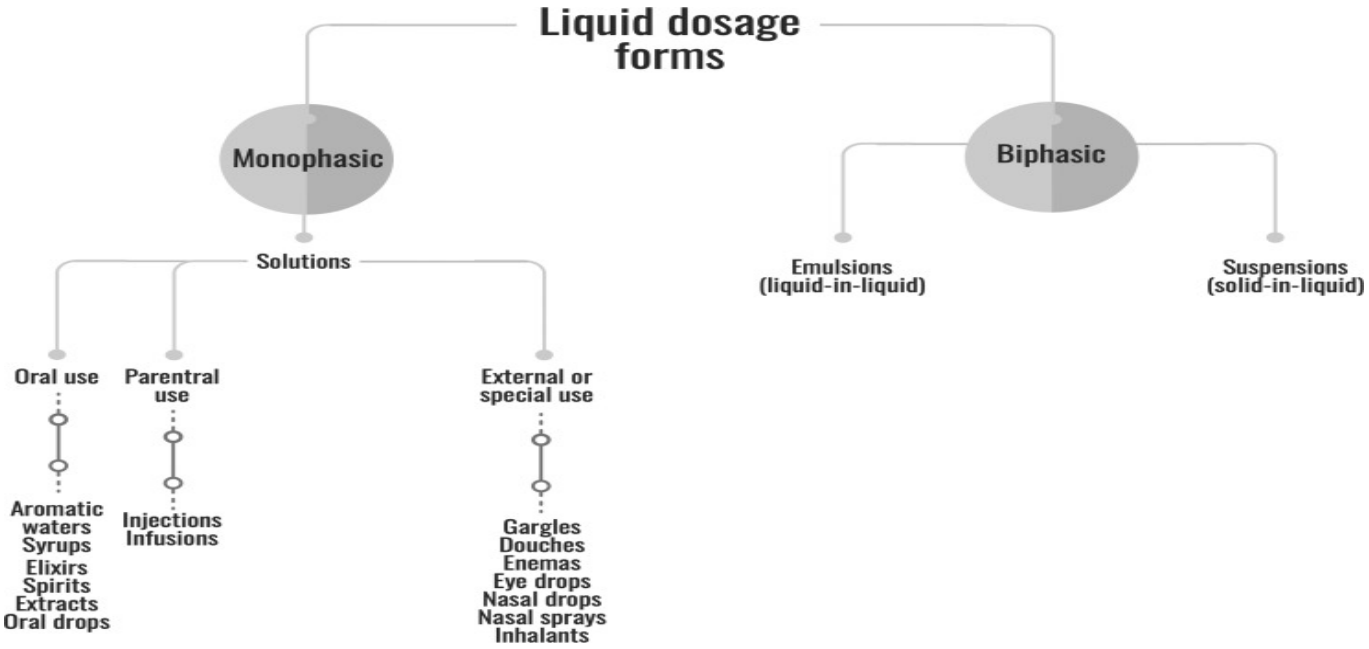
- Susceptible to microbial growth
- May need preservatives
- Bulky to store or transport
- Generally less stable than solids

2. Suspensions

Suspensions are **heterogeneous systems** where **insoluble drug particles** are distributed throughout a liquid base.

Characteristics:

- The drug is **not dissolved**, only **dispersed**.
- Requires **shaking before use** to re-suspend the particles.
- Stabilizers or **suspending agents** are added to prevent rapid settling.



Common Uses:

- For drugs that are poorly water-soluble (e.g., amoxicillin suspension)
- Pediatric formulations and dermatological products

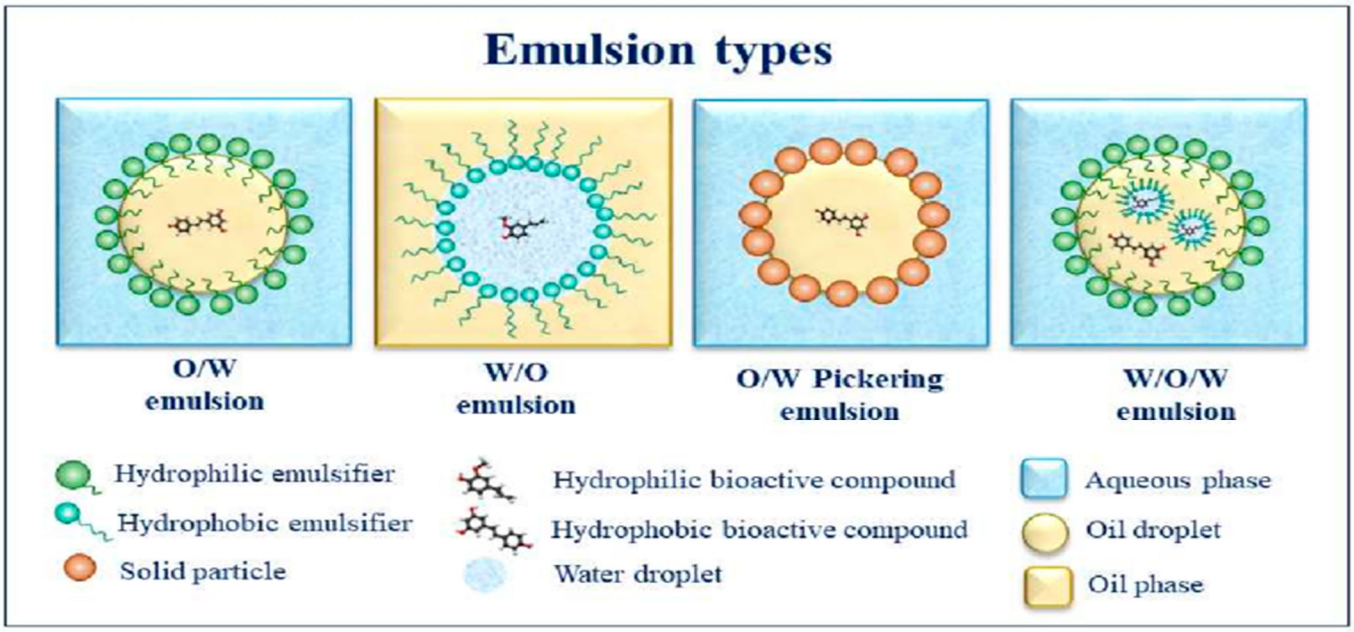
Advantages:

- Suitable for insoluble drugs
- Palatable formulations for children
- Enables liquid delivery of solid substances

Disadvantages:

- May **settle and cake**, making redispersion difficult
- **Shorter shelf life** than tablets
- Uniform dosing may be inconsistent without shaking

2. Emulsions



Emulsions are **two-phase systems** where one liquid (like oil) is **dispersed in another immiscible liquid** (like water), stabilized by an **emulsifying agent**.

Types:

- **Oil-in-Water (O/W):** Oil dispersed in water – common for oral or injectable use
- **Water-in-Oil (W/O):** Water dispersed in oil – mostly used for topical creams

Examples:

- Castor oil emulsion as a laxative
- Cream-based topical drugs

Advantages:

- Allows oily drugs to be given in liquid form
- Useful for both internal and external administration

Disadvantages:

- Can undergo **phase separation**
- Requires careful formulation and homogenization

4. Drops

Drops are **concentrated liquid formulations** administered in **small volumes**, often using a dropper for precise application.

