

A Text Book of

GENERAL PHARMACY

As per the New PCI Syllabus **NEP 2020**

BP102T



1st SEM.

Bachelor of Pharmacy



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⊙ Dr. Chatlapelli Kishore

⊙ Dr. Snehamayee Mohapatra

⊙ Dr. Shilpi Prasad

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PREFACE

This book has been prepared in accordance with the latest Pharmacy Council of India (PCI) syllabus for B.Pharm students as per NEP 2020. It provides a concise and systematic introduction to the fundamental concepts of pharmacy and pharmaceutical sciences.

The book is organized into five units. The first unit introduces the pharmacy profession, its history, scope, pharmacopoeias and prescription handling. The second unit covers pharmaceutical calculations, posology, dosage forms and pharmaceutical ingredients. The third unit focuses on solid dosage forms such as powders, tablets and capsules. The fourth unit describes monophasic and biphasic liquid preparations, including solutions, suspensions and emulsions. The fifth unit discusses semisolid dosage forms, including ointments, creams, gels and suppositories. In each unit Multiple choice types questions, short answer type questions and long answer types questions are added for better understanding of subjects.

Throughout the book, every effort has been made to present the subject matter in a logical, concise and easy-to-understand format. Illustrations, tables, examples, and practical applications have been incorporated wherever appropriate to facilitate effective learning. The content aims not only to prepare students for university examinations but also to develop a sound understanding of pharmaceutical principles that will serve as a foundation for advanced studies and professional practice.

It is hoped that this book will prove to be a valuable resource for B.Pharm students, teachers, and pharmacy professionals. Constructive suggestions from readers for further improvement of future editions will be highly appreciated.

Authors

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Unit I

Introduction to Profession of Pharmacy, Pharmacopoeias and Prescription



Syllabus

- **History of the Profession of Pharmacy in India:** In relation to pharmacy education, pharmaceutical industries and organizations – evolution, development and milestones.
- **Scope of the Pharmacy Profession:** Role and responsibilities of pharmacists in retail/community pharmacy, hospital and clinical pharmacy, and industrial pharmacy including research and development.
- **Pharmacopoeias:** Introduction to IP, BP, USP, BPC, International Pharmacopoeia, other pharmacopoeias and the National Formulary of India; structure and content of the Indian Pharmacopoeia; study of one model IP monograph.
- **Introduction to Prescription:** Structure and format/parts of prescription, handling of prescriptions, Latin terminology related to prescriptions.



INTRODUCTION TO PROFESSION OF PHARMACY, PHARMACOPOEIAS AND PRESCRIPTION



LEARNING OBJECTIVES

After studying this chapter, the learner will be able to:

- Understand the concept, definition, and importance of pharmacy as a healthcare profession.
- Understand the historical development of the pharmacy profession in India.
- Understand the evolution of pharmacy education and major milestones in pharmacy practice in India.
- Identify the scope of the pharmacy profession in community, hospital, clinical, industrial, and regulatory settings.
- Understand the functions of pharmaceutical industries related to research and development, production, quality control, quality assurance, and regulatory affairs.
- Understand the concept, objectives, classification, and importance of pharmacopoeias.
- Recognize the history, structure, and salient features of Indian Pharmacopoeia and other major pharmacopoeias.
- Understand the concept and importance of prescriptions in pharmacy practice.
- Recognize common prescription errors and their preventive measures.
- Identify the standard format used for writing prescriptions.

1. HISTORY OF THE PROFESSION OF PHARMACY IN INDIA

1.1 INTRODUCTION TO HISTORY OF THE PROFESSION OF PHARMACY IN INDIA

Pharmacy is a branch of health science that deals with the preparation, dispensing and proper use of medicines. It combines scientific knowledge with healthcare services to ensure safe and effective medication use for patients.

The profession of pharmacy plays an important role in maintaining public health by:

- Manufacturing medicines.
- Dispensing prescribed drugs.
- Providing drug information.
- Ensuring safe and rational use of medicines.
- Participating in patient care and disease prevention.

Definition of Pharmacy

Pharmacy is the branch of Science and Art. It embraces a knowledge of the Identification, Cultivation, Collection, Selection, Pharmacological action, Preservation, Combination, Synthesis, Fermentation, Analysis and Standardization of drugs and medicines for Diagnosis, testing and treatment of diseases using natural, synthetic, semisynthetic, mineral, etc. substances.

2. SCOPE OF PHARMACY PROFESSION

2.1 INTRODUCTION TO SCOPE OF PHARMACY PROFESSION

- Pharmacy is a dynamic, multidisciplinary healthcare profession that encompasses the entire lifecycle of medicines from **discovery and development to manufacturing, quality assurance, distribution, dispensing and patient counselling.**
- While traditionally cantered on compounding and dispensing medications, the profession has undergone a profound transformation. Recently, pharmacy integrates cutting-edge domains such as **pharmaceutical sciences, biotechnology, nanotechnology, pharmacogenomics, artificial intelligence (AI), data analytics and public health policy.**
- Pharmacists serve as critical intermediaries in the healthcare ecosystem, ensuring that medicines are not only accessible but also used **safely, effectively and rationally.**

2.1.1 Community /Retail Pharmacy

- Community pharmacy, also known as retail pharmacy, is one of the oldest and most widely practised branches of the pharmacy profession.
- It serves as the primary point of contact between the public and the healthcare system, making pharmaceutical care readily accessible to patients.



❑ Key Functions of Community Pharmacists

- **Medication Dispensing and Prescription Verification:** Dispense medicines accurately and review prescriptions to prevent medication errors and ensure patient safety.
- **Patient Counselling and Education:** Guide patients on medication use, dosage, side effects, interactions, storage and lifestyle modifications.
- **Medication Therapy Management (MTM):** Optimise medication therapy, identify drug-related problems and improve treatment outcomes.
- **Preventive Healthcare Services:** Support vaccination, health promotion, smoking cessation and disease prevention programs.
- **Health Screening and Monitoring:** Conduct basic health checks such as blood pressure, blood glucose, cholesterol and BMI assessments.
- **Chronic Disease Management Support:** Assist patients with diabetes, hypertension, asthma, cardiovascular diseases and other chronic conditions.
- **OTC Medication Guidance and First-Aid Advice:** Recommend appropriate OTC medicines, provide first-aid advice and refer patients when necessary.
- **Pharmaceutical Supply Chain Management:** Manage medicine inventory, ensure product availability and maintain proper storage and cold-chain conditions.

2.1.2 Hospital and Clinical Pharmacy & Patient Care

- Hospital and Clinical Pharmacy is a specialized branch of pharmacy practice that focuses on the safe, effective and rational use of medications within healthcare institutions while providing direct patient-centered care.



❑ Emerging & Future Domains in Pharmacy

The pharmacy profession is rapidly evolving beyond traditional roles, with emerging technologies and advanced healthcare innovations creating new opportunities for pharmacists in research, clinical practice, biotechnology and digital health.



Table 2.1: Domains and their scope

DOMAIN	SCOPE
Pharmacogenomics	Personalized drug therapy based on an individual's genetic makeup to maximize efficacy and minimize adverse effects.
Precision Medicine	Development of customized treatment strategies for cancer, rare diseases, and chronic disorders using genetic and molecular profiling.
3D Printing of Drugs	Production of patient-specific dosage forms with customized doses, release profiles, and on-demand manufacturing capabilities.
Nanomedicine	Design of nanoparticle-based drug delivery systems for targeted therapy and improved treatment outcomes.
CRISPR & Gene Editing	Development of innovative therapies that modify genes to treat inherited and genetic disorders.
mRNA Technology	Research and development of next-generation vaccines and therapeutics using messenger RNA platforms.
One Health Approach	Integration of human, animal, and environmental health to address antimicrobial resistance, zoonotic diseases, and global health challenges.
Artificial Intelligence (AI) in Pharmacy	Application of AI in drug discovery, clinical decision-making, predictive analytics, and personalized medicine.
Digital Therapeutics	Software-based interventions designed to prevent, manage, or treat medical conditions.
Regenerative Medicine	Development of stem cell therapies, tissue engineering, and regenerative treatments for damaged organs and tissues.
Biopharmaceuticals & Biosimilars	Research, development, and manufacturing of biologics, biosimilars, and advanced therapeutic products.
Digital Health & Telepharmacy	Delivery of pharmaceutical care through telemedicine, remote monitoring, and digital healthcare platforms.

3. PHARMACOPOEIAS

3.1 INTRODUCTION TO PHARMACOPOEIAS

- The Pharmacopoeia derived from the Greek word 'Pharmakon' means 'drug' and 'poeia' means 'make'. Pharmacopoeia is a book describing drugs, chemicals and medicinal preparations especially one issued by an officially recognized authority and serving as a standard.
- These regulations are presented in separate articles, general and specific, relating to individual drugs and are published in the form of a book called a Pharmacopoeia.
- Pharmacopoeia is an official book published by the Ministry of Family and Health Welfare containing the approved list of drugs with description, preparation, tests for identification, purity & potency. It also facilitates the regulation of drug trade by drug control authorities.
- The head office of Indian Pharmacopoeia Commission is situated at Ghaziabad.

❑ History of Pharmacopoeia

- **1601** – Pharmacopoeia Augustana, the first known pharmacopoeia, published in Augsburg, Bavaria.
- **1699** – Edinburgh Pharmacopoeia published by the College of Physicians, Edinburgh.

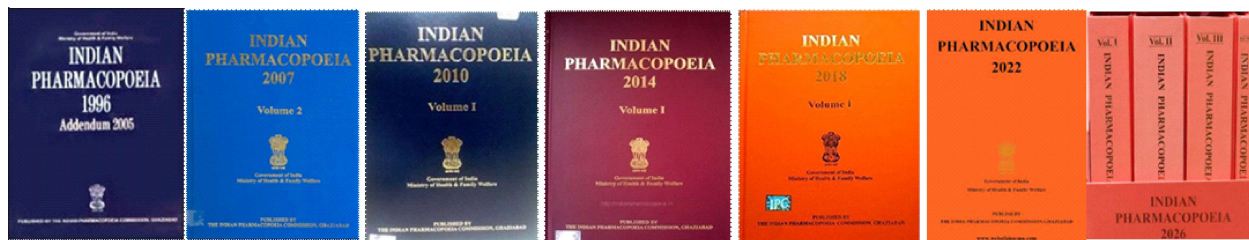


Table 3.1: Indian Pharmacopoeia: Editions, Supplements & Features

EDITION	SUPPLEMENT	FEATURES	CHAIRMANSHIP
1 st - 1955	1960	- Covers 986 monographs - Titles of monograph in Latin language - Weight and measure in metric system	Dr. B. N. Ghosh
2 nd - 1966	1975	- Titles of monograph in Latin language to English - Name of drugs first came - New analytical technique was added	Dr. B. Mukherji
3 rd - 1985 (2 Volume)	1989 and 1991	- Dissolution had been added - Microbial limit test prescribed for liquid preparation - Flame photometry electrophoresis, fluorometry was added	Dr. Nityanand
4 th - 1996 (2 Volume) (Blue)	2000, 2002 & 2005	- Computer generated formula was used - IR and UV spectrophotometry test was added - Contain 1149 monographs and 123 appendices	Dr. Nityanand
5 th - 2007 (3 Volume) (Blue)	2008	- Volume one contain general notice, structure of IPC - Volume three contain general monographs	Dr. Nityanand
6 th - 2010 (3 Volume) (Blue)	2012	- Products of biotechnology, herbal products were added. - Antiretroviral drug was added	Shri. K. Chandramouli
7 th - 2014 (4 Volume) (Red)	2015 and 2016	- Contain 2548 monographs 19 new Radiopharmaceutical monographs was added among this 577 are new	Dr. Gulab Nabi Azad
8 th - 2018 (4 Volume) (Orange)	2019 & 2021	- General chemical test and TLC eliminated - More specific test like IR, UV Spectrophotometer was added - Pyrogen test replaced by Bacterial Endotoxin test	Dr. C.K. Mishra
9 th - 2022 (Orange)	2024	- Launched in 1st July 2022 at Vigyan Bhawan, New Delhi 92 new monographs including 60 Chemical, 21 Vitamins, Minerals, Amino acids, Fatty acids etc. - This has led to the total number of 3152 monographs in the current edition of IP.	Dr. Mansukh Mandaviya
10 th Edition (4 Volume)	2026	- Total monographs: 3340 121 new monographs added 5 new general chapters introduced - Expanded coverage: Anti-TB, anti-diabetic, anti-cancer drugs, iron supplements 20 blood component monographs included for the first time (transfusion medicine)	Shri Jagat Prakash Nadda

3.1.3 British Pharmaceutical Codex (BPC)

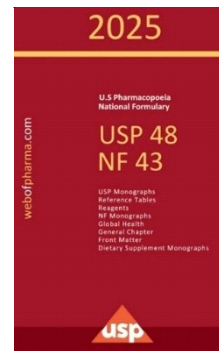
- The British Pharmaceutical Codex (BPC) is a reference book for medical practitioners and pharmacists.
- The first edition of BPC was published in **1907** by the Pharmaceutical Society of Great Britain.
- Later editions were published in **1911, 1923, 1934, 1949, 1954, 1959, 1963, 1968, and 1973.**
- In **1959**, it was decided that BPC and British Pharmacopoeia (BP) would come into effect on the same dates.

❑ Features of BPC

- It contains information about many new drugs and preparations.
- It provides standards for drugs and pharmaceutical preparations not included in BP.
- It gives information about uses, actions, side effects, precautions and treatment of poisoning.
- It contains formulae, methods of preparation, doses, storage conditions and containers for pharmaceutical preparations such as mixtures, powders, eye drops, ointments, creams, pastes and suppositories.

❑ The BPC differs from BP in:

- BPC contains more drugs and preparations.
- It contains additional information on standard of drugs, surgical dressing, pharmaceutical preparations, etc.
- It provides action and uses of drugs.
- It contains formula and preparation methods of some other formulations



3.1.4 United States Pharmacopoeia (USP)

❑ Introduction and History of United State Pharmacopoeia

- The United States Pharmacopoeia is a pharmacopoeia for the United States published annually by the United States Pharmacopoeial Convention, a nonprofit organization that owns the trademark and also owns the copyright on the pharmacopoeia itself.
- USP is published in a combined volume with the National Formulary which has a role in federal law.
- **1820:** The first edition of USP was published by United States Pharmacopoeial Convention on December 15th, 1820 in both Latin and English language.
- **1830:** The 1st revision of USP was published in 1830 and was resolved to revise USP at 10 years intervals.
- **1850:** In 1850, the colleges of pharmacy in USA were invited to participate in revision of USP.
- **1860 and 1860:** USP 4th and USP 5th edition were published which includes newer medicines and remedies.
- **1880 and 1890:** USP 6th and USP 7th editions were published respectively.
- On 5th July 1974, unification of USP and NF was announced.
- **1995:** The first edition of USP23-NF18 was published in 1995 and its 10th supplement was published in 1999.
- **2009:** USP32-NF27 was published and contained more than 4200 monographs and over 200 general chapters.

- In complex prescriptions, the inscription is divided into:
 - **Base:** The main active drug that produces the therapeutic effect.
 - **Adjuvant:** A substance added to enhance the action or improve the taste of the preparation.
 - **Vehicle:** A substance used to dissolve the ingredients or increase the volume of the preparation.
 - Nowadays, most medicines are available in ready-made formulations, so compounding of prescriptions is rarely required.
- 5. Subscription**
- It contains instructions to the pharmacist for preparing and dispensing the medicine, including the number of doses to be supplied.
- 6. Signatura (Signa)**
- It contains instructions for the patient about how to use the medicine.
 - These instructions are written on the prescription and transferred to the label of the medicine container.
- **The instructions usually include:**
- Quantity of medicine to be taken
 - Frequency of use or administration
 - Route or method of administration
 - Special instructions, such as dilution directions
- 7. Renewal instructions**
- The prescriber indicates whether the prescription can be refilled and how many times it may be renewed.
 - This is especially important for narcotic and habit-forming drugs to prevent misuse.
- 8. Signature, address and registration no. of the prescriber**
- The prescription must contain the prescriber's signature, address, and registration number.
 - This is especially important in prescriptions for narcotic and habit-forming drugs to prevent misuse.