Types:

- **Eye Drops (Ophthalmic):** Must be sterile, used for infections or glaucoma
- **Ear Drops (Otic):** For ear conditions like wax buildup or infections
- **Nasal Drops:** Used for nasal congestion, allergies
- **Oral Drops:** Concentrated liquids given to children (e.g., multivitamins)

Advantages:

- Precise dosing
- Rapid action, especially at mucosal sites
- Suitable for local applications

Disadvantages:

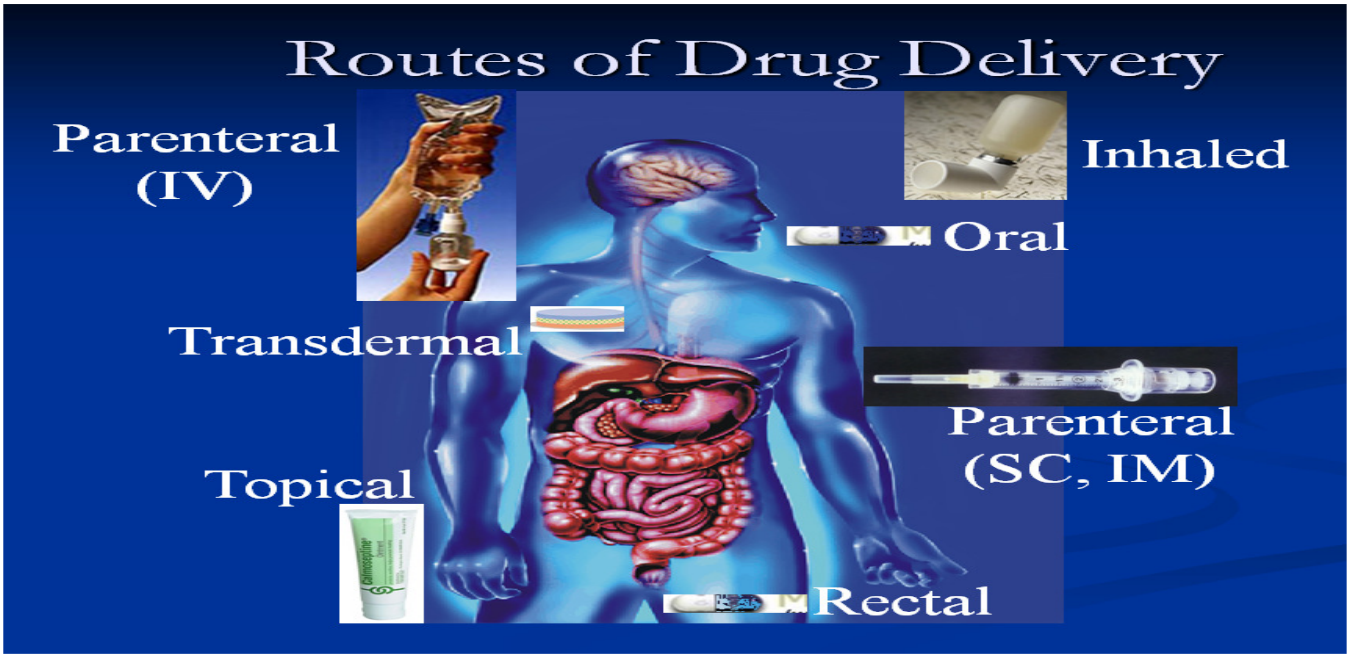
- Must be sterile (especially eye and ear drops)
- Limited shelf life once opened

5. Injections (Parenteral Solutions)

These are **sterile, pyrogen-free liquid preparations** designed for **direct administration into the body** through injection.

Routes:

- **Intravenous (IV)** – Direct into veins for rapid effect
- **Intramuscular (IM)** – Into muscle tissue
- **Subcutaneous (SC)** – Under the skin
- **Intradermal (ID)** – Into the skin layer



Examples:

- Normal saline
- Dextrose solutions
- Injectable antibiotics

Advantages:

- Immediate onset of action
- 100% bioavailability
- Bypasses the digestive tract

Disadvantages:

- Invasive and may cause discomfort
- Requires sterile equipment and trained personnel

6. Topical Liquid Preparations

Examples:

- **Lotions:** Emulsified liquids for large skin areas
- **Liniments:** Alcoholic or oily liquids applied by rubbing
- **Mouthwashes:** For oral hygiene or localized oral treatments
- **Gargles:** Used to treat sore throat or oral infections

Advantages:

- Provide localized action
- Lower systemic side effects

Disadvantages:

- May cause irritation or allergic reactions
- Short duration of therapeutic action

Comparison Table: Liquid Dosage Forms

Dosage Form	Key Features	Common Applications
Solutions	Clear, completely dissolved drug	Oral, IV, ophthalmic, nasal
Suspensions	Particulate matter in liquid	Pediatric meds, topical drugs
Emulsions	Two immiscible liquids with an emulsifier	Oral oils, creams, parenteral nutrition
Drops	Small volume delivery via dropper	Eye, ear, nasal, or oral delivery
Injections	Sterile, rapid-action formulations	Emergency or systemic treatments
Topical Liquids	Applied on skin or mucosa	Skin conditions, oral hygiene

Ideal for children and the elderly due to ease of swallowing and faster absorption.

a. Solutions

Clear mixtures where the drug is completely dissolved.

- **Aqueous solutions:** Water-based.
- **Syrups:** Thick, sweet liquids ideal for oral use.
- **Elixirs:** Sweetened hydro-alcoholic preparations.

b. Suspensions

Contain insoluble particles dispersed in a liquid. Must be shaken before use.

c. Emulsions

Two immiscible liquids (e.g., oil and water) stabilized by emulsifiers.

d. Drops

Administered in small volumes, often used for eyes, nose, or orally.

3. Parenteral Dosage Forms

These bypass the digestive system and are administered via injection. Strict aseptic conditions are essential.

a. Injections

- **IV (Intravenous):** Direct into the bloodstream; immediate effect.
- **IM (Intramuscular):** Into muscle tissue; slower than IV.
- **SC (Subcutaneous):** Into subcutaneous fat.
- **ID (Intradermal):** Into the skin's dermal layer; often for testing.

b. Infusions

Large-volume intravenous therapy administered over time.

c. Implants

Solid forms placed under the skin for slow, long-term drug release.

4. Inhalation Dosage Forms

Target the lungs for rapid systemic or local action.

a. Metered Dose Inhalers (MDIs):

Deliver accurate doses of aerosolized drugs.

b. Dry Powder Inhalers (DPIs):

Administer powdered medications via inhalation.

c. Nebulizers:

Convert liquid drugs into mist for inhalation, often used in respiratory care.

5. Semi-Solid Dosage Forms

Primarily used on the skin or mucous membranes for localized effects.

a. Ointments

Greasy bases offering prolonged contact; suitable for dry or scaly skin.

b. Creams

Emulsified systems (oil-in-water or vice versa); lighter and less greasy.

c. Gels

Water-based, transparent, and non-greasy; offer cooling sensation.

d. Pastes

Contain a high solid content; thick and provide protective barriers.

6. Topical and Transdermal Forms

a. Topical Preparations

Applied to skin, eyes, or ears for localized action.

- Examples: Lotions, eye drops, ear drops.