PARTS OF A PRESCRIPTION	
1. Date, <u>15/8/2025</u>	
2. Name, <u>Anirudh Sharma</u> Age, <u>25</u> Sex, <u>Male</u> Address of Patient, <u>Basant Vihar Bilaspur (C.G.)</u>	
3. Rx (Superscription) – 'You Take' (Take thou)	
4. Inscription (Contains name and quantities of the prescribed ingredients) Paracetamol 500mg	
5. Subscription (Direction to the pharmacist for preparing the prescription and the no. of doses to be dispensed) Tab. Paracetamol 10	
6. Signatura (Direction to patient how to use the medicine) BID for 5 days After meal	
7. Renewal instruction (Number of times the prescription can be refilled or renewed)	8. Signature, address and registration number of the prescriber

Fig. 4.2: Format of Prescription

Bis in die, Bis die	b.i.d., b.d.	Twice a day
Ter in die, Ter die	t.i.d., t.d.	Three time a day
Quater in die	q.i.d., q.d.	Four times a day
Sexies in die	Sex. in d.	Six times a day
Bis terve in die	b.t.i.d	Two or three times a day
ter quaterve die	q.t.d	Three or four times a day
Quotidie	quot.	Daily

❖ Different Times of the day

LATIN TERM	ABBREVIATION	MEANING
Primo mane	prim. m.	Early in the morning
Prima luce	prim. luc.	Early in the morning
Mane	m.	In the morning
Omni mane	o.m.	Every morning
Omni nocte	o.n.	Every night
Inter nocte	inter noct.	During the night
Nocte	n.	At night
Hac nocte	hac noct.	Tonight
Nocte et mane	n.et.m.	Night and morning
Nocte maneque	n.m.	Night and morning
Vespere	vesp.	In the evening
Jentaculum	jentac.	Breakfast
Hora somni	h.s.	At bedtime
Hora decubitus	h.d.	At bedtime
Prandium	prand.	Dinner
Jentaculum	jentac.	Breakfast

❖ Hour Time

LATIN TERM	ABBREVIATION	MEANING
Omni hora, Quaque hora	o.h., qq.h.	Every hour
Quaque secunda hora	qq. sec. h.	Every alternate hour
Singulis horis	sing. hor.	Every hour
Secundis horis	sec. hor.	Every two hours
Alternis horis	alt. hor.	Every two hours
Tertis horis	tert. hor.	Every three hours
Quartis horis	quart. hor.	Every four hours
Sexties horis	Sext. hor.	Every six hours
Omni quarta hora, Quaque quarta hora	o.q.h., qq. q. h.	Every fourth hour

❖ Correlated Time

LATIN TERM	ABBREVIATION	MEANING
Ante cibos, Ante cibum	a.c.	Before meals, Before food
Post cibos, Post cibum	p.c.	After meals, After food
Inter cibos, inter cibum	i.c.	Between meals, Between food

❖ Other terms

LATIN TERM	ABBREVIATION	ENGLISH MEANING
Dolore urgente	Dol. urg.	When the pain is severe
Frequenter	freq.	Frequently
Lente	-	Slowly

Unit II

Pharmaceutical Calculations, Posology, Introduction to Dosage forms and Active Pharmaceutical Ingredients and Excipients



Syllabus

- **Metric system of weights and measures; calculations based on alligation, proof spirit, isotonic solutions, dilute solutions (percentage and ratio) and geometric dilution; scientific notation of units and measures.**
- **Posology: Definition and dose calculation based on age, body weight and body surface area.**
- **Introduction to Dosage Forms: Routes of administration and classification of dosage forms.**
- **Introduction to Active Pharmaceutical Ingredients and Excipients: Definition, ideal characteristics and importance.**



PHARMACEUTICAL CALCULATIONS, POSODOLOGY,INTRODUCTION TO DOSAGE FORMS AND ACTIVE PHARMACEUTICAL INGREDIENTS AND EXCIPIENTS



LEARNING OBJECTIVES

After studying this chapter, the learner will be able to:

- Understand the metric system of weights and measures used in pharmaceutical calculations.
- Perform calculations involving scientific notation and conversion of pharmaceutical units.
- Solve problems based on Alligation, Proof spirit, Isotonic solutions, Percentage strength, Ratio strength and Geometric dilution.
- Understand the concept and importance of posology in determining the appropriate drug dose.
- Calculate drug doses based on age, body weight, and body surface area (BSA).
- Understand the concept and classification of pharmaceutical dosage forms.
- Identify the different routes of drug administration and their significance.
- Understand the concept, ideal characteristics, and importance of Active Pharmaceutical Ingredients (APIs) and Excipients.
- Classify pharmaceutical excipients and describe the functions of major excipients used in dosage forms.

1. PHARMACEUTICAL CALCULATIONS

1.1 INTRODUCTION TO PHARMACEUTICAL CALCULATIONS

Pharmacy students must learn the correct use of balances, weights, and volume measuring devices, as accurate measurement is essential for the preparation, manufacturing, testing, and dispensing of medicines. This branch of science is known as metrology, which deals with the science of measurement.

1.1.1 Weights and Measures

- Weight is the measure of the gravitational force acting on a body and is directly proportional to its mass. Mass remains constant, whereas weight may vary slightly with latitude, altitude, temperature, and pressure. These variations are usually ignored except in very precise weighing or when handling large quantities.
- Measure is the determination of the volume or extent of a body. Temperature and pressure significantly affect the measurement of liquids and gases, so they are considered during precise measurements.
- The standard weights and measures used in the United States are based on the United States National Prototype Standards of the Meter and Kilogram. These standards are made of platinum-iridium and are maintained by the National Institute of Standards and Technology (NIST), Washington, D.C.



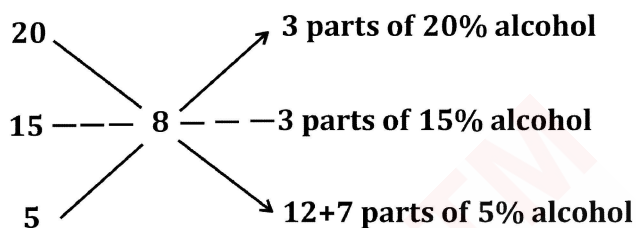
□ History of Weights and Measures

- The origin of weights and measures began with the need for a standard method of comparing the weight of objects. Weight is measured by comparing it with standard weights using balances or scales. Different nations adopted different standards, many of which were based on parts of the human body, such as the nail, foot, span, pace, cubit (forearm length), and fathom (arm stretch).

Examples: Calculate the amount of 20%, 15% and 5% alcohol should be mixed to get to produce 150ml of 8 % alcohol.

Solution:

Using the allegation method:



Total parts = 3+3+12+7 = 25 parts

Therefore, when 3 parts of 20% alcohol, 3 parts of 15% alcohol and 19 parts of 5% alcohol are mixed together, the resulting solution will produce 8% alcohol.

i. Volume of 20% alcohol required

25 parts : 150ml : 3 parts : V

$$V = \frac{150 \times 3}{25} = 18 \text{ ml}$$

ii Volume of 15% alcohol required

25 parts : 150ml :: 3 parts : V

$$V = \frac{150 \times 3}{25} = 18 \text{ ml}$$

iii. Volume of 5% alcohol required

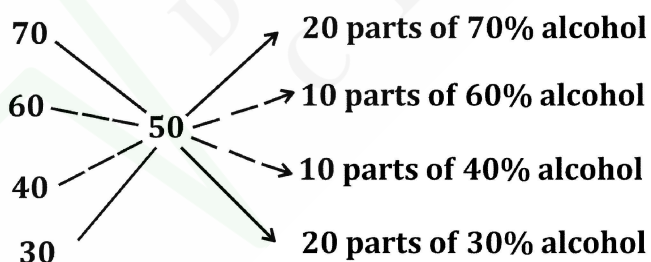
25 parts : 150ml :: 19 parts : V

$$V = \frac{150 \times 19}{25} = 114 \text{ ml}$$

Example: Calculate the amount of 70%, 60%, 40% and 30% alcohol should be mixed to get 50% alcohol.

Solution:

Using the allegation method



Therefore, when 20 parts of 70% alcohol, 10 parts of 60% alcohol, 10 parts of 40% alcohol and 20 parts of 30% alcohol are mixed together, the resulting solution will produce 50% alcohol.

Check :

$$(20 \times 70) + (10 \times 60) + (10 \times 40) + (20 \times 30)$$

$$= 1400 + 600 + 400 + 600$$

$$= 3000$$

$$(20+10+10+20) 50 = 60 \times 50 = 3000$$

Example: Calculate the volume of each of 90%, 60%, 30% and water are required to produce 500 ml of 50% alcohol.

1.1.4 Isotonic Solution

An isotonic solution is a solution that has the same osmotic pressure as body fluids. It causes no swelling or shrinking of cells and produces no discomfort when applied to delicate body tissues such as the eye, blood, or nasal mucosa. A **0.9% sodium chloride** solution is the standard isotonic solution.

Hypertonic Solution

A hypertonic solution has a higher osmotic pressure than body fluids. When cells are placed in a hypertonic solution, water moves out of the cells, causing them to shrink and become wrinkled (crenation). For example, **2.0% sodium chloride** solution is hypertonic to blood.

Hypotonic Solution

A hypotonic solution has a lower osmotic pressure than body fluids. When cells are placed in a hypotonic solution, water enters the cells, causing them to swell and eventually burst (hemolysis). For example, **0.2% sodium chloride solution** or distilled water is hypotonic to blood.

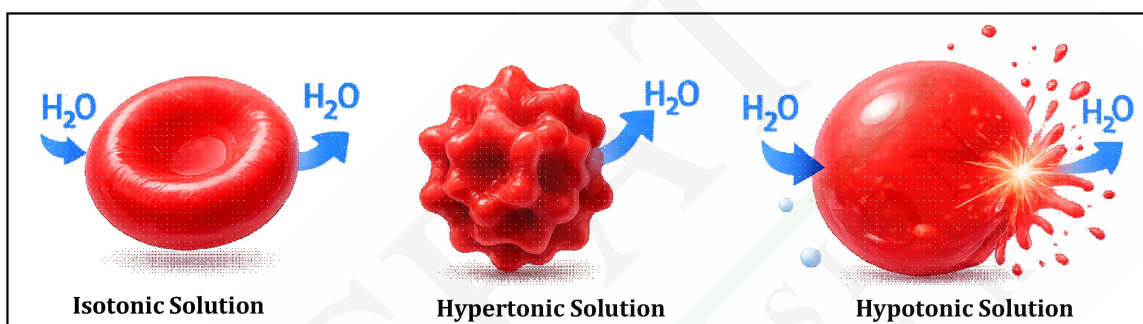


Fig. 1.2: Effect of Tonicity on Red Blood Cells (RBCs)

❑ Methods of Adjusting the Tonicity

- Used to calculate the quantity of **sodium chloride, dextrose, or other substances** to render drug solutions isotonic.
- Methods are divided into **two classes**:

Table 1.10: Classification of Methods for Adjusting Isotonicity

CLASS I METHODS	CLASS II METHODS
- Sodium chloride or other substance is added to the drug solution. - Freezing point of solution is lowered to -0.52°C. - Solution becomes isotonic with body fluids.	- Water is added to the drug in sufficient quantity. - An isotonic solution is formed first. - Preparation is brought to final volume with isotonic or buffered isotonic diluting solution.
- Cryoscopic method - Sodium chloride equivalent method	- White-Vincent method - Sprowls method

❑ Calculations for Solutions Iso-osmotic with Blood and Tears

1. Based on Freezing Point method

- Certain physical properties of solutions, called colligative properties, depend only on the number of particles present in solution and not on the nature of the dissolved substance.
- The two important colligative properties are osmotic pressure and depression of freezing-point. Since both are proportional to the number of particles in solution, they are proportional to each other.
- Therefore, depression of freezing-point is used as an indirect measure of osmotic pressure, as it is simpler and more accurate to determine.

Example: Calculate the % w/w of a solution containing 40 gm boric acid in 200 gm solution.

Solution:

Given

- Mass of solute = 40 gm
- Total mass of solution = 200 gm

$$\%w/w = \frac{\text{Mass of solute}}{\text{Total mass of the solution}} \times 100$$

$$\%w/w = \frac{40}{200} \times 100$$

$$\%w/w = 0.2 \times 100 = 20\%$$

Example: How many grams of sodium chloride are required to prepare 500 gm of 5% w/w solution

Solution:

Given

- % w/w = 5%
- Total mass of solution = 500 gm

$$\%w/w = \frac{\text{Mass of solute}}{\text{Total mass of the solution}} \times 100$$

$$\%w/w = \frac{5 \times 500}{100}$$

$$\%w/w = \frac{2500}{100}$$

$$\%w/w = 25\text{gm}$$

4. Percent volume by weight (%v/w)

Percent volume by weight (% v/w) is defined as the volume of solute (in ml) present in 100 gm of solution.

$$\%v/w = \frac{\text{Volume of solute(ml)}}{\text{Total mass of solution (gm)}} \times 100$$

Example: Calculate the % v/w of a solution containing 20 mL glycerin in 200 gm solution.

Solution:

Given

- Volume of solute = 20 mL
- Total mass of solution = 200 gm

$$\%v/w = \frac{\text{Volume of solute(ml)}}{\text{Total mass of solution (gm)}} \times 100$$

$$\%v/w = \frac{20}{200} \times 100$$

$$\%v/w = 0.1 \times 100 = 10\%$$

Example: A solution contains 15 mL alcohol in 150 g solution. Find the % v/w.

Solution:

Given

- Volume of solute = 15 mL
- Total mass of solution = 150 gm

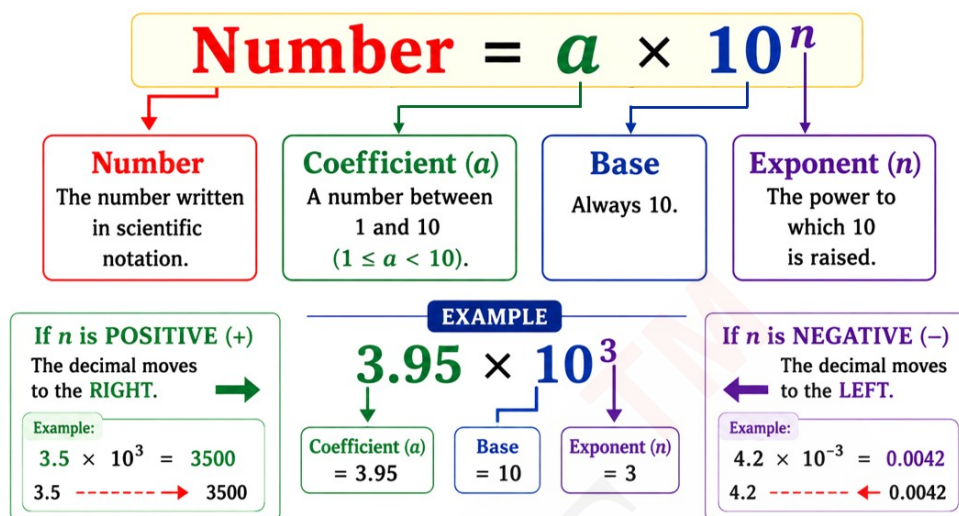


Fig. 1.4: Scientific Notation

Rules for Writing Scientific Notation

To express a number in scientific notation:

- Move the decimal point so that only one non-zero digit remains to the left of the decimal.
- If the decimal point is moved to the left, the exponent of 10 is positive (+).
- If the decimal point is moved to the right, the exponent of 10 is negative (-).
- The coefficient must always be greater than or equal to 1 and less than 10. The following table illustrates the conversion of common decimal numbers into their corresponding scientific notation.

Table 1.11: Examples of Numbers Expressed in Scientific Notation

STANDARD NUMBER	SCIENTIFIC NOTATION
2500	2.5×10^3
48,900	4.89×10^4
6200000	6.2×10^6
0.0056	5.6×10^{-3}
0.00000032	3.2×10^{-7}
0.45	4.5×10^{-1}

Addition and Subtraction, Multiplication and Division with Scientific Notation

A. Addition and Subtraction

Before adding or subtracting numbers in scientific notation, **the exponents (powers of 10) must be the same**. If they are different, first convert one number so that both have the same exponent.

Formula

If the exponents are the same:

$$(a \times 10^n) \pm (b \times 10^n) = (a \pm b) \times 10^n$$

Examples

i. Addition

$$(3.5 \times 10^3) + (2.1 \times 10^3)$$

Since the exponents are the same,

$$= (3.5 + 2.1) \times 10^3$$

$$= 5.6 \times 10^3$$

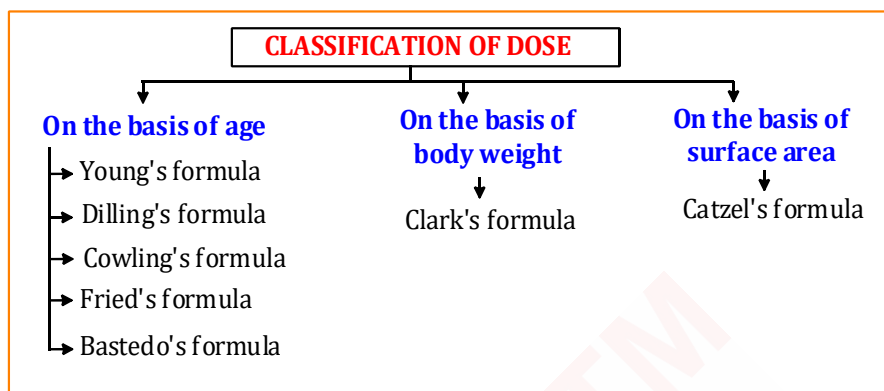


Fig. 2.1: Classification of Dose Calculation

1. Methods based on age of child:

There are number of methods by which the dose for a child can be calculated from the adult dose

i. Young's formula: This formula is used widely to calculate the doses for children of **12 years**.

$$\text{Child dose} = \left[\frac{\text{Age of child in years}}{\text{Age of child in years} + 12} \right] \times \text{Adult dose}$$

Example: Calculate the dose for a 6-year-old child if the adult dose is 300 mg.

Solution:

Given

- Age of child = **6 years**
- Adult dose = **300 mg**

$$\text{Child dose} = \frac{\text{Age of child in years}}{\text{Age of child in years} + 12} \times \text{Adult dose}$$

$$\text{Child dose} = \frac{6}{6 + 12} \times 300$$

$$\text{Child dose} = \frac{6}{18} \times 300$$

$$\text{Child dose} = 100 \text{ mg}$$

ii. Dilling's formula: This formula is used widely to calculate the doses for children in between **4 to 20 years of age**. This formula is considered better because it is easier quick to calculate the dose.

$$\text{Child dose} = \left[\frac{\text{Age of child in years}}{20} \right] \times \text{Adult dose}$$

Example: If the adult dose is 500 mg, find the dose for an 18-year-old child.

Solution:

Given

- Age of child = **18 years**
- Adult dose = **500 mg**

$$\text{Child dose} = \frac{\text{Age of child (years)}}{20} \times \text{Adult dose}$$

c. Ophthalmic Powder

Sterile powder intended for application to the eye or for preparing ophthalmic solutions.

Example: - Antibiotic ophthalmic powder

d. Dusting Powder

Finely divided powder intended for external application to the skin.

Examples: - Clotrimazole dusting powder, Talcum powder

e. Dental Powder

Powder intended for cleaning and polishing the teeth.

Examples: - Tooth powder, Herbal dental powder

2. Liquid Dosage Forms

- Liquid dosage forms are pharmaceutical preparations in which one or more active ingredients are dissolved, suspended, or emulsified in a suitable liquid vehicle. They are intended for oral, topical, or external administration.

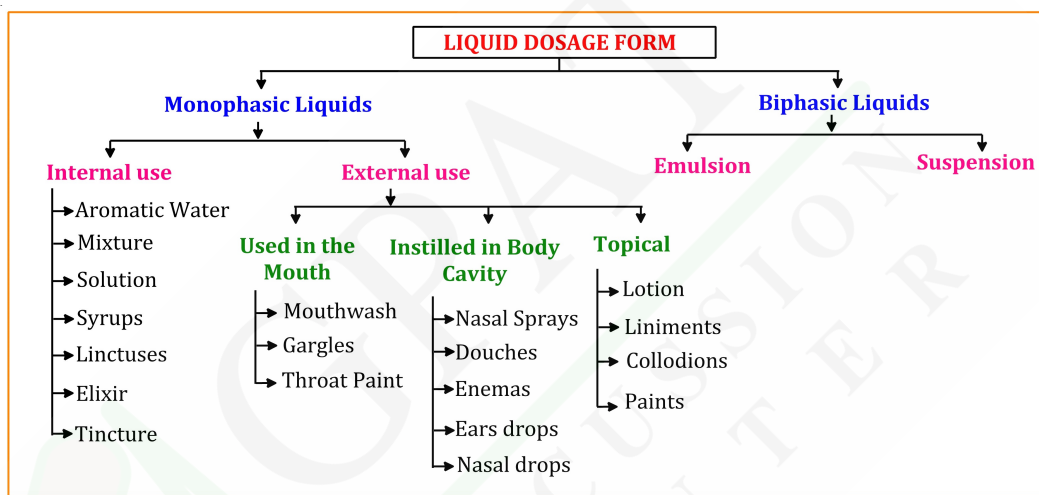


Fig: 3.3 Liquid Dosage Forms

A. Monophasic liquids dosage form**□ For Internal Use**

These preparations are administered by the oral route to produce systemic or local therapeutic effects.

i. Aromatic water

Aromatic waters are clear, saturated aqueous solutions containing volatile oils or aromatic substances. They are mainly used as flavoring agents, perfuming agents, and occasionally for mild therapeutic purposes.

Examples: Peppermint Water, Rose Water.

ii. Mixture

Mixtures are oral liquid preparations containing one or more medicaments dissolved, suspended, or dispersed in a suitable vehicle. They are generally prescribed for short-term treatment and are supplied in multidose containers.

Example: Antacid Mixture.

iii. Solution

Solutions are clear, homogeneous liquid preparations in which the drug is completely dissolved in water or another suitable solvent. They provide rapid absorption because the drug is already in dissolved form.

Example: Potassium Iodide Solution.

e. Enema

Enemas are liquid preparations introduced into the rectum for bowel evacuation, diagnosis, or local/systemic drug administration.

iii. Topical Preparations**a. Lotion**

Lotions are liquid preparations applied externally to the skin without rubbing. They provide cooling, soothing, protective, or antipruritic effects.

b. Liniment

Liniments are alcoholic or oily liquid preparations applied to the skin **with rubbing** to relieve muscular pain, stiffness, and inflammation.

c. Collodion

Collodion is a solution of pyroxylin in ether and alcohol. After application, the volatile solvents evaporate, leaving a thin protective film over the affected area.

d. Paint

Paints are medicated liquid preparations applied to the skin or mucous membrane with the help of a brush, cotton swab, or applicator.

B. Biphasic Liquid Dosage Forms**i. Emulsion**

An emulsion is a biphasic liquid preparation in which one immiscible liquid is dispersed as fine droplets in another liquid with the help of an emulsifying agent. Depending on the continuous phase, emulsions are classified as Oil-in-Water (O/W) or Water-in-Oil (W/O) emulsions.

Examples: Cod Liver Oil Emulsion, Liquid Paraffin Emulsion.

ii. Suspension

A suspension is a biphasic liquid preparation in which insoluble solid particles are uniformly dispersed throughout a liquid vehicle. Since the particles settle on standing, suspensions should always be shaken before administration.

Example: Paracetamol Suspension.

3. Semisolid dosage form

Semisolid dosage forms are pharmaceutical preparations having a consistency intermediate between solid and liquid dosage forms. They are intended mainly for external application to the skin or mucous membranes, although some are designed for rectal, vaginal, or urethral administration.

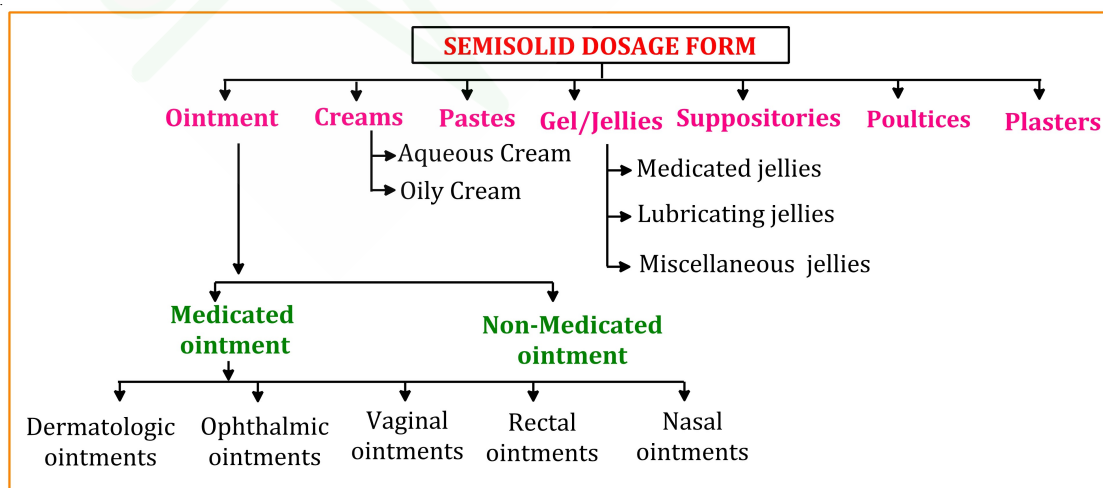


Fig: 3.4 Semisolid Dosage form

Uses: - Asthma, Chronic Obstructive Pulmonary Disease (COPD) and Bronchitis

Examples: - Salbutamol Nebulizer Solution, Ipratropium Nebulizer Solution.

3.1.2 Routes of Drug Administration

Routes of drug administration is the path or method by which a drug is introduced into the body to produce its therapeutic effect. The choice of route depends on the drug properties, patient condition, desired onset of action and site of action.

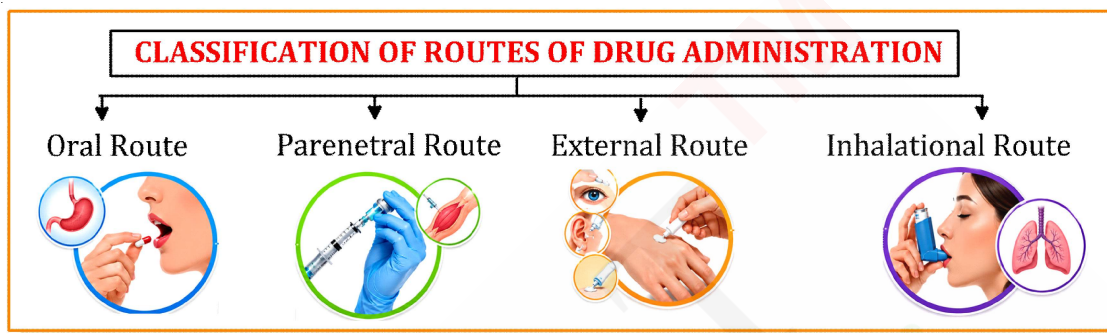


Fig. 3.6: Routes of Drug Administration

1. Oral Route

The oral route is the most common and convenient route in which the drug is administered through the mouth and swallowed, after which it is absorbed from the gastrointestinal tract into the bloodstream.

Examples: – Tablets, Capsules, Syrups, Suspensions, Powders, Oral solutions.

❑ Advantages and Disadvantages of Oral Route

❖ Advantages

- Easy and convenient to use.
- Safe and painless.
- Economical.
- Suitable for long-term therapy.
- No trained personnel required.

❖ Disadvantages

- Slow onset of action.
- Drug may be destroyed by gastric acid or digestive enzymes.
- Subject to first-pass metabolism.
- Not suitable for unconscious or vomiting patients.

2. Parenteral Route

The parenteral route involves the administration of drugs by injection, bypassing the gastrointestinal tract. It is used when rapid action or complete drug availability is required.

Examples: – Injections, Infusions, Injectable suspensions.

❑ Types of Parenteral Route

- **Intravenous (IV)** – Into a vein.
- **Intramuscular (IM)** – Into a muscle.
- **Subcutaneous (SC)** – Under the skin.
- **Intradermal (ID)** – Into the skin.

- Antioxidants are used to prevent the oxidation of active substances and excipients in the finished product. There are three main types of antioxidants:
 - True Antioxidants (water insoluble):** They act by a chain-termination mechanism by reacting with free radicals, e.g. butylated hydroxytoluene.
 - Reducing Agents (water soluble):** They have a lower redox potential than the drug and get preferentially oxidized, e.g. ascorbic acid. Thus, they can be consumed during the shelf-life of the product.
 - Antioxidant Synergists (chelating agents):** These enhance the effect of antioxidants, e.g. EDTA.

Table 4.9: Antioxidants commonly used for Aqueous system and Oil system

ANTIOXIDANTS COMMONLY USED			
FOR AQUEOUS SYSTEMS		FOR OIL SYSTEMS	
Sodium sulfite	Ascorbic acid (Vitamin C)	Ascorbyl palmitate	Butylated hydroxy toluene
Sodium metabisulfite	Isoascorbic acid	Hydroquinone	Butylated hydroxy anisole
Sodium bisulfite	Thioglycerol	Propyl gallate	α -tocopherol
Sodium thiosulfate	Thioglycolic acid	Nordihydroguaiaretic acid	Lecithin
Sodium formaldehyde /sulfoxylate	Cysteine hydrochloride		
Sulfur dioxide	Acetylcysteine		

Table 4.10: Antioxidants used in sterile products

(REDUCING AGENTS)	CONC. (%)
Ascorbic acid	0.02–0.1
Sodium bisulfite	0.1–0.15
Sodium metabisulfite	0.1–0.15
Sodium formaldehyde sulfoxylate	0.1–0.15
Thiourea	0.005
BLOCKING AGENTS	CONC. (%)
Ascorbic acid esters	0.01 – 0.015
Butylated hydroxytoluene (BHT)	0.005–0.02
Tocopherols	0.05–0.075

❖ **Ideal Characteristics of an Antioxidant**

- Effectively prevents oxidation.
- Non-toxic, non-irritant and pharmacologically inert.
- Compatible with the drug and other excipients.
- Chemically and physically stable during storage.
- Effective at low concentrations.
- Does not affect the colour, odour, taste or therapeutic activity of the formulation.
- Stable over a wide pH and temperature range.
- Economical and easy to incorporate.

❖ **Importance of Antioxidants**

- Prevent oxidation of drugs and excipients.
- Improve the chemical stability of pharmaceutical formulations.

Solid Dosage Forms

Unit III



Syllabus

- **Powders:** Classification, advantages and disadvantages; dusting powders, effervescent powders, efflorescent powders, hygroscopic powders and eutectic mixtures; introduction to excipients and methods of preparation.
- **Tablets:** Definition, types of tablets including moulded tablets and pills with examples; advantages and disadvantages; introduction to excipients and methods of preparation.
- **Capsules:** Definition, types of capsules, advantages and disadvantages, capsule sizes; introduction to excipients and methods of preparation.



SOLID DOSAGE FORMS



LEARNING OBJECTIVES

After studying this chapter, the learner will be able to:

- Identify the various types of solid dosage forms and their pharmaceutical applications.
- Understand the concept, characteristics, advantages, and limitations of pharmaceutical powders.
- Outline the formulation, preparation, packaging, labeling, and storage requirements of powders for internal and external use.
- Understand the concept, classification, advantages, and disadvantages of tablets.
- Classify the different types of tablets and their pharmaceutical applications.
- Recognize the formulation components and functions of tablet excipients used in tablet manufacturing.
- Understand the methods of tablet manufacturing, including wet granulation, dry granulation, and direct compression.
- Understand the concept, classification, advantages, and disadvantages of capsules.
- Differentiate between hard gelatin capsules and soft gelatin capsules.
- Outline the formulation, manufacturing, filling, and sealing processes of capsules.

INTRODUCTION TO SOLID DOSAGE FORMS

A solid dosage form is a pharmaceutical formulation in which the drug substance is present in a solid state, either alone or in combination with excipients. Solid dosage forms are mostly administered as unit dosage forms and deliver the drug to the body through oral, buccal, sublingual, rectal, vaginal, or other routes of administration.

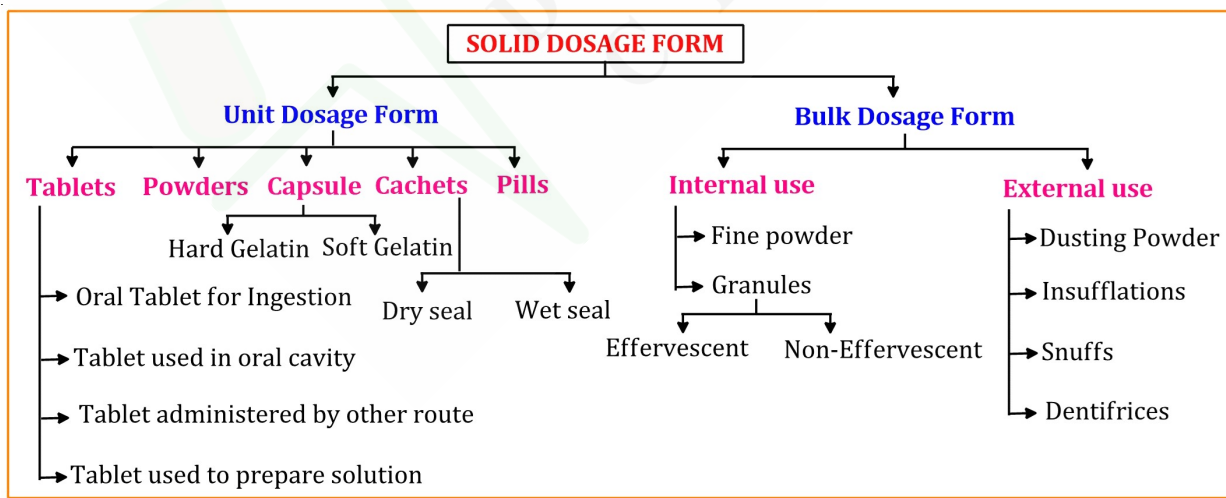


Fig. 1.1: Classification of Solid Dosage Forms

Advantages and Disadvantages of Solid Dosage Forms

Advantages

- **High Stability** – More stable than liquid dosage forms and have a longer shelf life.