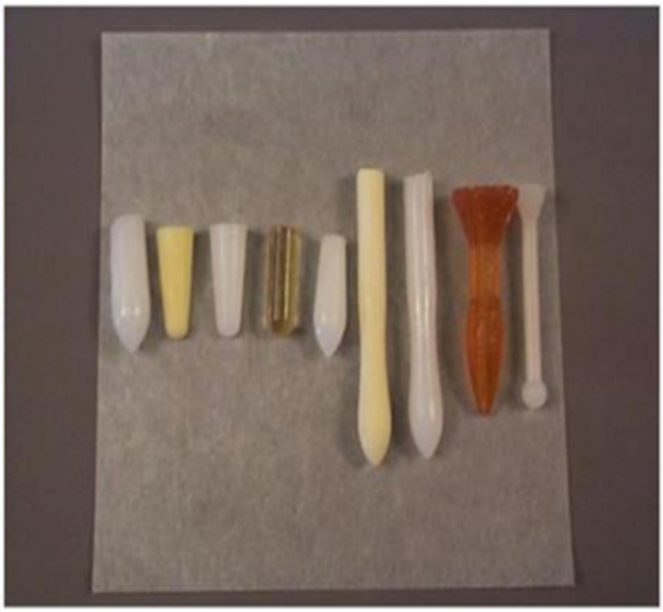
b. Transdermal Patches

Adhesive systems delivering drugs through the skin into systemic circulation over time.

- Used for conditions like chronic pain, nicotine dependence, or hormonal therapies.

7. Rectal and Vaginal Dosage Forms

Useful when oral administration isn't practical or for local effects.



a. Suppositories

Solid forms inserted into the rectum or vagina that melt at body temperature.

b. Enemas

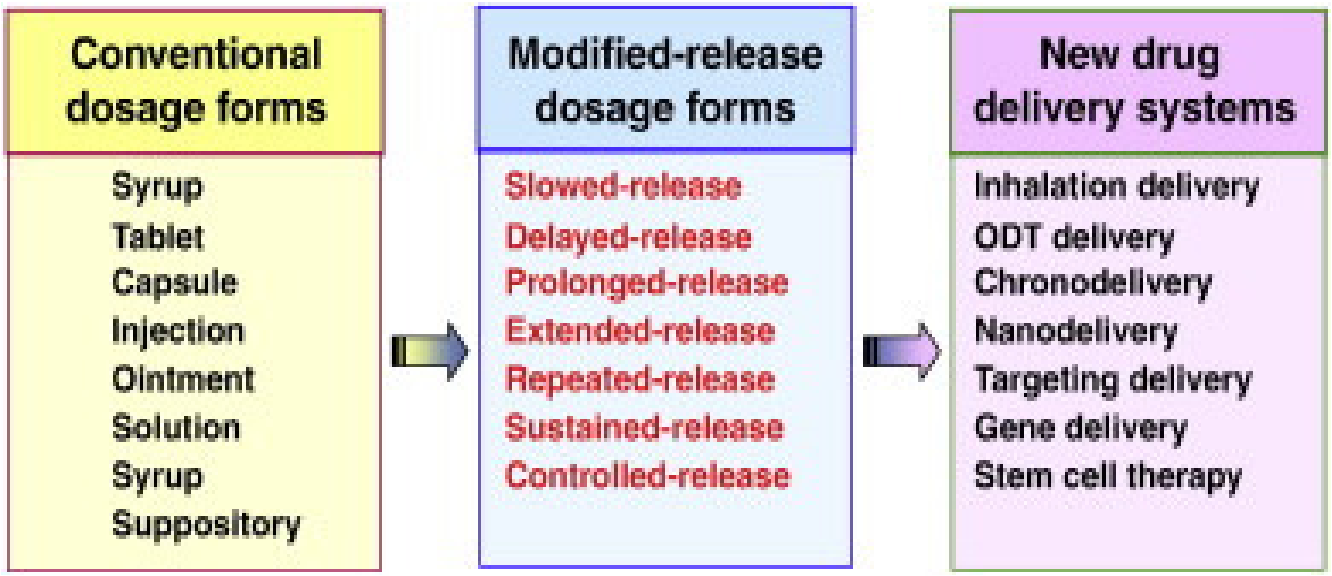
Liquid medications delivered rectally for local or systemic effects.

c. Pessaries

Solid forms specifically for vaginal administration.

d. Vaginal Rings

Flexible polymer rings offering sustained drug release over weeks.



8. Novel and Controlled-Release Dosage Forms

Designed to improve therapeutic outcomes by controlling drug release rates and targeting delivery.

a. Modified-Release Forms

- **Extended-Release (ER/XR):** Slows down release over time.
- **Sustained-Release (SR):** Maintains drug levels within therapeutic range.
- **Delayed-Release (DR):** Releases drug after a set delay, often post-stomach.

b. Osmotic Pumps

Utilize osmotic pressure for a controlled, steady release of the drug.

c. Nanoparticles and Liposomes

Advanced delivery systems for improved targeting, reduced side effects, and enhanced bioavailability.

Table: Routes, Forms, and Uses

Dosage Form	Route of Administration	Purpose/Use
Tablets/Capsules	Oral	Convenient systemic delivery
Solutions/Suspensions	Oral/Topical	Rapid action, suitable for children
Injections/Infusions	Parenteral	Fast action, emergency use
Inhalers/Nebulizers	Inhalation	Respiratory therapy
Ointments/Creams/Gels	Topical	Local skin or mucosal treatment
Suppositories/Enemas	Rectal/Vaginal	Local/systemic when oral not possible
Transdermal Patches	Skin	Long-term controlled systemic effect
Modified/Controlled Forms	Varies	Targeted or sustained drug delivery

CONCLUSION

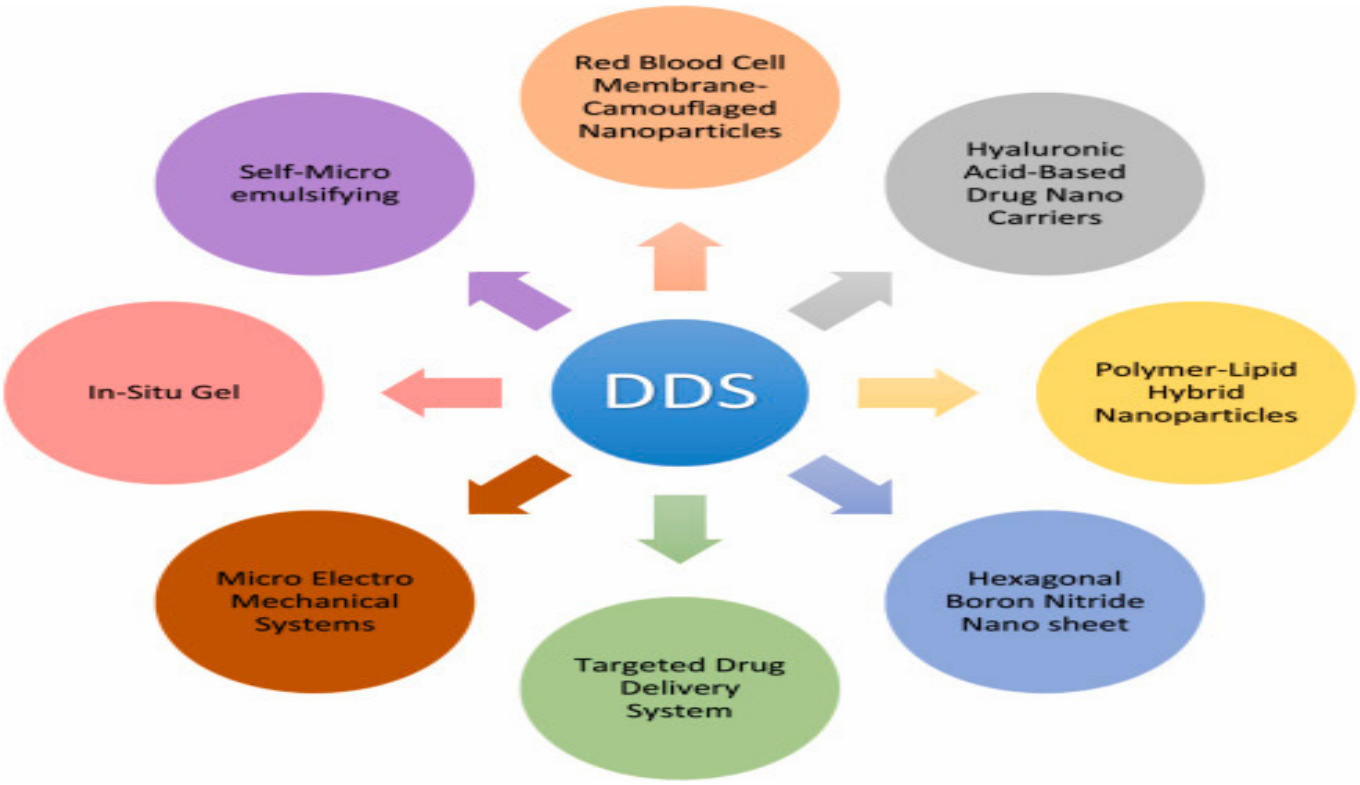
Pharmaceutical dosage forms represent the cornerstone of effective drug therapy. They are carefully designed to deliver medications **accurately**, **safely**, and **efficiently**, ensuring the drug reaches the desired site of action at the right concentration and time—with minimal side effects.

Each type of dosage form—such as **solids, liquids, semi-solids, injectables, inhalables, topicals, transdermals, rectals**, and **advanced delivery systems**—has a specific role based on the **drug's chemical nature**, **route of administration**, and **therapeutic objectives**.

A comprehensive understanding of dosage forms allows healthcare providers and pharmacists to:

- Ensure proper drug administration and dosing,
- Improve patient adherence to treatment plans,
- Reduce the likelihood of adverse effects,
- And adapt therapies to meet individual patient needs.

Future Outlook: Advancements in Drug Delivery



The development of pharmaceutical dosage forms is rapidly evolving due to innovations in **technology**, **personalized medicine**, and **biomedical engineering**. Future trends include:

1. **Personalized Medication**
   - Creation of individualized dosage forms based on a person's **genetic makeup**, **health condition**, and **lifestyle needs**.
   - **3D printing technologies** for manufacturing patient-specific tablets, implants, and drug delivery devices.
2. **Targeted and Intelligent Delivery Systems**
   - Use of **nanoparticles, liposomes**, and **micelles** to direct drugs to specific tissues or cells, especially in **oncology** and **infectious diseases**.
   - Smart systems that respond to **biological stimuli** such as pH, enzymes, or temperature to release the drug at the right time and place.
3. **Modified and Extended-Release Technologies**
   - Ongoing improvement in **sustained-release**, **controlled-release**, and **delayed-release** dosage forms.
   - These innovations aim to **enhance therapeutic outcomes**, **reduce dosing frequency**, and **boost patient convenience**.
4. **Eco-Friendly and Biodegradable Options**
   - Incorporation of **biodegradable polymers** in implants, injectables, and patches.
   - Focus on **sustainable packaging** and **environmentally safe formulation techniques** to reduce pharmaceutical waste.
5. **Non-Invasive and Patient-Friendly Delivery Routes**
   - Expansion of **needle-free** systems such as **inhalers**, **buccal tablets**, **transdermal patches**, and **nasal sprays**.
   - Development of **oral forms of biologics** like insulin that traditionally required injection.

The future of pharmaceutical dosage forms goes beyond improving drug absorption—it's about **transforming the patient experience**. By combining **biotechnology**, **materials science**, and **digital tools**, next-generation drug delivery systems aim to make medications **more precise, more effective, and easier to use**.

As research continues, pharmaceutical science will play an even greater role in **shaping personalized, sustainable, and life-enhancing therapies** for populations around the world.

Dosage forms refer to the physical forms in which drugs are formulated and administered to ensure therapeutic efficacy. They are designed to deliver active pharmaceutical ingredients (APIs) to specific sites within the body.

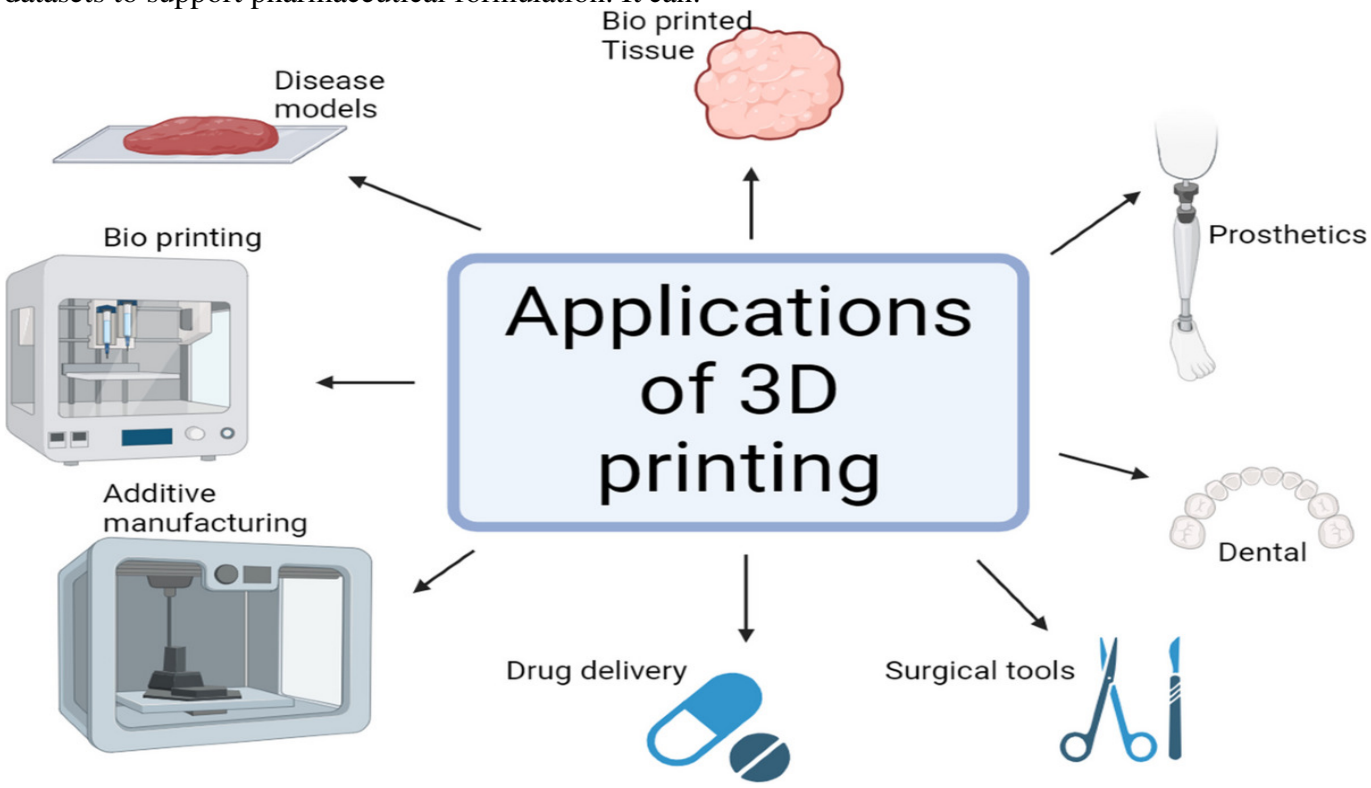
Common types of dosage forms include:

- **Solid dosage forms**: Tablets, capsules, and powders
- **Liquid dosage forms**: Syrups, suspensions, and emulsions
- **Semisolid dosage forms**: Creams, gels, and ointments
- **Parenteral dosage forms**: Injections and intravenous infusions
- **Advanced delivery systems**: Liposomes, nanoparticles, transdermal patches, and 3D-printed pharmaceuticals

Artificial Intelligence in Dosage Form Development

1. Formulation Design and Prediction

AI, particularly machine learning (ML) and deep learning, has the capacity to process large, complex datasets to support pharmaceutical formulation. It can:



- Identify optimal combinations of excipients and active ingredients
- Predict potential incompatibilities between formulation components
- Minimize experimental trials through predictive modeling
- Simulate drug release profiles and absorption behavior

Example: ML models predicting tablet disintegration time or improving solubility predictions for poorly water-soluble compounds.