- **Accurate Dose** – Provide precise and uniform dosing.
- **Convenient Handling** – Easy to carry, store and transport.
- **Easy Administration** – Simple and convenient for self-medication.
- **Taste Masking** – Unpleasant taste and odour of drugs can be masked.
- **Economical** – Manufacturing, packaging and transportation costs are less as compare to other dosage form.
- **Modified Release Possible** – Sustained-release and controlled-release formulations can be prepared.
- **Less Risk of Microbial Contamination** – Compared to liquid preparations.

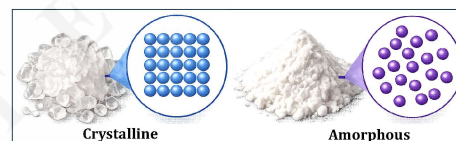
❖ Disadvantages

- **Difficulty in Swallowing** – Not suitable for infants, elderly or unconscious patients.
- **Slower Onset of Action** – Requires disintegration and dissolution before absorption.
- **Not Suitable for all Drugs** – Drugs unstable in the GI tract or with poor solubility may not be suitable.
- **Dose Adjustment Difficult** – Fixed-dose forms do not allow easy dose modification.
- **GI Irritation** – Some drugs may cause irritation to the gastrointestinal tract.
- **Not Suitable for Emergency Conditions** – Delayed action compared to injections.
- **Bioavailability Variations** – Drug absorption may be affected by food, pH and GI motility.

1. POWDERS

1.1 INTRODUCTION TO POWDERS

- Pharmaceutical powders are solid dosage forms of medicament, in which one or more drugs are mixed in a finely divided state, with or without excipients. Powders are available in crystalline or amorphous form and they can be used either internally or externally



- **Particle size matters** in physical, chemical and biological properties of dosage form.
Smaller particles → Dissolve faster → Better absorption → Quicker drug action

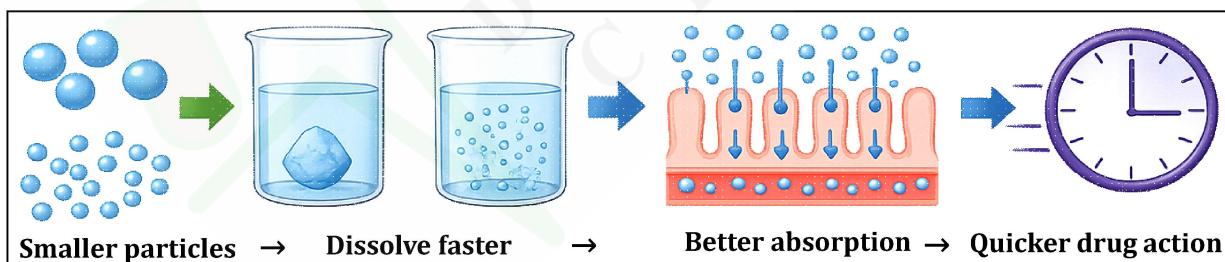


Fig. 1.2: Importance of Particle Size in Dosage Forms

❑ Advantages and Disadvantages of Powders

❖ Advantages

- **Greater Stability** – Powders are more stable than liquid dosage forms.
- **Suitable for Large Doses** – Large quantities of bulky drugs can be conveniently administered as powders.
- **Flexible Dosing** – Physicians can prescribe specific quantities according to individual patient needs.
- **Easy Administration** – More convenient for children and elderly patients compared to tablets and capsules.

Lubricant/Glidant	Materials that improve the flowability and spreadability of the powder.	Talc, Colloidal silicon dioxide
Perfume/Color (Optional)	Added to improve the odour and appearance of the preparation.	Rose perfume, Lavender perfume, Approved cosmetic colors

❑ Method of Preparation

1. Weigh all ingredients accurately according to the formula.
2. Powder and sieve each ingredient separately through Sieve No. 120 or 180 to obtain a fine particle size.
3. Mix the powders thoroughly using geometric dilution to ensure uniform distribution of the medicament.
4. Re-sieve the mixture to obtain a homogeneous and free-flowing powder.
5. Transfer the powder into a suitable dry, wide-mouthed or sifter-top container.

❑ Container

Dusting powders are dispensed in perforated or shifter top containers or in aerosol containers. They are applied by sprinkling directly on to the affected area or applied by using powder puff or a sterile gauze pad.

❑ Label

Auxiliary Labels

- For External use only
- Store in a dry place

Directions for Use

- "Lightly dust on the affected area as directed."
- "Sprinkle lightly on the affected area two or three times a day."

Special Warning (for Medicinal Dusting Powders)

- "Do not apply on open wounds and broken skin."

❑ Storage

Dusting powders should be stored at room temperature or in a dry place.

(b) Insufflations

- Insufflations are medicated dusting powders intended for administration into body cavities such as the nose, throat, ear, and vagina using an insufflator.
- An insufflator is a device that sprays the powder as finely divided particles over the site of application.
- They are used to produce local effects (e.g., treatment of ENT infections) or systemic effects when a drug is unsuitable for administration through the GIT.
- The powder should be very fine, non-irritant, and non-sensitizing.
- **Examples:** - Camphor, Menthol, Ammonium chloride insufflation, Boric acid insufflation

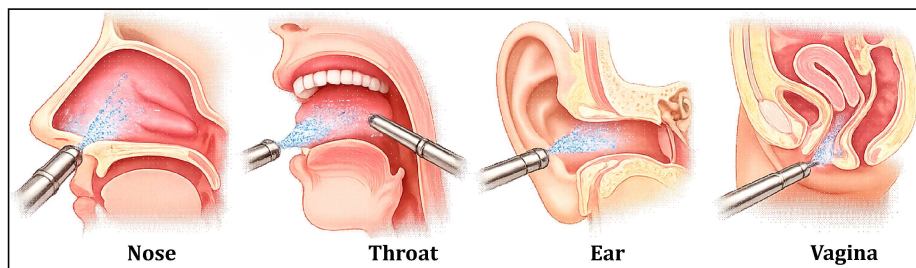


Fig. 1.5: Action of Insufflator

(b) Compound powders

Compound powders contain two or more than two active ingredients, which are mixed together and then dispensed as individual doses. Therefore these powders are also called as compound divided powders.

Examples: -

1. Powder containing combination of Aspirin, paracetamol and caffeine powder
2. Aspirin and caffeine powder.

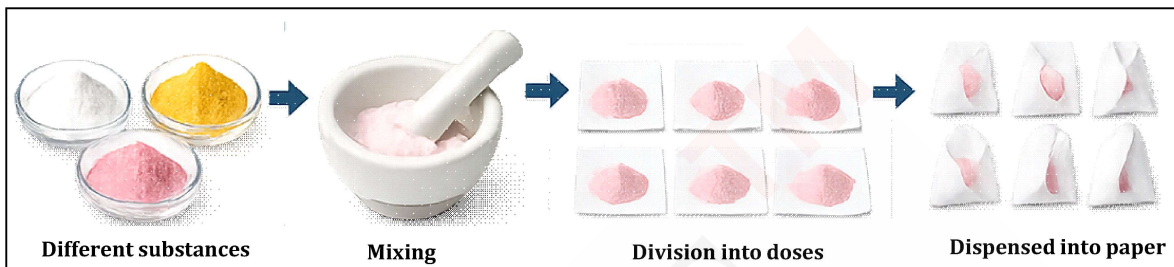


Fig. 1.7 Preparation of Compound Powder

Advantages and Disadvantages of Simple and Compound Powders

Advantages

- Suitable for bulky drugs and large doses.
- Faster absorption than tablets and capsules.
- Flexible dosing; dose can be adjusted easily.
- Certain drugs are more stable in dry powder form than in liquid preparations.
- Easy to prepare and economical.

Disadvantages

- Accurate dose measurement is difficult, especially for bulk powders.
- Unpleasant taste and odour are difficult to mask.
- Bulky and inconvenient to carry.
- Not suitable for hygroscopic, deliquescent, or volatile drugs unless specially packed.
- Risk of contamination if not stored properly.

Uses of Simple and Compound Powders

- Used for oral administration of drugs.
- Used as antacids, laxatives, and digestive preparations.
- Used for nutritional supplements containing vitamins and minerals.
- Suitable for drugs requiring large doses.
- Can be dissolved or mixed with water before administration.

Formulation of Simple and Compound powder

Table 1.6: Formulation of Simple and Compound powder

COMPONENT	FUNCTION	EXAMPLES
Active Ingredient	Provide therapeutic action	Sodium bicarbonate, Magnesium trisilicate, Rhubarb powder
Diluent	Increase bulk and ensure uniform mixing	Lactose, Starch
Flavoring Agent	Improve taste	Orange flavor, Peppermint
Sweetening Agent	Mask unpleasant taste	Sucrose, Saccharin sodium
Coloring Agent	Improve appearance	Approved food colors

Method of Preparation

1. Accurately weigh all ingredients.
2. Powder each ingredient separately if necessary.

2. Method 2

The eutectic substances are first triturated together to form a liquid. An adsorbent is then added, which absorbs the liquid and converts it into a free-flowing powder.

Example: Insufflation containing Camphor, Menthol, and Ammonium Chloride

❑ Container

- Eutectic mixtures (powders) consists volatile substances like camphor menthol, thymol etc. Hence to prevent their volatalization, they are dispensed as follows.
- If eutectic powder is meant for internal use, it should be dispensed in double wrapped paper packets and these packets are then placed in airtight, wide mouthed plastic or glass container.
- If the eutectic powder is for external use (eg. Insufflation) that should be dispensed in small shifter top plastic boxes.

❑ Label

- Take as directed by the physician.
- Store in a cool place.
- Keep in an airtight container.
- Protect from heat and moisture.
- Keep out of reach of children.

❑ Storage

Eutectic powders (mixtures) should be stored in a cool place in an air tight container, to prevent the volatalization of ingredients, at higher temperature

2. TABLETS

2.1 INTRODUCTION TO TABLETS

- Tablets are defined as compressed **solid unit dosage** form of medicament comprising of one or more active ingredients along with suitable pharmaceutical excipients.
- Tablets are usually circular in shape and may be flat or biconvex in appearance.

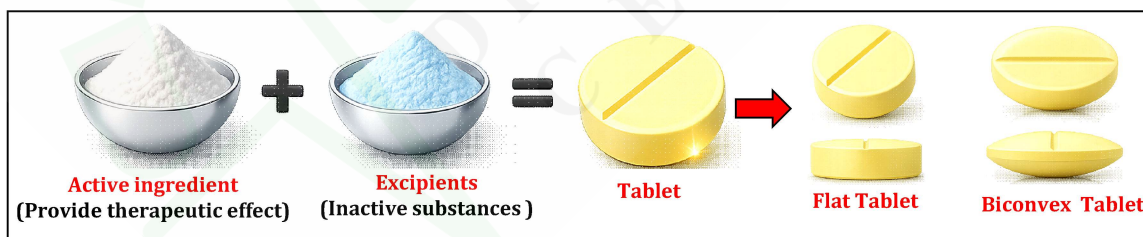


Fig. 2.1: Introduction to Tablets

- Tablets are prepared by compaction of powdered or granular medicament alone or in combination with other excipients by exerting high pressures with the aid of tablet machines.
- Tablets are available as uncoated and coated forms.
- Uncoated tablets have no coating and may be single or multilayered, while coated tablets have one or more layers covering the core.

❑ Advantages and Disadvantages of Tablets

❖ Advantages

- Tablets have the greatest dose precision and the least content variability.
- Its cost is lowest of all oral dosage form.
- It is lighter, compact, easiest and cheapest to package and strip.

vii. Controlled Release Tablet

- Controlled-release tablets are designed to release the drug at a predetermined rate for an extended period, maintaining therapeutic drug levels and reducing dosing frequency.
- Principle:** The drug is released slowly and continuously from the tablet using matrix systems, coated particles, osmotic systems, or special film coatings.
- Examples:** - Theophylline (Theo-Dur) and Indomethacin (OROS system)

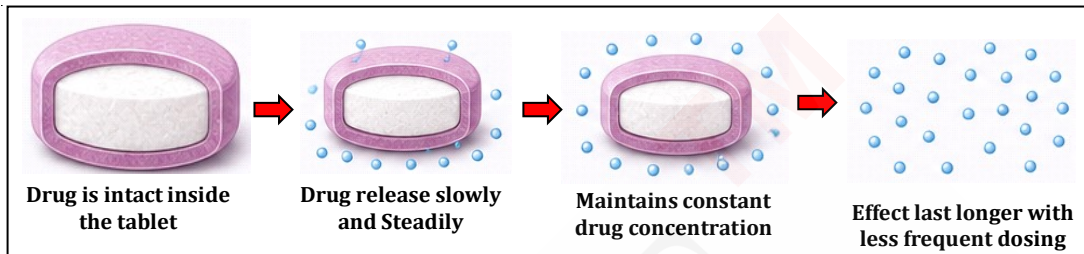


Fig. 2.3: Mechanism of Controlled Release Tablet

Types:

- Matrix-controlled release tablets
- Osmotic-controlled release tablets (OROS)
- Film-coated controlled-release tablets

□ Advantages and Disadvantages of Controlled-Release Tablets

❖ Advantages

- Maintains uniform blood drug concentration for a prolonged period.
- Reduces dosing frequency, improving patient compliance.
- Minimizes fluctuations between peak and trough drug levels.
- Reduces side effects associated with high peak concentrations.
- Provides prolonged therapeutic effect.

❖ Disadvantages

- Higher manufacturing cost than conventional tablets.
- Risk of dose dumping if the tablet is damaged or crushed.
- Not suitable for drugs with a short biological half-life or narrow therapeutic index.
- Difficult to adjust the dose once administered.
- Not suitable when a rapid onset of action is required.

viii. Sustained release tablets

- Sustained-release tablets are designed to release the drug slowly over an extended period of time, thereby maintaining therapeutic drug levels for a longer duration and reducing the frequency of dosing.
- Example:** - Theophylline (Theo-Dur), Metformin (Metformin SR), Diclofenac Sodium, Nifedipine, Propranolol

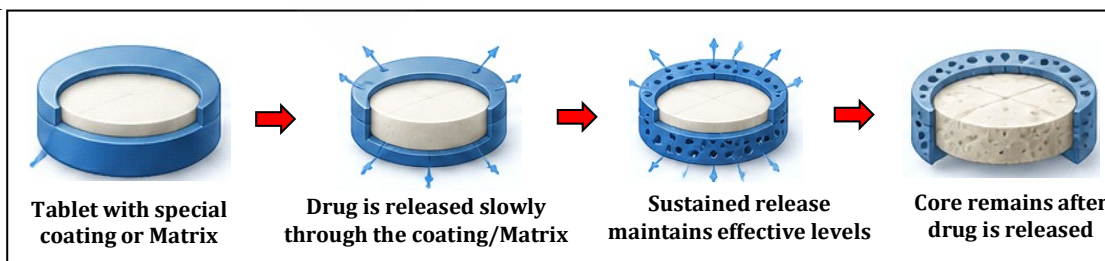


Fig. 2.4: Mechanism of Sustained Release Tablets

iii. Hypodermic Tablet

Hypodermic tablets are tablets containing one or more drugs along with readily water-soluble ingredients. They are intended to be dissolved in sterile water or Water for Injection (WFI) to prepare an injectable solution immediately before use.

Examples: - Morphine Sulfate, Atropine Sulfate

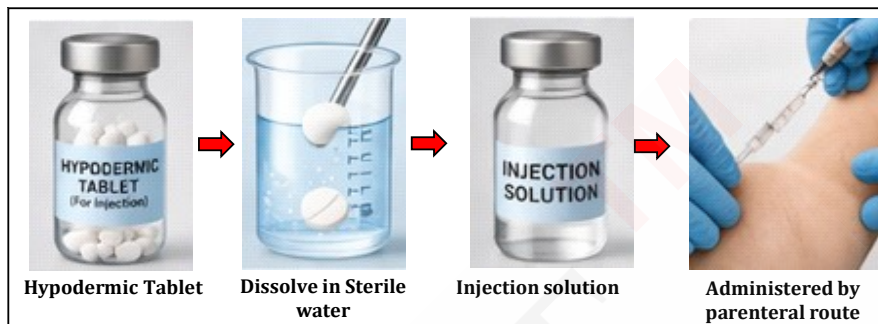


Fig. 2.5: Hypodermic Tablet

□ Advantages and Disadvantages Hypodermic Tablet

❖ Advantages

- **Accurate Dose** – Provides a precise quantity of drug.
- **Good Stability** – More stable during storage than many liquid injections.
- **Longer Shelf Life** – Solid form generally has better stability.
- **Reduced Storage Space** – Requires less space compared to ready-made injectable solutions.
- **Convenient for Emergency Preparation** – Can be reconstituted when needed.

❖ Disadvantages

- **Preparation Required Before Use** – Must be dissolved in sterile water before injection.
- **Risk of Contamination** – Improper reconstitution may lead to microbial contamination.
- **Time-Consuming** – Additional preparation step delays administration.
- **Possibility of Dosing Errors** – Incorrect dilution can affect dose accuracy.
- **Need for Strict Sterility** – Reconstitution requires aseptic conditions.

iv. Tablet Triturates (Moulded Tablet)

- Tablet triturates are small, usually cylindrical molded or compressed tablets prepared by mixing potent drugs with lactose and a suitable binder such as acacia. The mixture is moistened, molded into tablets, and then dried.
- These tablets were formerly prepared extemporaneously by pharmacists for dispensing small doses of potent drugs. Alcohol was commonly used as the moistening agent to facilitate rapid drying.
- **Examples:** - Nitroglycerin, Atropine Sulfate



□ Advantages and Disadvantages of Tablet Triturate

❖ Advantages

- Suitable for potent drugs administered in very small doses.
- Provide accurate dosing of medicaments.
- Rapidly dissolve due to their porous structure.
- Easy to prepare by the moulding method.
- Useful when only a small quantity of drug is required.

6. Flavours

- Used mainly in chewable tablets and mouth-dissolving tablets to improve palatability.
- Flavour oils may be added as solvents, adsorbed on absorbents, or emulsified in granulating agents.
- Concentration of flavor oils is usually 0.5–0.75% to avoid affecting tablet properties.
- **Examples:** -

Table 2.6: Flavouring agent used in Tablet

TASTE TO BE MASKED	MASKING AGENT
Acid (Sour)	Lemon, Lime, Orange, cherry, grapefruit, Citrus flavors, liquorice, root beer
Bitter	Coffee, Grapefruit, Cherry, Peach, Raspberry, Orange, Lemon, Lime, wild cherry, walnut, chocolate, mint spice, mint combinations, passion fruit, anise
Metallic	Berries, mints, grape, marsh-mallow, orange
Salty	Butterscotch, maple, apricot, peach, vanilla, wintergreen mint
Sweet	Vanilla, Fruit and berry

7. Sweeteners

Sweeteners are primarily used in chewable tablets to improve taste and reduce the need for sugar.

Table 2.7: Sweetening agents used in Tablet

SWEETENING AGENTS	CHARACTERISTICS
Sodium Cyclamate	• 30 times sweeter than Sucrose • Banned in the USA [Carcinogenic (Due to metabolite cyclohexylamine)]
Cyclamate	• 70 times sweeter than Sucrose
Mannitol	• 72 times sweeter than Sucrose • Negative heat of solution, Widely used in chewable tablets
Aspartame	• Methyl ester of aspartic acid and Phenylalanine • 200 times sweeter than sugar, Non-Carcinogenic • Hydrolyzes to Aspartylphenylalanine & Diketopiperazine- Not stable at high temp. • It is contraindicated in patients suffering from Phenylketone urea.
Acesulfame Potassium (Ace K)	• 200 times sweeter than Sucrose • Tradename – Sunett and Sweet One
Saccharin	• 500 times sweeter than sugar, Carcinogenic (Due to cyclohexylamine formation) • Tradename – Sweet'N Low
Sucralose	• 600 times sweeter than Sucrose, Non-caloric • Tradename – Splenda
Neotame	• 7000 to 13,000 times sweeter than Sugar, Non-caloric • Tradename - Newtame

2.1.4 Method of preparations

1. Direct compression method

- The simplest tablet manufacturing method in which powders are blended and compressed directly without granulation. Most drugs require directly compressible diluents to improve flow and compressibility.

• Directly Compressible Diluent

An inert excipient that can be compressed easily and retains its compressibility after mixing with drugs and other excipients. It should have good flowability, compressibility, inertness, tastelessness, reworkability, disintegration ability, and low cost.

- The added liquid forms bridges between particles, improving flowability and compressibility. Granulation passes through four stages:
- i. **Pendular State** – Liquid bridges form; low granule strength.
- ii. **Funicular State** – Bridges merge; strength increases.
- iii. **Capillary State** – Voids completely filled with liquid; **maximum granule strength** (optimum stage).
- iv. **Droplet State** – Excess liquid forms droplets; granule strength decreases.

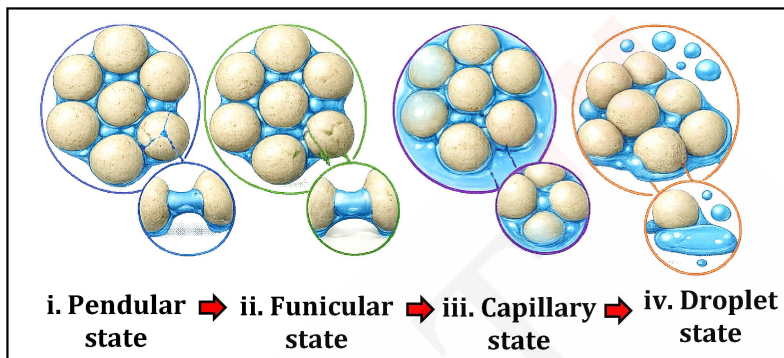


Fig. 2.8: Stages of Wet Granulation

- After wet massing, the material is wet screened, dried, dry screened, and finally compressed into tablets.

Process:

Mixing → Wet Massing → Wet Screening → Drying → Dry Screening → Compression.

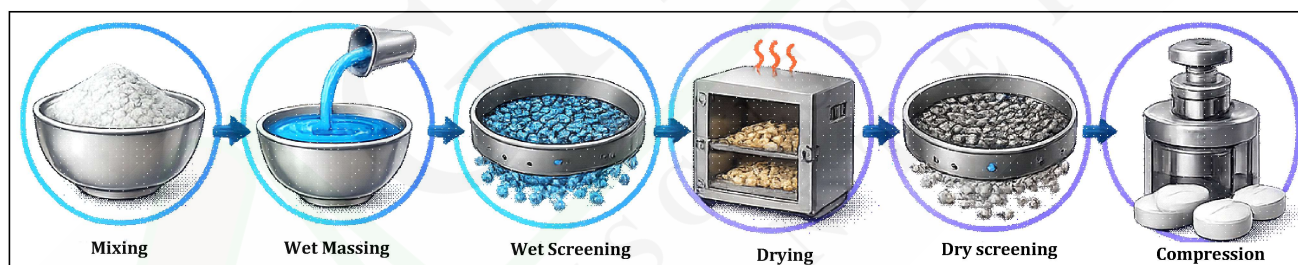


Fig. 2.9: Process of Wet Granulation

Advantages

- Produces strong and uniform granules.
- Improves flowability and compressibility.
- Suitable for a wide range of drugs and excipients.

Precautions

- Avoid overwetting, which can produce hard aggregates.
- When volatile or flammable solvents are used, proper ventilation, grounding of equipment, and explosion-proof systems are necessary.
- Solvent vapors must be controlled according to environmental and safety regulations.

3. CAPSULES

3.1 INTRODUCTION TO CAPSULES

- The word capsule comes from the **Latin word capsula**, which means a **small container**.
- Capsules are solid medicines in which the drug is **enclosed inside a gelatin** shell that dissolves in the body.

Soft	0.8/1	Tube, vaginal, water miscible-based or shell hardening products and those destined primarily for cold, dry areas.
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iii. Preservative

A preservative is a substance added to a formulation to prevent the growth of microorganisms (bacteria, fungi, and molds) and increase the shelf life of the product.

Examples: - Methylparaben (4 parts), Propylparaben, (1 part)

iv. Colourant

A colourant is a substance added to impart colour to the dosage form for identification, elegance, and patient acceptability.

Examples: - FD&C and D&C water soluble dyes, certified lakes, pigments, and vegetable colours.

v. Opacifier

An opacifier is a material added to make the capsule shell opaque (non-transparent) and protect light-sensitive drugs from degradation.

Examples: - Titanium dioxide 0.2 to 1.2%

vi. Flavouring Agent

A flavouring agent is a substance added to improve the taste and odour of pharmaceutical preparations, making them more palatable.

Examples: - Ethyl vanillin, Peppermint oil, Orange oil, Lemon oil

vii. Sweetening Agent

A sweetening agent is a substance added to provide sweetness and improve the taste of pharmaceutical products.

Examples: - Sucrose, Saccharin sodium

viii. Solubility Enhancer

A solubility enhancer is a substance added to increase the solubility and dissolution rate of a drug or formulation component.

Examples: - Fumaric acid

❑ Filling capacity of Hard Gelatin Capsule

- The ones most commonly employed for human use range from size 0, the largest, to size 5, the smallest.
- Size 00 capsules may occasionally be required because of the volume of material to be filled, but this size is not used commercially in large volume.
- Hard gelatin capsules are available in various size ranges on the basis of capsule size and volume to be filled as given in Table below:

Table 3.3: Filling capacity of Hard Gelatin Capsule

CAPSULE SIZE		VOLUME (in ml)	WEIGHT (in mg)
000 (Largest)		1.35	950
00		0.95	650
0		0.75	450
1		0.55	300
2		0.40	250
3		0.30	200
4		0.25	150
5 (Smallest)		0.15	100

3.1.2 Difference between Hard and Soft Gelatin Capsules

Table 3.4: Difference between Hard and Soft Gelatin Capsules

PROPERTY	HARD GELATIN CAPSULE	SOFT GELATIN CAPSULE
Definition	Hard gelatin capsules shell consists of two parts namely a body and a cap.	Soft gelatin capsules, also called as soft-gels are sealed hermetically as single piece capsules
Material to be filled	Powder and solid substances	Semi solid and liquid
Shape	Cylindrical	Round, oval and tube-like
Components	Gelatin, titanium dioxide, colouring agent and plasticizers	Gelatin, plasticizers, Preservative, colouring agent, sugar, flavouring agent and opacifying agent
Ratio of plasticizers	0.4:1	0.8:1
Filling and sealing	Hard gelatin capsules are sealed after they are filled to ensure that the medicines do not come out of the capsule due to rough handling	Filling and sealing of soft gelatin capsules are done in a combined operation on machines.
Method of preparation	Auger fill, Vibrator fill, Piston pump, Punch method and Feton capsule filling	Plate process, Rotary die process, Accogel process, Bubble method and The Reciprocating die process
Moisture content	13-16% w/w	6-10% w/w
Disintegration time (min)	30	60



ASSESS YOURSELF



Multiple Choice Questions

1. What is a powder in pharmaceutical terms

- (a) A liquid mixture of various chemicals
- (b) A compressed solid drug
- (c) A suspension of solid particles in a gel
- (d) A finely divided particulate material in dry form

2. Bulk powders for internal use are generally restricted to

- (a) Injectable sterile preparations
- (b) Highly potent drugs requiring accurate dosing
- (c) Hormonal and cytotoxic medications
- (d) Non-potent substances such as laxatives

3. Which of the following is used to introduce the medicated dusting powder into the nose or throat

- (a) Nebulizer
- (b) Insufflator
- (c) Inhaler
- (d) Applicator

4. Dispensing of bulk drugs in large dose can be done as

- (a) Powders
- (b) Ointments
- (c) Gels
- (d) Pastes

5. Which type of powder is used as an antipruritic

- (a) Efflorescent powder
- (b) Hygroscopic powder
- (c) Dusting powder
- (d) Deliquescent powder

6. Method for mixing potent drug powder with large volume of diluent is

- (a) Tumbling
- (b) Geometric dilution
- (c) Sifting
- (d) Levigation

7. Which powder is used for cleaning teeth

- (a) Snuffs
- (b) Dentifrices
- (c) Insufflations
- (d) Effervescent powders

8. Cachets are classified into

- (a) Hard and Soft
- (b) Fine and Coarse
- (c) Dry seal and Wet seal
- (d) Internal and External

Unit IV

Monophasic and Biphasic Liquids Dosage Forms



Syllabus

- **For internal use** – Aromatic waters, syrups, elixirs and linctus (definition and preparation).
- **For external use and body cavities** – Liniments, lotions, throat paints, applications, gargles, mouthwashes, enemas, eye drops, ear drops, nasal drops and tinctures with examples.
- Study of official preparations; introduction to excipients and methods of preparation.
- **Suspensions**- Definition and types (flocculated and deflocculated), advantages and disadvantages, formulation excipients and general methods of preparation.
- **Emulsions**- Definition and types, emulsifying agents, tests for identification of types of emulsions, formulation excipients and general methods of preparation.



MONOPHASIC AND BIPHASIC LIQUIDS DOSAGE FORMS



LEARNING OBJECTIVES

After studying this chapter, the learner will be able to:

- Understand the concept and characteristics of Monophasic Liquid Dosage Forms.
- Classify monophasic liquid dosage forms used for internal and external administration.
- Understand the formulation, preparation, packaging, labeling, storage, uses, advantages, and limitations of Aromatic Waters, Syrups, Elixirs, and Linctuses.
- Understand the formulation, preparation, packaging, labeling, storage, and uses of Throat Paints, Liniments, Lotions, Gargles, and Tinctures.
- Understand the concept, classification, formulation, and pharmaceutical importance of Suspensions.
- Understand the concept, classification, formulation, and pharmaceutical importance of Emulsions.
- Apply appropriate packaging, labeling, and storage requirements for Monophasic and Biphasic Liquid Dosage Forms.

1. MONOPHASIC LIQUID DOSAGE FORMS

1.1 INTRODUCTION TO MONOPHASIC LIQUID DOSAGE FORMS

Monophasic liquid dosage form is homogeneous single phase pharmaceutical preparation consisting of two or more components (solute) dissolved in continuous phase (Solvent). It is represented by the true solution. The component of solution present in larger amount is known as 'solvent' and the component present in relatively smaller proportion is known as 'solute'.

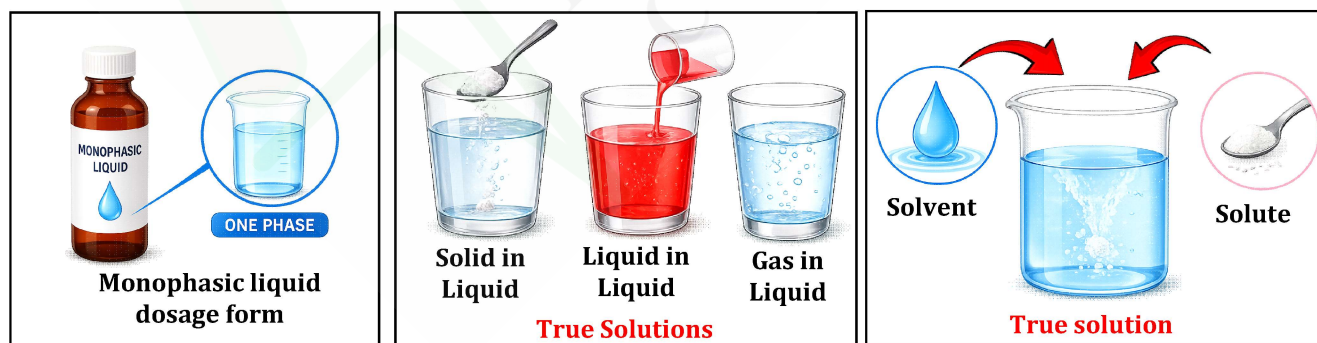


Fig: 1.1: Monophasic Liquid Dosage forms

□ Method of Preparation

Preparation of the syrup depends on the physical and chemical characteristics of the substance employed for its preparation. Four methods are commonly used for preparation of syrups.