2. Optimization of Formulation Parameters

AI can fine-tune various formulation variables such as:

- Particle size distribution
- Tablet compression force
- Coating thickness uniformity
- Polymer ratios in controlled-release matrices

Example: AI algorithms determining the ideal polymer concentration in hydrogel-based drug delivery systems.

3. 3D Printing and Personalized Medicine

AI supports the use of 3D printing in pharmaceuticals by:

- Designing tailored dosage forms for individual patient needs
- Modeling mechanical strength and dissolution rates
- Optimizing printing conditions and material selection

Example: Spritam® (levetiracetam), the first FDA-approved 3D-printed drug, demonstrates AI's potential in personalized therapeutics.

4. Quality Assurance and Process Monitoring

Using AI-driven technologies like computer vision and real-time analytics, manufacturers can:

- Monitor production in real-time
- Detect defects during manufacturing
- Anticipate equipment failures
- Ensure consistent quality across batches

Example: Image-based AI systems analyzing tablet coatings for uniformity and defects.

5. Drug Stability and Shelf-Life Prediction

AI models can forecast how a drug will behave under various storage conditions, predicting:

- Chemical degradation pathways
- Product stability over time
- Optimal packaging and storage requirements

Example: Neural networks trained to predict shelf-life across varying humidity and temperature conditions.

6. Regulatory and Documentation Support

AI tools streamline compliance by:

- Assisting with regulatory documentation and submissions
- Monitoring changes in pharmacopeial standards
- Ensuring adherence to Good Manufacturing Practices (GMP)

Popular AI Techniques in Pharmaceutical Sciences

- **Machine Learning**: Random Forest, XGBoost, Support Vector Machines (SVM)
- **Deep Learning**: CNNs (Convolutional Neural Networks), RNNs (Recurrent Neural Networks)
- **Natural Language Processing (NLP)**: Used for analyzing scientific texts and regulatory materials
- **Reinforcement Learning**: For self-learning formulation strategies
- **Genetic Algorithms**: For multi-objective formulation optimization

Emerging Trends in Research

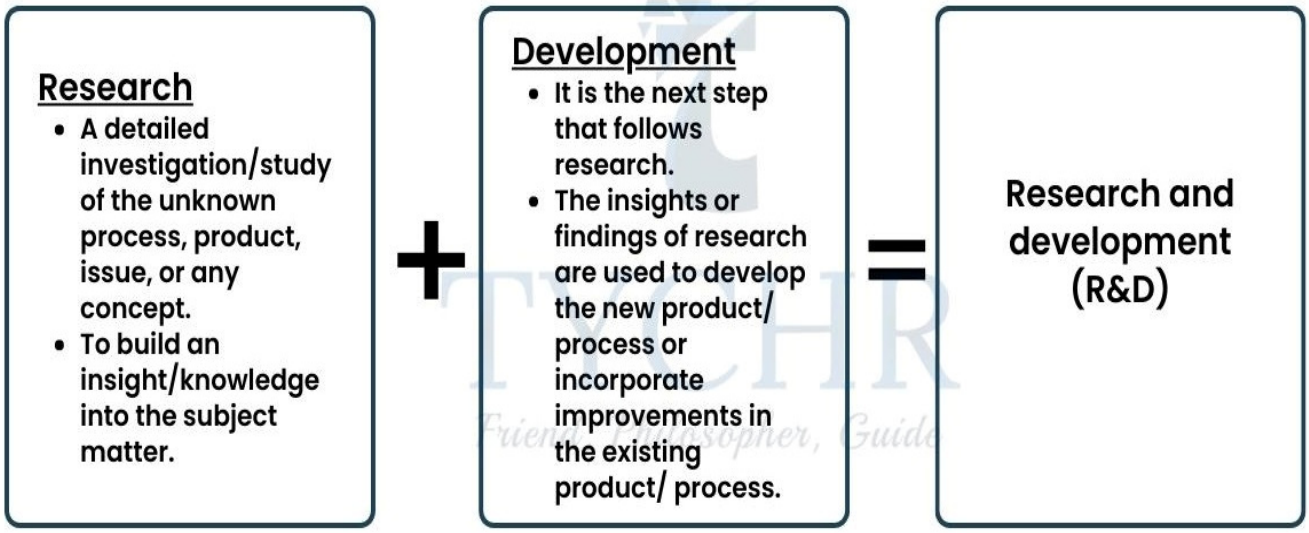
- AI-powered formulation of nanomedicines
- Explainable AI for transparent model decisions in drug design
- Precision medicine and pharmacogenomics enabled by AI
- Integrating AI with Quality by Design (QbD) principles

Challenges and Considerations

- Ensuring access to high-quality, reliable data
- Gaining regulatory trust and approval for AI-driven methods
- Improving the interpretability and transparency of AI decisions
- Seamless integration with traditional pharmaceutical workflows

Global Market

Metric	Estimate	Details
Market Size (2024–2025)	~$1.65 to $1.77 trillion USD	According to sources like Grand View Research, Cognitive Market Research, and Precedence Research, the pharmaceutical sector's global value is currently in the range of $1.65 to $1.77 trillion. Slight differences exist due to varying forecasting methods.
Projected Market Value (2030–2034)	~$2.3 to $3.0+ trillion USD	Industry analysis suggests the global pharma market may grow to over $3 trillion by the early 2030s, driven by innovation and increasing healthcare demands.
Compound Annual Growth Rate (CAGR)	~6.1% to 6.3% (2025–2034)	Most studies forecast steady growth of around 6% annually over the next decade, although specific regions and drug segments may experience higher rates.



Product Segment Breakdown

- **Small Molecules**: These continue to dominate the market, contributing approximately **50–60%** of total pharmaceutical revenues.
- **Biologics & Biosimilars**: Although currently a smaller segment, biologics and biosimilars are expanding rapidly and expected to gain more market share in the coming years.

Regional Market Share

- **North America** holds the largest share of global pharmaceutical sales, contributing around **40–55%** of total revenue.
- **Europe and Asia-Pacific** are also key contributors, with **Asia-Pacific identified as the fastest-growing region** due to rising healthcare investments and manufacturing capabilities.

Research & Development (R&D)

Metric	Estimate	Details
R&D Expenditure (2022)	~$250 billion USD	The global pharmaceutical sector invested approximately $250 billion in R&D activities in 2022. This figure is expected to reach around **$350 billion by 2029**, according to McKinsey.
Drug Pipeline	~24,000 active drug candidates	Data from Statista shows that over **24,000 drugs are in development** globally, across more than **6,800 companies**. This highlights the industry's strong focus on innovation, though not all candidates will reach market approval.

Manufacturing Insights

- The **global pharmaceutical manufacturing market** was valued at approximately **$503.4 billion USD in 2023**, with forecasts projecting it to grow to **$913.65 billion USD by 2030**—a CAGR of roughly **8.9%**.
- **India** remains a key global player, with over **3,000 large-scale pharmaceutical manufacturers** and more than **10,000** smaller producers, including those involved in bulk drugs and intermediates.

Trends and Strategic Developments

- Leading pharmaceutical firms allocate **20–30% of their prescription drug earnings** toward research and development. For instance, Roche is projected to invest around **23%** of its revenue in R&D during 2024.
- Segments such as **generics, biosimilars, biologics, and OTC (over-the-counter) products** are expanding steadily. However, while **branded prescription drugs** still dominate the market in revenue terms, they face increased competition from more affordable alternatives.

Stages of the Industrial Pharmacy Process

1. Preformulation Studies

🔹 **Goal**: To evaluate the fundamental physical and chemical characteristics of both the active pharmaceutical ingredient (API) and the excipients before formulation.

Key assessments include:

- Solubility profile
- Stability (thermal, photostability, pH-dependent)
- Particle size and surface characteristics
- Crystal form (polymorphism)
- Flowability and compressibility

Why it matters: Guides the selection of suitable excipients and formulation strategies.

2. Formulation Development

🔹 **Goal**: To design a drug product that is safe, effective, and stable.

This stage involves:

- Selecting the dosage form (e.g., tablet, capsule, suspension)
- Choosing and optimizing excipients (binders, fillers, lubricants, preservatives)
- Conducting dissolution studies and drug release tests
- Developing prototype formulations for evaluation

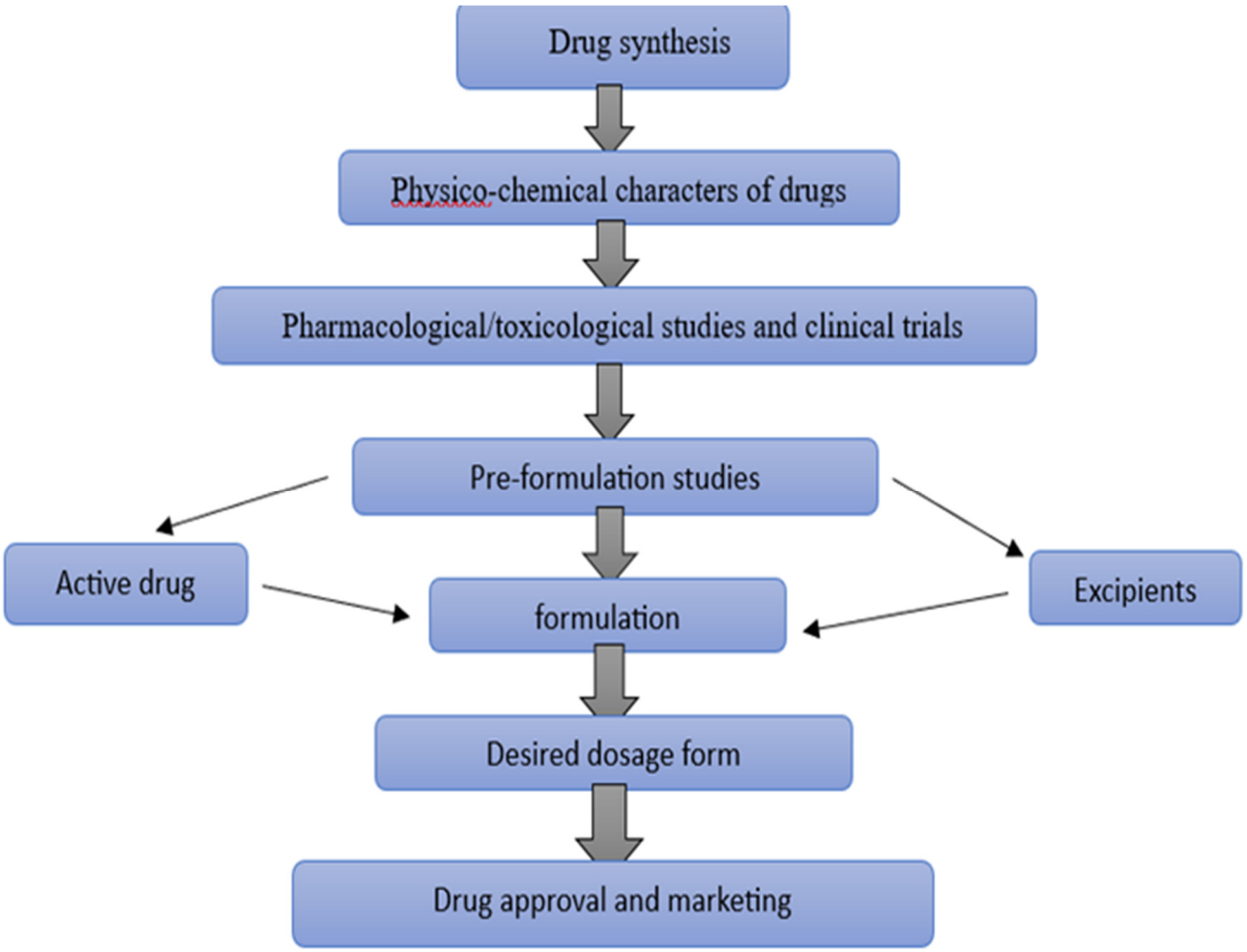
Tools Used: Statistical tools like **Design of Experiments (DoE)**, **AI/ML models**, and **simulation software** are often applied to optimize formulation parameters.

3. Process Development & Scale-Up

🔹 **Goal**: To adapt the lab-developed formulation for large-scale, commercial production.

Main activities:

- Refining key manufacturing parameters (e.g., mixing speed, granulation time, compression force)
- Creating batch production records and manufacturing SOPs
- Identifying and controlling **Critical Process Parameters (CPPs)**
- Ensuring consistent performance during scale-up to pilot and industrial scale



Key Concept: **Quality by Design (QbD)** is used to ensure product quality is built into the process.

4. Manufacturing Process

The manufacturing procedure varies based on dosage form:

➤ **Solid Dosage Forms (Tablets, Capsules)**

- Ingredient weighing and blending
- Granulation (wet or dry)
- Drying using fluid bed or tray systems
- Tablet compression or capsule filling
- Coating (film or sugar-based)

➤ **Liquid Dosage Forms**

- Preparing the solution or suspension
- Filtration and removal of air
- Filling containers and sealing
- Sterilization (if required)

➤ **Semisolid Dosage Forms**

- Heating oil and aqueous phases
- Emulsifying and homogenizing
- Filling into tubes or jars

➤ **Parenteral Preparations**

- Maintaining sterility throughout production
- Aseptic filling into vials or ampoules

- Freeze-drying (lyophilization) if needed
- Final sterilization by heat or filtration

Note: All production must comply with **Good Manufacturing Practices (GMP)** to ensure product safety and efficacy.

5. Packaging

🔹 **Goal**: To safeguard the product and facilitate proper use by the consumer.

Packaging activities include:

- Blister packaging, strip packing, bottle filling
- Product labeling and serialization
- Tamper-proof sealing
- Ensuring the compatibility and stability of packaging materials

Purpose: Maintains the **identity, integrity, and shelf-life** of the drug product.