1. Agitation without heat

- This method is used for the preparation of syrups containing volatile substances. In this process, the active ingredient is dissolved in the solution and thoroughly agitated in a glass-stoppered bottle. The bottle is kept tightly closed to prevent contamination and loss of volatile substances during preparation.
- This method is commonly used for preparing a wide variety of syrups, especially cough syrups.
- Examples: - Guaifenesin Syrup, Codeine Syrup, Ephedrine Sulfate Syrup

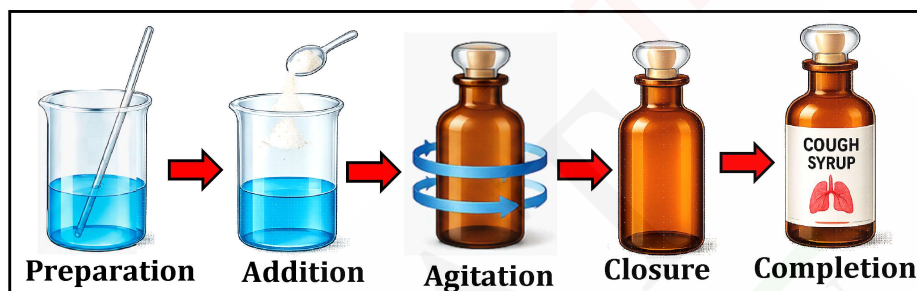


Fig. 1.4: Agitation without heat

2. Solution with heat

- This method is commonly used for preparing syrups when the ingredients are non-volatile and not affected by heat. It is a simple and less time-consuming method.
- In this process, sucrose is added to the aqueous solution and heated until it dissolves completely. The final volume is then adjusted by adding the remaining quantity of distilled water.
- Note: Excessive heating should be avoided because it increases the inversion of sucrose.

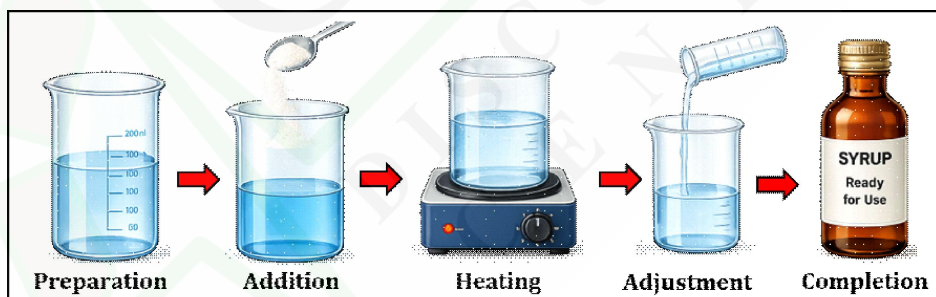


Fig. 1.5: Solution with heat

3. Addition of a medicated liquid

- This method is used when **tinctures, fluid extracts, or other medicated liquids** are added to syrup to prepare a medicated syrup.
- During the process, **precipitation may occur** due to the presence of resinous or oily substances. Therefore, care should be taken to ensure that the medicated substances do not precipitate after mixing.

4. Percolation

- In this method, sucrose is percolated with purified water as a menstrum. The menstrum (it may be purified water or flavoured liquid), is allowed to pass through a column of crystalline sucrose to dissolve it.
- The percolate is collected and repassed repeatedly, until whole amount of sucrose has been dissolved. Finally sufficient purified water is added to make up the final volume.

1. Preparation of Bactericidal/Fungicidal Vehicle

- Eye drops may use aqueous or oily vehicles.
- Preservatives may be added to prevent bacterial and fungal growth.
- The vehicle should be isotonic and non-irritating to the eye.

Table 1.13: Common Preservatives Used

PRESERVATIVES	CONCENTRATION
Phenylmercuric nitrate/acetate	0.002%
Benzalkonium chloride	0.01%
Chlorhexidine acetate	0.01%
Chlorobutol	0.5%
Thiomersal	0.1%

2. Preparation of solution of medicament (s) and adjuvants

- The medicament is dissolved in the prepared vehicle.
- Adjuvants such as buffers, tonicity adjusters, antioxidants, and stabilizers are added.
- The solution is mixed thoroughly to obtain a uniform preparation.

Table 1.14: Adjuvants Used in the Eye Drops

ADJUVANTS	PURPOSE	EXAMPLES
Thickening Agents	• Increase viscosity of eye drops. • Prolong contact time of drug in the eye.	• Methyl cellulose • Carboxymethyl cellulose • Polyvinyl alcohol • Polyethylene glycol
Buffers	• Maintain and adjust pH of eye drops. • Help in stability, comfort, and better therapeutic effect.	• Borate buffer → boric acid + borax • Phosphate buffer → sodium acid phosphate + sodium phosphate • Citrate buffer → citric acid + sodium citrate
Antioxidants	• Protect eye drops from oxidation. • Sometimes air is replaced with inert gas for protection.	• Sodium metabisulphite (0.05–0.5%) • Sodium thiosulphate (0.1–0.2%)
Chelating Agents	• Remove traces of heavy metals. • Also increase preservative activity.	Disodium edetate
Wetting Agents	Help proper penetration into the cornea.	• Polysorbate 20 • Polysorbate 80
Isotonicity Adjusting Agents	• Make eye drops isotonic with lachrymal (tear) fluid. • Buffers and suitable solutions are used for adjustment.	0.9% sodium chloride.

3. Clarification

- Eye drops are filtered through a membrane filter (0.8 µm).
- Clear solution is immediately filled and sealed in containers to avoid contamination.

4. Sterilization

- The eye-drops are sterilized by autoclaving or heating with bactericide at 98° to 100°C for 30 minutes or filtration through bacteria proof filter.

SUSPENSION

2.2 INTRODUCTION TO SUSPENSION

- Pharmaceutical suspensions are biphasic liquid dosage form in which insoluble solids are dispersed in a liquid medium. Finely divided solid particles (0.5–5 μm) are dispersed in a liquid or semisolid vehicle.
- Solid particles constitute as = Dispersed phase (Internal phase)
- Liquid vehicle constitutes as = Continuous phase (External or Dispersion phase)
- Suspensions are used orally, parenterally, and externally.

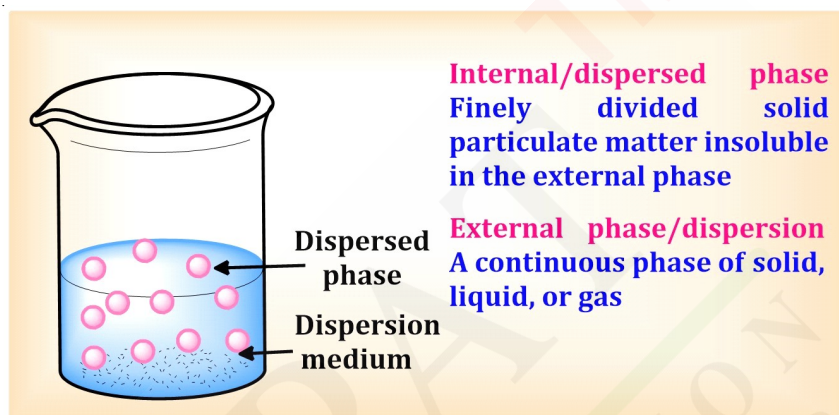


Fig. 2.2 : Suspension

❑ Qualities of a Good Suspension

- Particle settles slowly and uniformly distributed again easily on shaking.
- Pours smoothly and uniformly from the container.
- Should be chemically stable and inert.
- Particles should not form hard cake.
- Should be free from large particles to avoid gritty feel, bad taste, and irritation.

❑ Advantages and Disadvantages of Suspensions

❖ Advantages

- Easy to swallow - Useful for children and elderly patients.
- Suitable for large doses - large amounts of insoluble drugs can be taken easily.
- Better stability - Insoluble drugs are more stable than drugs in solution form.
- Better effectiveness - Finely dispersed particles give faster action and better bioavailability.
- Masks unpleasant taste - Bad taste of drugs is less noticeable.
- Can provide sustained release - Helps in slow and prolonged drug action.
- Useful for insoluble drugs - best liquid dosage form for insoluble drugs.

❖ Disadvantages

- Fine particles may form aggregates or undergo changes during milling.
- Fine powders may adsorb preservatives, requiring higher preservative concentration.
- Sedimentation may cause inaccurate dosing and difficult re-dispersion.
- Drug absorption is slower than from solutions.

❖ Based on Nature of Suspending agent

1. Flocculated suspension

- In a flocculated suspension, the suspended particles are loosely held together to form floccules (aggregates) by weak attractive forces. These floccules settle rapidly but form a loose sediment that is easily redispersed.

➤ Advantages of Flocculated suspensions

- Prevents the formation of hard cake.
- Sediment is easily redispersed by gentle shaking.
- Can provide prolonged or controlled drug release.

➤ Disadvantages of Flocculated suspensions

- Less elegant in appearance because floccules may stick to the container walls.
- Lower bioavailability due to slower drug dissolution and absorption.
- Faster sedimentation rate.

2. Deflocculated Suspensions

In a deflocculated suspension, each suspended particle remains as a separate entity. Sedimentation occurs slowly, but a compact hard cake may form on standing.

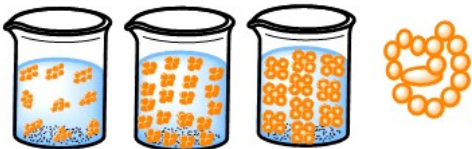
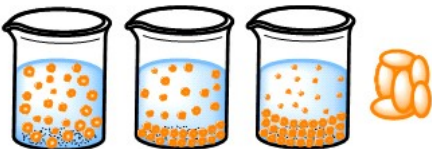
➤ Advantages of Deflocculated Suspensions

- Elegant appearance.
- Slow sedimentation rate.
- Higher bioavailability due to faster dissolution and absorption of individual particles.

➤ Disadvantages of Deflocculated Suspensions

- Forms a hard compact cake on storage.
- Difficult to redisperse even after shaking.
- May result in non-uniform drug distribution and inaccurate dosing.

Table 2.1: Comparison between Flocculated and Deflocculated suspensions

FLOCCULATED SUSPENSION	DEFLOCCULATED SUSPENSION
Particles form loose aggregates and form a network like structure.	Individual particle exists as separate entity
The rate of sedimentation is high	The rate of sedimentation is slow
Sediment is rapidly formed	Sediment is slowly formed.
Sediment is easy to redisperse.	Sediment is difficult to redisperse.
Sediment is loosely packed and does not form a hard cake.	Sediment is very closely packed and a hard cake is formed.
Supernatant liquid is clear	Supernatant liquid is not clear
The floccules stick to the sides of the bottle	The floccules do not stick to the sides of the bottle
Suspension is not pleasing in appearance 	Suspension is pleasing in appearance 

❑ Containers

For Oral Suspensions

- Dispensed in narrow-mouthed clear or amber-colored glass bottles.
- Closed with a metallic screw cap.
- Adequate air space should be left above the liquid for proper shaking.

Suspensions for External Use

- Dispensed in colored, fluted, narrow-mouthed plastic bottles.
- Closed with colored plastic screw caps or hinged lids to distinguish them from internal preparations.

❑ Label

- Along with general requirements of label, suspensions should bear auxiliary label like, "Shake well before use."
- If suspension is meant for external use it should bear, auxiliary label as "For external use only" and "Shake well before use".

❑ Storage

- Store in a **cool place or at room temperature (not exceeding 25°C)**.
- Avoid high temperatures, as viscosity decreases with increasing temperature.
- Do not store at freezing temperatures, as this may cause aggregation of suspended particles.

EMULSION

2.3 INTRODUCTION TO EMULSION

- An emulsion is a biphasic (heterogeneous) liquid preparation containing two immiscible liquids.
- Globule size ranges from **0.1–100 μm** .
One liquid is dispersed as small globules into the other liquid.
- **Dispersed phase (Internal phase)** : Liquid present as globules.
- **Continuous phase (External phase/Dispersion medium)**: Liquid in which globules are dispersed.
- Emulsions are thermodynamically unstable because the two liquids are immiscible and tend to separate on standing. The dispersed droplets may coalesce, leading to phase separation.
- To increase stability, an emulsifying agent is added. It forms a protective film around the dispersed globules, preventing coalescence and keeping the droplets uniformly dispersed.
- **Examples** : - Ferric ammonium citrate emulsion, Castor oil emulsion, Arachis oil emulsion, Turpentine Oil emulsion, Liquid Paraffin Castor oil emulsion, Liquid Paraffin and Phenolphthalein emulsion.

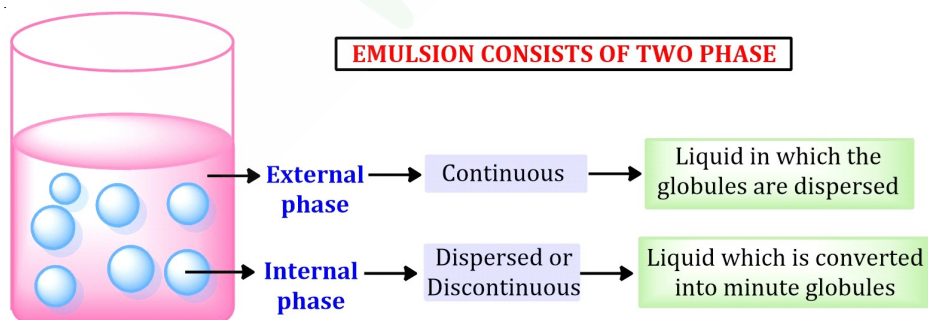


Fig. 2.5: Emulsion

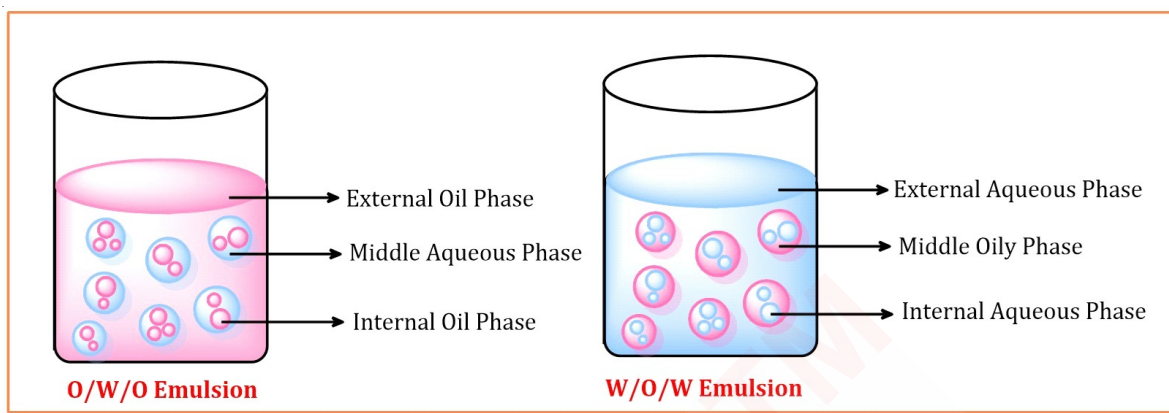


Fig. 2.8: O/W/O and W/O/W Emulsion

(b) Microemulsions

- Microemulsions are clear transparent or translucent dispersions of oil-in-water or water-in-oil.
- They are defined as the dispersions of one insoluble liquid in the other liquid and are often called solubilized systems.
- Both o/w and w/o microemulsions are interconvertible by adding excess of internal phase or by changing the emulsifying agent.
- Micro-emulsions contain globules of the size about, $0.01\ \mu\text{m}$ ($10\ \text{nm}$).

Preparation

- **w/o type:** Oil + emulsifying agent mixed with slight heat, then water added.
- **o/w type:** Oil mixed with emulsifying agent and poured into water with continuous stirring.

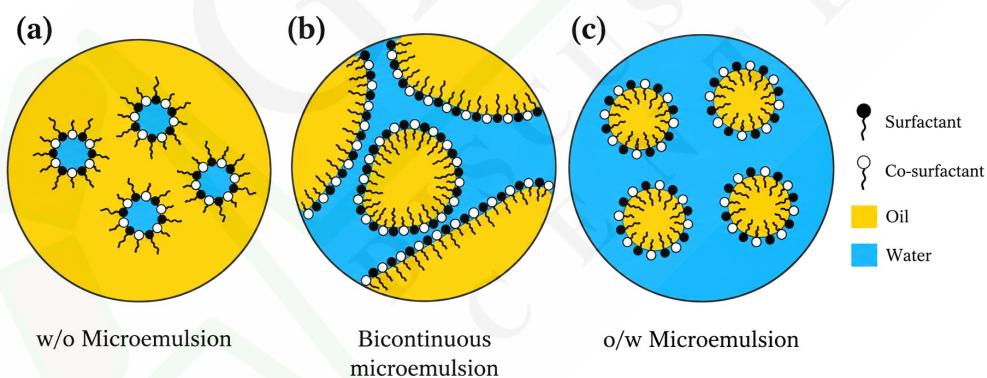


Fig. 2.9: Microemulsion

□ Identification Test for Emulsion

1. Dilution test

- An emulsion can be diluted only with its continuous (external) phase without breaking. If it is diluted with the dispersed (internal) phase, the emulsion becomes unstable and may crack or separate.

a. Oil-in-Water (O/W) Emulsion

- In an O/W emulsion, oil droplets are dispersed in water, and water acts as the external (continuous) phase.
- **Observation:**
When diluted with water, the emulsion remains stable because water is the continuous phase.
When diluted with oil, the emulsion becomes unstable and may crack or separate because oil is the dispersed phase.

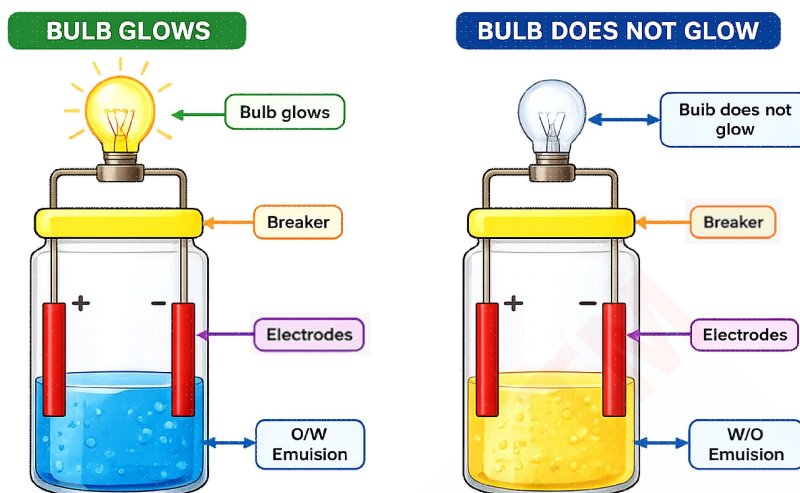


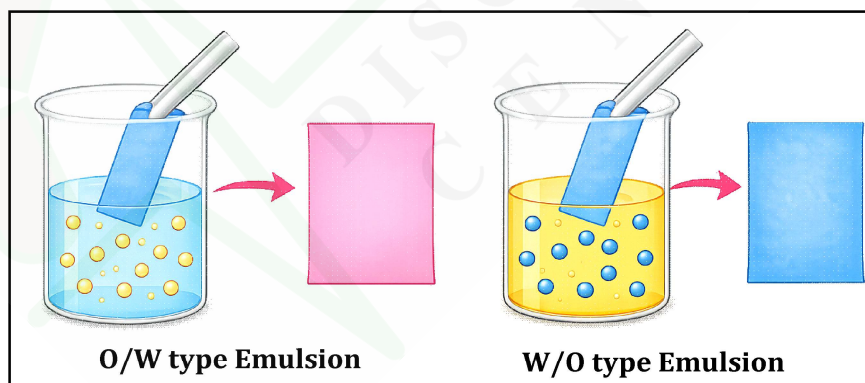
Fig. 2.13: Conductivity test

4. Fluorescence test

- Certain fixed oils possess the physical property of fluorescing in the presence of ultraviolet radiation.
- On microscopic observation of emulsion under ultraviolet radiation, the whole field
 - Fluorescence indicates that oil is present in continuous phase (w/o type emulsion) and droplets
 - Fluorescence indicates that oil is present in disperse phase (o/w type emulsion)

5. Cobalt Filter Paper (CoCl_2) Method

- A dry cobalt filter paper (blue) is immersed in an emulsion.
 - (a) If the paper turns to pinkish colour, then it is said to be o/w type of emulsion.
 - (b) If the paper does not change, then it is w/o type of emulsion.
- This method is not accurate if emulsions are unstable.

Fig. 2.14: Cobalt Filter Paper (CoCl_2) Method

□ Formulation of Emulsion

1. Emulsifying agent

- Emulsifying agents reduce the interfacial tension between the oily phase and aqueous phase, helping them mix together and form a stable emulsion.
- **They are also called:** Emulgers, Emulsifiers
- No single emulsifying agent has all the properties needed for a perfectly stable emulsion. Therefore, two or more emulsifying agents are often used together.

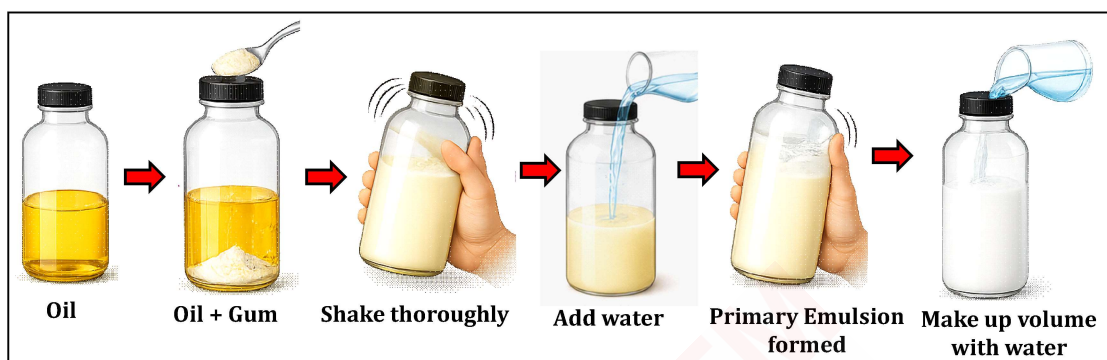


Fig. 2.16 : Bottle method

❖ Other Methods of Preparing Emulsions

- Different homogenizers and blenders are used to prepare emulsions.
- Hand homogenizer
- Silverson mixer homogenizer

1. Hand Homogenizer

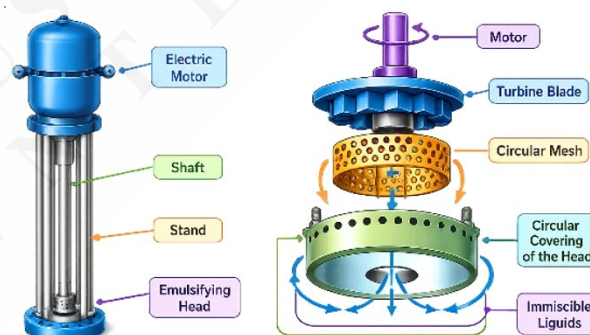
- It is a hand-operated homogenizer used to prepare fine emulsions.
- The coarse emulsion is placed in the hopper of the homogenizer.
- Up-and-down movement of the handle:
 - Draws the emulsion through the inlet valve
 - Forces it through a fine orifice
- Large oil globules break into smaller globules of uniform size, producing a fine emulsion.

2. Silverson Mixer Homogenizer

- It contains an emulsifier head covered with a fine stainless-steel mesh.
- The emulsifier head has rotating blades driven by an electric motor.
- The blades rotate at very high speed and produce strong shearing action.

✓ Working

- The emulsifier head is dipped into immiscible liquids.
- On starting the motor, liquids are sucked through fine holes.
- Rapid blade rotation breaks oil into fine globules.
- Fine emulsion is formed and expelled out.
- Continuous intake and expulsion create a circulation pattern for uniform mixing.



□ Differences between Emulsion and Suspension

Table 2.10: Differences between Emulsion and Suspension

FEATURE	EMULSION	SUSPENSION
Definition	A biphasic liquid preparation containing two immiscible liquids, one dispersed in the other	A biphasic liquid preparation containing insoluble solid particles dispersed in a liquid medium
Dispersed Phase	Liquid	Solid
Continuous Phase	Liquid	Liquid

ANSWER KEY

1-c	2-c	3-b	4-b	5-c	6-a	7-b	8-a	9-c	10-b
11-c	12-b	13-b	14-b	15-c	16-d	17-a	18-a	19-b	20-c
21-b	22-a	23-d	24-c	25-b	26-a	27-c	28-b	29-b	30-c
31-b	32-a	33-b	34-b	35-b	36-a	37-b	38-c	39-b	40-c
41-b	42-a	43-b	44-b	45-c	46-b	47-d	48-b	49-b	50-b

Short answer question

1. Define monophasic liquid dosage forms and discuss their advantages.
2. Discuss the advantages and disadvantages of aromatic waters.
3. Differentiate between syrups and elixirs.
4. Write a short note on linctuses.
5. Define suspensions and discuss their advantages and disadvantages.
6. Explain the characteristics of an ideal suspension.
7. Describe the essential characteristics of ophthalmic preparations (eye drops).
8. Define enemas and discuss their storage conditions.
9. Write a short note on tinctures.
10. Define emulsions with suitable examples and discuss their advantages and disadvantages.
11. Classify emulsifying agents with suitable examples.
12. Discuss the ideal properties of an emulsifying agent.
13. Differentiate between Oil-in-Water (O/W) and Water-in-Oil (W/O) emulsions.
14. Explain the method of preparation of eye drops and discuss the role of preservatives used in ophthalmic formulations.
15. Describe the formulation of elixirs.
16. Write a short note on lotions.
17. Explain the formulation and characteristics of suspensions containing indiffusible solids.
18. Differentiate between flocculated and deflocculated suspensions.
19. Discuss the role of wetting agents and thickening agents in the formulation of suspensions.
20. Differentiate between diffusible and indiffusible solids with suitable examples.

Long answer question

1. Define monophasic liquid dosage forms and explain their classification, advantages, and disadvantages.
2. Define syrups and explain the various methods of syrup preparation with suitable examples.
3. Illustrate the preparation of a pharmaceutical syrup using an appropriate method and justify the selection of ingredients.
4. Define elixirs and explain their formulation, advantages, and disadvantages.
5. Define eye drops and discuss the formulation requirements of ophthalmic solutions.
6. Define emulsions and describe their classification and identification tests.
7. Describe the formulation components and methods used in the preparation of emulsions.
8. Analyze the factors affecting the physical stability of suspensions.
9. Define tinctures and discuss the methods used for their preparation.
10. Differentiate between suspensions and emulsions based on composition, characteristics, and pharmaceutical applications.

Unit V

Semisolid Dosage Forms and Suppositories



Syllabus

- **Definitions, classification, advantages and disadvantages, ointment bases and other excipients used in semisolid dosage forms; general methods of preparation of ointments, pastes, creams and gels.**
- **Suppositories / Pessaries: Definition, types of suppositories, advantages and disadvantages, formulation excipients used in suppositories, properties of ideal suppository bases, types of suppository bases, displacement value and general method of preparation.**



SEMISOLID DOSAGE FORMS AND SUPPOSITORIES



LEARNING OBJECTIVES

After studying this chapter, the learner will be able to:

- Understand the concept of semi-solid dosage forms and suppositories.
- Classify the different types of semi-solid dosage forms.
- Differentiate the characteristics, advantages, and disadvantages of ointments, creams, pastes, gels, and jellies.
- Recognize the formulation ingredients used in semi-solid dosage forms.
- Perform the methods of preparation of ointments, creams, pastes, gels, and suppositories.
- Identify the ideal properties, containers, labeling requirements, and storage conditions of semi-solid dosage forms.
- Classify suppositories and recognize their bases and methods of preparation.

1. SEMISOLID DOSAGE FORMS

1.1 INTRODUCTION TO SEMISOLID DOSAGE FORMS

- Semisolid dosage forms are pharmaceutical preparations with a consistency between solid and liquid, designed primarily for external application on the skin or mucous membranes like the eye, nose, rectum and vagina.
- They produce local or sometimes systemic effects.
- They contain one or more drugs dissolved or uniformly mixed in a suitable base with excipients like emulsifiers, preservatives, antioxidants and stabilizers.



Fig. 1.1: Semisolid Dosage Forms

□ Types of Semisolid Dosage Forms

❖ Ointments

- Greasy, viscous preparations.
- Usually contain less than 20% water.
- Used for protective, emollient or medicinal effects.

□ Classification of Semisolid Dosage Forms

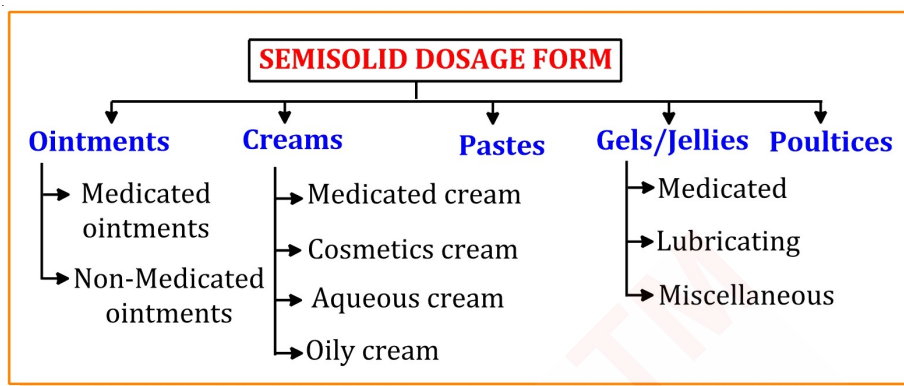


Fig. 1.2: Classification of Semisolid dosage forms

1.1.1 Ointment

- Ointments are the topical semi-solid preparations meant for external application to the skin or mucous membrane to produce local or systemic effect. Ointments usually contain a medicament dissolved, suspended or emulsified in an ointment base. They may contain suitable antimicrobial preservative to avoid microbial contamination. The ointment usually acts as protective or emollient for skin.
- Examples:** - Paraffin ointment B.P.C, Simple ointment B.P., Hydrocarbon ointment Base, Boric acid Ointment, Simple ointment B.P.



□ Types of Ointment

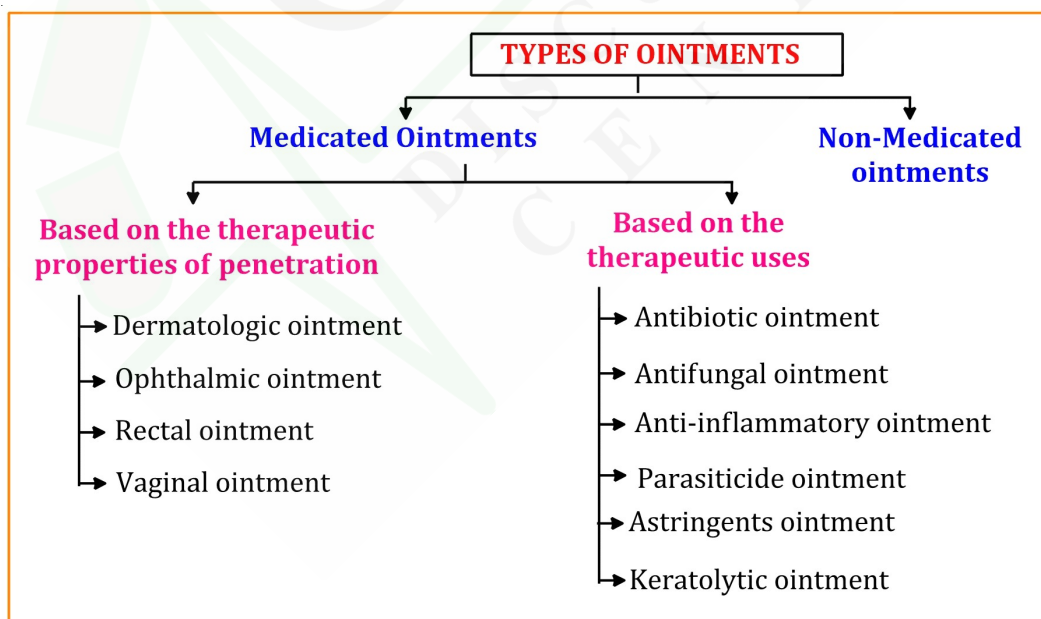


Fig. 1.3: Types of Ointment

1. Medicated Ointment

- Contain drug which show local or systemic effects.