6. Quality Control (QC) & Quality Assurance (QA)

🔹 **Quality Control (QC):**

Involves analytical testing to ensure raw materials and final products meet required standards:

- Identity, assay, purity, and dissolution rate
- Microbiological tests
- Stability studies under ICH guidelines

🔹 **Quality Assurance (QA):**

Focuses on systems and documentation to maintain consistent quality:

- Reviewing production and QC records
- Investigating deviations and implementing CAPA
- Conducting internal audits
- Document control and compliance oversight

Guidelines followed: Must adhere to global pharmacopeial standards (USP, BP, IP) and regulatory frameworks (FDA, EMA, etc.).

7. Regulatory Affairs

🔹 **Goal**: To compile, submit, and manage documentation for regulatory approval and post-approval compliance.

Key tasks:

- Preparing dossiers in CTD/eCTD formats
- Filing applications such as **ANDA**, **NDA**, or **DMF**
- Responding to regulatory queries and inspection observations
- Handling product lifecycle updates (e.g., renewals, variations)

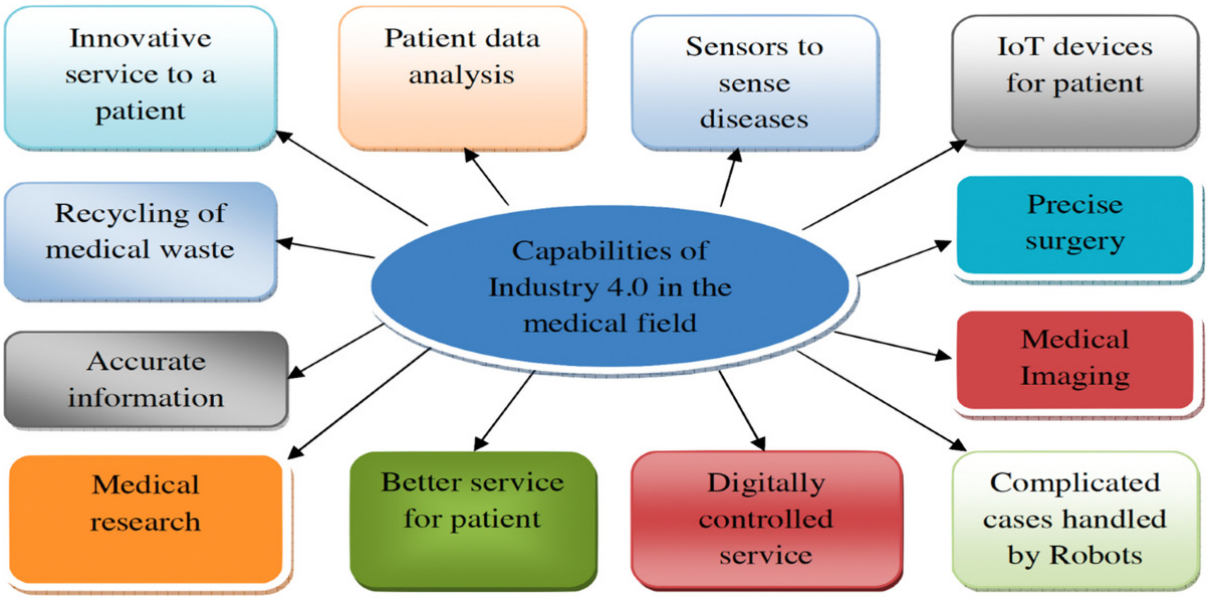
Documentation Includes: Drug master files, GMP certificates, stability data, and clinical reports (if required).

8. Product Release & Distribution

Once QA approves the product:

- It is released for market distribution
- Shipped to pharmacies, hospitals, or distributors
- Cold chain logistics are managed for temperature-sensitive medications

Core Concepts in Industrial Pharmacy



- **GMP** – Ensures product is consistently produced and controlled
- **QbD** – Designs quality into the process from the beginning
- **PAT** – Real-time monitoring of manufacturing processes
- **SOPs** – Standard Operating Procedures guide every operation
- **ICH Guidelines** – International norms for drug development and quality

The pharmaceutical landscape is being reshaped by rapid technological innovations. These advances are transforming how drugs are discovered, developed, manufactured, and delivered to patients. Here's a breakdown of the most significant trends and technologies shaping the future of pharma.

1. Artificial Intelligence (AI) and Machine Learning (ML)

Applications:

- **Drug Discovery**: AI algorithms can model and predict effective drug molecules, significantly reducing the time and cost traditionally required in R&D.
- **Target Identification**: AI helps analyze complex biological data to identify promising therapeutic targets.
- **Clinical Trial Optimization**: Machine learning improves trial design by selecting ideal participants, predicting outcomes, and minimizing risks.
- **Drug Safety Monitoring**: NLP (Natural Language Processing) tools can scan clinical records and social media to detect adverse drug reactions early.

Future Potential:

- AI could reduce drug development timelines from several years to under 12 months.
- AI-created drug candidates are already entering clinical trials (e.g., by Insilico Medicine, Exscientia).

2. Personalized and Precision Medicine

Concept:

- This approach customizes treatments based on an individual's **genetic profile**, **environment**, and **lifestyle**.

Supporting Technologies:

- **Genomic Analysis**: Tools like next-generation sequencing (NGS) help detect genetic mutations and disease risks.
- **Pharmacogenomics**: Studies how genetic differences affect drug response.
- **Biomarker Discovery**: Enables tailored treatments for specific patient groups.

Impact:

- Reduces ineffective treatments.

- Enhances therapeutic outcomes.
- Supports personalized therapies, particularly in oncology and rare diseases.

3. mRNA Technology & Biologic Therapies

Post-COVID Expansion:

- mRNA platforms are now being utilized for:
  - **Cancer treatment**
  - **Custom vaccines**
  - **Infectious diseases** like HIV and influenza
  - **Rare genetic disorders**

Advanced Biologics:

- **Antibody-Drug Conjugates (ADCs)**: Combine targeted antibodies with toxic agents to treat cancers.
- **Bispecific Antibodies**: Target two antigens at once for improved precision.
- **Cell and Gene Therapy**: CAR-T, CRISPR, and stem cell therapies aim to cure rather than manage chronic diseases.

4. Innovative Drug Delivery Systems

Emerging Technologies:

- **Nanotechnology**: Nanoscale drug carriers deliver drugs precisely, reducing systemic side effects.
- **Smart Delivery Systems**: Release drugs in response to stimuli like pH or temperature.
- **Implantable Devices**: Biodegradable implants and microchips allow long-term, controlled drug release.
- **Needle-Free Solutions**: Patches and jet injectors improve ease of use and patient compliance.

5. Continuous Manufacturing and Automation

Evolution in Manufacturing:

- Traditional batch production is being replaced by **continuous processing**, which is faster, cheaper, and more scalable.

Key Enablers:

- **Process Analytical Technology (PAT)** for real-time quality monitoring.
- **Digital Twins** simulate production lines to test improvements virtually.
- **Robotics and Automation** increase accuracy and reduce manual errors.

Advantages:

- Accelerated production timelines.
- Enhanced consistency and regulatory compliance.

6. Blockchain for Pharma Supply Chains

Use Cases:

- **Supply Chain Security**: End-to-end visibility prevents counterfeit medications.
- **Clinical Trial Integrity**: Immutable ledgers secure patient data and trial results.
- **Regulatory Automation**: Smart contracts can automate compliance and logistics.

7. Neurotechnology & Digital Therapeutics

Software-Based Therapies:

- **Digital Therapeutics (DTx)**: Evidence-backed software solutions treat mental health, chronic diseases, and behavioral conditions.
  - Example: *reSET* app for substance use disorder.