❖ Types of Ointment Base

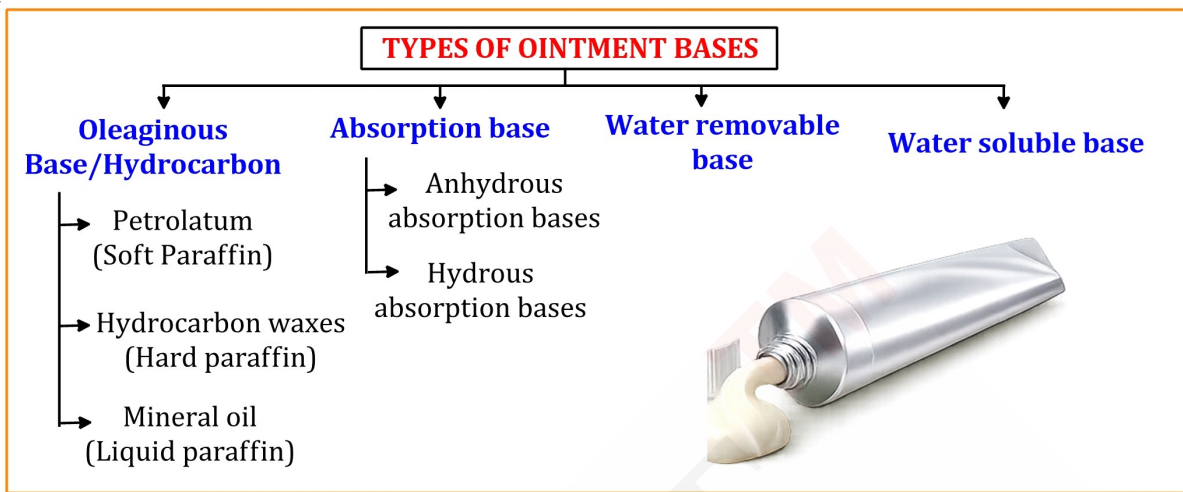


Fig. 1.4: Types of Ointment Bases

1. Oleaginous bases/Hydrocarbon base

- Oleaginous bases are also termed as hydrocarbon bases, on application to the skin they have an emollient and protective effect. It is difficult to remove hydrocarbon bases from skin due to their oily nature. These bases consist of vegetable oils, animal fats and waxes.
- Examples:** - Soft paraffin, Hard paraffin, and Liquid paraffin (mineral oils).

i. Petrolatum (Soft Paraffin)

- It is purified mixture of semi-solid hydrocarbons obtained from petroleum. It is available in two varieties namely, yellow soft paraffin and white soft paraffin. Both of these having melting point between 38-56°C. White soft paraffin is prepared by bleaching yellow paraffin. White soft paraffin is used when medicament is white or colourless. White soft paraffin is never used in the preparation of ophthalmic ointments because the white soft paraffin may contain small traces of bleaching agent which are generally left over after bleaching the yellow soft paraffin. Hence, the white soft paraffin may cause irritation to the eye.



ii. Hydrocarbon Waxes (Hard paraffin)

- Hard paraffin is a purified mixture of solid hydrocarbons obtained from petroleum. It is colourless or white translucent, odour-less, tasteless waxlike substance.
- Hydrocarbon waxes are used in **ointments and creams** to increase viscosity and prevent separation of mineral oil.



➤ Types of Hydrocarbon Waxes

- Paraffin Wax:** Obtained from petroleum; melting point 35–75°C.
- Ozokerite:** Natural mined wax composed of saturated hydrocarbons (C_{35} – C_{55}); melting point 65–75°C.
- Ceresin:** Mixture of **ozokerite and paraffin wax**; melting point depends on paraffin content. Ozokerite and ceresin can retain oils in a matrix structure and prevent **sweating or oozing** of oils.
- Synthetic waxes:** Are prepared from vegetable oils and natural waxes by hydrogenation. They contain long-chain hydrocarbons (C_{18} – C_{36}) and possess thermoplastic and crystalline properties.

4. Slowly add the **aqueous phase to the oily phase** with continuous stirring.
5. Continue stirring during cooling until a **smooth semisolid cream or ointment** is formed.

4. By chemical reaction

- In this method, ointment is prepared by chemical reaction between, the medicament and one or more of ingredients of the base.
- **Examples:** - Non-staining iodine ointment, Strong mercuric nitrate ointment.

❑ Container

- Ointments are dispensed in wide-mouthed glass or plastic jars (ointment jars/squat pots) with airtight screw caps. Nowadays, collapsible tubes are preferred because they reduce bacterial contamination during use. Metallic tubes should be internally coated with a suitable lacquer to prevent interaction between the metal and ointment.

❑ Label

- For External use only.
- Store in a Cool place.
- How to apply the ointment.
- Quantity to be applied.
- Frequency of application.

❑ Storage

- Ointments should be stored in a cool place because high temperatures may cause melting and affect their consistency.

1.1.2 Creams

- Creams are semisolid, viscous preparations containing one or more drugs dissolved or dispersed in a suitable base for external use. They are applied to the skin or mucous membranes. Creams usually contain a water-soluble base, so they can be easily washed off from the skin. They are softer, lighter, and less greasy than ointments and do not leave a visible oily layer on the skin. Creams intended for application on large open wounds should be sterile.
- **Examples:** - Cetriride cream, Zinc and ichthammol cream, Vanishing cream, Shaving cream, cold cream.



❑ Classification of creams

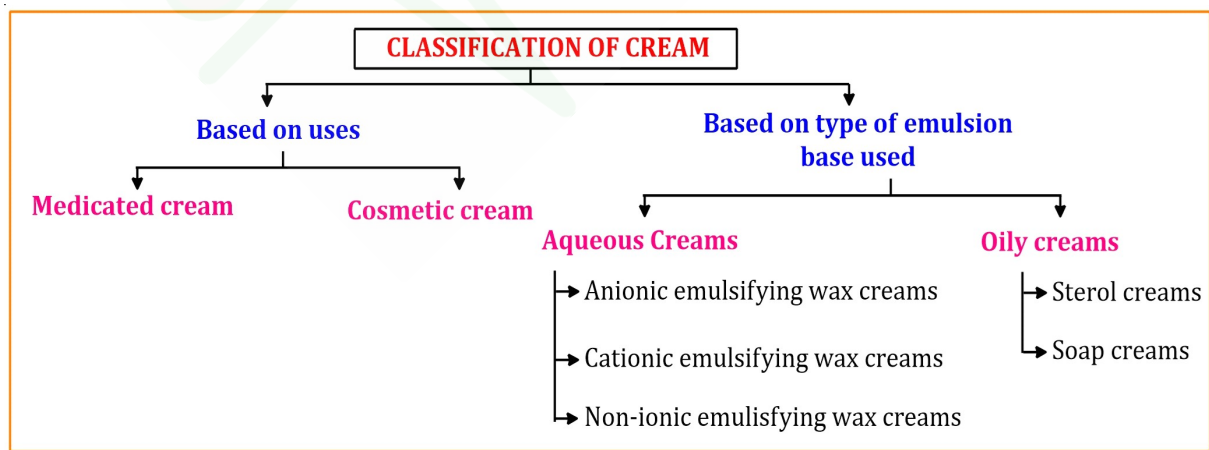


Fig. 1.5: Classification of Creams

3. Add the finely powdered medicament gradually with continuous stirring.
4. Stir until a uniform paste is obtained.
5. Cool, fill into suitable containers, and label.

❑ Container

- Pastes are dispensed in wide mouthed, glass or plastic bottles with tight screw cap with a liner, to prevent evaporation of water, because evaporation of water hardens the paste, which is found very difficult to spread over a lint.
- Now-a-days, paste is dispensed in metallic or plastic collapsible tube, to prevent the microbial contamination and loss of water, by evaporation.

❑ Label

- For External use only,
- Store in a Cool place.

❑ Storage

- Pastes should be stored in a cool temperature, to prevent the evaporation of aqueous phase (water), at higher temperature.

❑ Difference between Pastes and Ointments

Table 1.2: Difference between Pastes and Ointments

PASTES	OINTMENTS
They contain large amount of finely powdered solids such as starch, zinc oxide, calcium carbonate etc.	They contain medicaments which are generally dissolved/suspended/emulsified in the base.
They are very thick and stiff.	They are soft semisolid preparations.
They are less greasy.	They are more greasy.
They are generally applied with a spatula or spread on lint.	They are simply applied on the skin.
They form a protective coating to the area where it is applied.	They are used as protective or emollient for the skin.
Paste contains a large amount of powder which is porous in nature, hence perspiration can escape.	They are used for the protection of lesions.
They are less macerating than ointments.	They are more macerating in action.

1.1.4 Gels (Jellies)

- Jellies are thin, transparent or translucent, non-greasy semisolid preparations intended for external application to the skin or mucous membranes. They are mainly used for medication and lubrication. They are prepared from natural gums or synthetic derivatives of natural substances.
- **Examples:** - Sodium alginate jelly, Sodium carboxy methyl cellulose lubricating jelly, Ichthammol jelly, Compound resorcinol and ichthammol jelly, Ephedrine sulphate jelly.

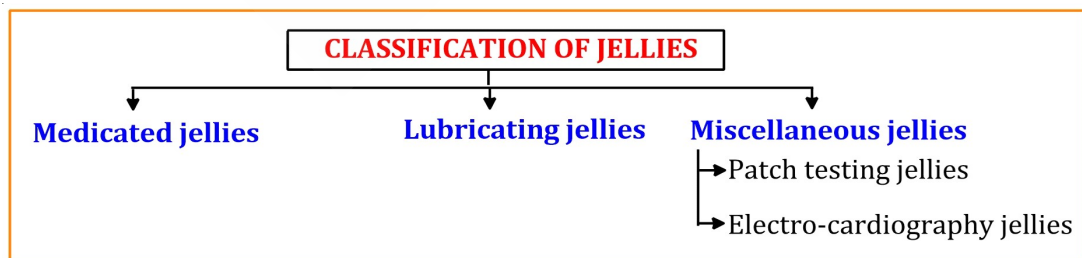


Fig. 1.6: Classification of Jellies

4. Add these ingredients to the hydrated gel with continuous gentle stirring.
5. Avoid vigorous stirring to prevent air entrapment.
6. Transfer the prepared jelly into suitable containers.

❑ Container

- Dispense jellies in well-closed, well-filled, wide-mouth glass containers to prevent water loss.
- Sterile jellies are usually packed in collapsible tubes.

❑ Label

- For external use only.
- Store in a cool place.

❑ Storage

- Store jellies in a cool place and keep the container tightly closed to prevent drying.

2. SUPPOSITORIES

2.1 INTRODUCTION TO SUPPOSITORIES

- Suppositories are medicated solid dosage forms of different shapes and sizes that are inserted into body cavities such as the rectum, vagina, urethra, nose, or ear (except the mouth). After insertion, they melt, dissolve, or disperse to produce local or systemic effects.
- **Examples:** - Boric acid suppository, Chloral hydrate suppository, Phenol suppository, Suppository of Eucalyptus oil, Zinc oxide glycerol gelatin suppository.



❑ Classification of Suppositories

- Suppositories are classified as:

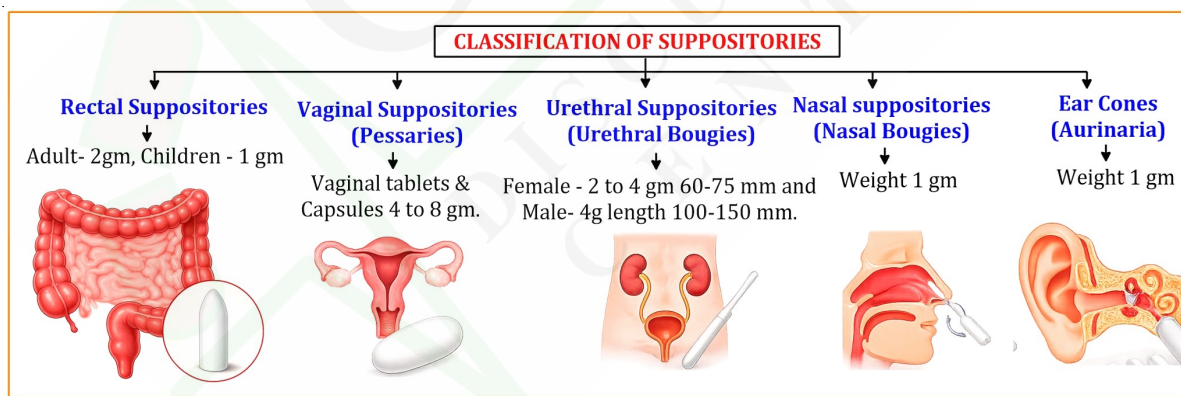


Fig. 2.1: Classification of Suppositories

1. Rectal suppositories

- These are the preparations meant for introduction into the rectum for their local or systemic effect.
- **Shape and size:** Cone, Torpedo shape, Adult- 2gm, Children – 1 gm.

2. Vaginal suppositories (Pessaries)

- They are semisolid bodies meant for introduction into vagina.
- Also known as pessaries and are larger than rectal suppositories.
- **Shape and size :** Rod shaped, wedge shaped, Globular or Oviform, Vaginal tablets & Capsules 4 to 8 gm.

3. Urethral suppositories (Urethral bougies)

- They are meant for introduction into the urethra.
- It is also known as bougies.

Disadvantages

- Slow process; not suitable for large-scale production.
- Air entrapment may occur, causing weight variation and oxidation of the base and drug.

Uses

- Used for small-scale and extemporaneous preparation, especially when the drug is heat-sensitive.

3. Pour molding

- Pour molding is the most commonly used method for preparing suppositories on both small and large scales.

Procedure

1. Melt the suppository base, preferably on a water or steam bath to avoid local overheating.
2. Incorporate the active ingredient by emulsifying or suspending it in the molten base.
3. Pour the medicated mass into cooled chrome- or nickel-plated metal molds.
4. Allow the suppositories to solidify and remove them from the molds.

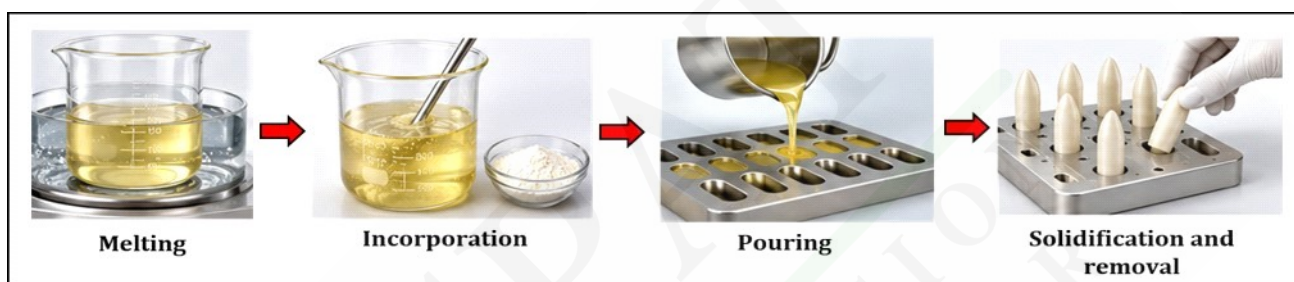


Fig. 2.5: Pour Molding

4. Automatic Molding Machine

An automatic molding machine is used for the continuous, large-scale production of suppositories by automatically performing filling, cooling, ejection, and mold cleaning.

Working

1. The prepared suppository mass is fed into a heated filling hopper and maintained at a constant temperature.
2. Lubricated chrome-plated brass molds are filled with a slight excess of the mass.
3. The filled molds are cooled until the suppositories solidify.
4. Excess material is scraped off and reused.
5. The solidified suppositories are ejected, and the molds are cleaned, lubricated, and reused.

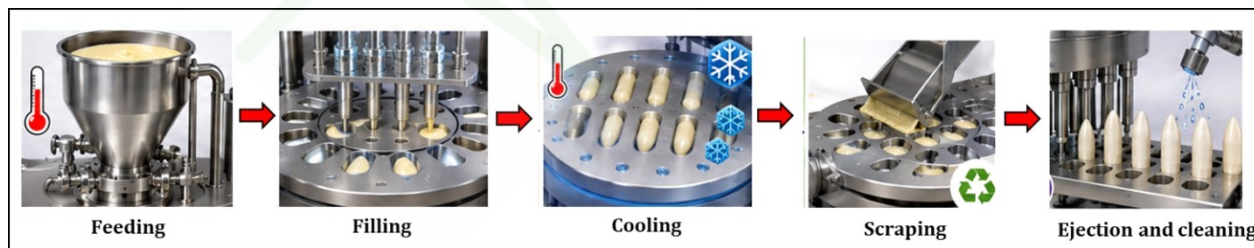


Fig. 2.6: Automatic Molding Machine

Output

- Rotary machine: 3,500–6,000 suppositories/hour.
- Straight-line machine: Up to 10,000 suppositories/hour.

Advantages

- Fully automated and continuous process.

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