Brain-Based Innovations:

- **Neurostimulation & BCIs**: Help treat neurological disorders like epilepsy and depression.
- **Electroceuticals**: Devices that electrically stimulate nerves as an alternative to traditional drugs.

8. 3D Printing of Pharmaceuticals

Personalization Through Printing:

- 3D printing enables **customized pills** with specific doses and release profiles.
- On-site drug printing may benefit remote hospitals or emergency situations.

Applications:

- **Polypills**: Combine multiple medications into one.
- **Pediatric & Geriatric Dosages**: Tailored to individual needs for safety and efficacy.

9. Eco-Friendly and Sustainable Pharma

Goals:

- Minimize environmental harm during drug production.
- Reduce dependency on toxic chemicals and solvents.

Methods:

- **Biocatalysis**: Enzymes used to drive chemical reactions.
- **Microbial Synthesis**: Using genetically engineered microbes for drug production.
- **Green Chemistry**: Eco-conscious methods for drug design and manufacturing.

10. Real-World Evidence (RWE) & Big Data in Drug Development

Definition:

- RWE involves analyzing real-world data from electronic health records, wearables, and insurance data to assess drug safety and effectiveness.

Benefits:

- Informs better post-market monitoring.
- Enables adaptive and more flexible clinical trials.
- Increasingly used by regulatory bodies (e.g., FDA and EMA) to support decisions.

Table: Technology & Applications

Technology	Primary Role	Examples
AI & ML	Drug discovery, clinical trial design	AlphaFold, Insilico Medicine
mRNA & Biologics	Personalized vaccines, rare disease treatment	Moderna, BioNTech
Precision Medicine	Customized therapies	Genomic-guided oncology treatments
Nanotechnology	Targeted delivery systems	Liposomal Doxorubicin (Doxil)
3D Printing	On-site, patient-specific drug production	Spritam (levetiracetam)
Blockchain	Secure supply chain, data integrity	MediLedger Project
Digital Therapeutics	Software-based treatment tools	reSET, EndeavorRx
Automation & Continuous Mfg.	Scalable, efficient production	Pfizer's API production lines
RWE & Big Data Analytics	Real-world performance monitoring	FDA's Sentinel Initiative
Gene Editing & CRISPR	Curative therapies for genetic diseases	Exa-cel for sickle cell anemia

The Future is Personalized, Digital, and Integrated

The pharmaceutical industry is transitioning towards:

- **Highly tailored treatments** based on individual biology.
- **Accelerated R&D** using digital tools.
- **Digital-physical healthcare integration** for holistic care.
- **Global access and equity** in healthcare solutions.

This future will rely on strong collaborations between **clinicians, data scientists, regulatory bodies, and technologists** to ensure innovations benefit all.

AKNOWLEDGEMENTS : The authors are thankful to all those who guided helped in writing this useful article.

REFERENCES

1.Lieberman, H.A., Lachman, L., & Schwartz, J.B.*Pharmaceutical Dosage Forms: Tablets (Volume 1)*
2. Ansel, H.C., Popovich, N.G., & Allen, L.V.*Pharmaceutical Dosage Forms and Drug Delivery Systems*
3. Banker, G.S., & Rhodes, C.T.*Modern Pharmaceutics*
4. Rathbone, M.J., Hadgraft, J., & Roberts, M.S.*Pharmaceutics: The Science of Dosage Form Design*
5. Khan, A.A.*Pharmaceutical Dosage Forms and Drug Delivery*
6. Remington: The Science and Practice of Pharmacy (recent edition)
7.Sharma R, Garg A, Sharma R, A Brief Review on Tablet as A Dosage Form with Special Reference to Fast Dissolving Tablets (FDTs), World Journal of Pharmaceutical and Life Sciences WJPLS, Volume 8, Issue 8, 58-62

8.Lachman l, Herbert A, Lieberman, Joseph L. Kanig: The theory and Practice of Industrial Pharmacy, Varghese publication house, 1990, 293-373.

9.Keerthi M, Kiran R, Rao V, Sannapu A, Dutt AG, et al. (2014) Pharmaceutical Mini-Tablets, its Advantages, Formulation Possibilities and General Evaluation Aspects: A Review. Int. J. Pharm. Sci. Rev. Res. 28: 214- 221

10.Kuccherkar, B.S., Badhan, A.C., Mahajan, H.S., Mouth dissolving tablets: A Novel drug delivery system, Pharma. Times, 2003; 35: 3-10.

11.The theory and practice of Industrial Pharmacy, Leon Lachmann, Herbert A. Lieberman, Joseph L. Kanig. Pg. 293-303, Fourth edition

12.Lachmann, L., Liebermann, H.A., Kiang, J.L., The Theory and Practice of Industrial Pharmacy, 3rd Ed., Varghese Publishing House, Bombay, 1998; 430- 440.

13.Y. Bi, H, Sunda, Y. Yonezawa, K. Danjo, and, and K. Lido, Chem. Pharm. Bull, 1996; 44(11): 2121.

14.Chaudhuri S. (2005). "The WTO and India"s Pharmaceutical Industry; patent protection, TRIPs and Development Counties", Oxford University Press, New Delhi: 45-188.

15.D. P. D. M. Jenisha Patel, "Artificial Intelligence in Pharma Industry- A Rising Concept," Journal of Advancement in Pharmacognosy, 2021, 1 (02), 54-64.

16.N. P. S.S Manikaran, ""Artificial Intelligence Milestones and Role in Pharma and Healthcare Sector," Pharma times, 2019, 51, 65-75.
17.R. J. Sanjay Kumar Jain, "Use of information technology in India's pharmaceutical industry," Asian Journal of Information and Communications, vol. 11, no. 02, pp. 97-112, 2019.

18.C. K. S. Arvapalli, "Artificial Intelligence in Pharma industry- A Review," International Journal of Innovative Pharmaceutical Sciences and Research, vol. 10, p. 506, 2019.

19.Shailesh S. New Generation of Tablet: Fast Dissolving Tablet. Pharmainfo. net. 2008; 6(1)8. Kumari S, Visht S, Sharma PK, Yadav RK. Fast dissolving drug delivery system: review article. Journal of Pharmacy Research. 2010; 3(6): 1444-9.

20.Slavkova M, Breitkreutz J. Orodispersible drug formulations for children and elderly. European Journal of Pharmaceutical Sciences. 2015; 75: 2-9.

21.Arshad, M.S.; Zafar, S.; Yousef, B.; Alyassin, Y.; Ali, R.; AlAsiri, A.; Pitt, K. A review of emerging technologies enabling improved solid oral dosage form manufacturing and processing. Adv. Drug Deliv. Rev. 2021, 178, 113840.

22.Podczeck F., Jones B.E. Pharmaceutical Capsules. Pharmaceutical Press; London, UK: 2004.

23. Yadav G, Kapoor A, Bhargava S. Fast dissolving tablets recent advantages: A review. International Journal of Pharmaceutical Sciences and Research. 2012; 3(3): 728.

24.Sharma A, Anghore D, Awasthi R, Kosey S, Jindal S, Gupta N, Raj D, Sood R. A Review on Current Carbon Nanomaterials and Other Nanoparticles Technology and Their Applications in Biomedicine. World Journal Pharmacy and Pharmaceutical Science. 2015 Oct 15; 4(12): 1088-113.

25. Punitha S, Reddy GS, Srikrishna T, Kumar ML. Solid dispersions: a review. Research Journal of Pharmacy and Technology. 2011; 4(3): 331-4.

