

Chapter 1 : Introduction to Pharmacopoeia 1-1 to 1- 27

Syllabus : History of the profession of Pharmacy in India in relation to Pharmacy education, industry, pharmacy practice, and various professional associations. Pharmacy as a career. Pharmacopoeia : Introduction to IP, BP, USP, NF and Extra Pharmacopoeia. Salient features of Indian Pharmacopoeia.

1.0	Glossary.....	1-1
1.1	History of Pharmacy	1-2
1.1.1	Historical Evolution of Profession of Pharmacy	1-2
1.2	History of Profession of Pharmacy in India.....	1-5
1.2.1	History of the Profession of Pharmacy in India in Relation to Pharmacy Education.....	1-5
1.2.2	History of the Profession of Pharmacy in India in Relation to Industry.....	1-6
1.2.3	History of the Profession of Pharmacy in India in Relation to Pharmacy Practice	1-7
1.2.4	History of the Profession of Pharmacy in India in Relation to Various Professional Associations... ..	1-8
1.3	Scope of Pharmacy.....	1-10
1.4	Pharmacy as a Career.....	1-11
1.4.1	Pharmacists in Pharmaceutical Industry.....	1-12
1.4.2	Pharmacists in Pharmacy Practice	1-13
1.4.3	Pharmacist in Pharmacy Education	1-14
1.4.4	Pharmacist in Management (Government).....	1-14
1.4.5	Integrated Pharmacy.....	1-15
1.5	Pharmacopoeias.....	1-15
1.5.1	Indian Pharmacopoeia (IP)	1-16
1.5.2	British Pharmacopoeia (BP)	1-17
1.5.3	United States Pharmacopoeia (USP).....	1-19
1.5.4	National Formulary (NF)	1-20
1.5.5	Introduction to Extra Pharmacopoeia	1-20
1.5.6	Salient Features of Indian Pharmacopoeia.....	1-23
1.5.6(A)	Salient Features of IP 1985 (3rd Edition)	1-23
1.5.6(B)	Salient Features of IP 1996 (4th Edition)	1-23
1.5.6(C)	Salient Features of IP 2014 (7th Edition)	1-24
1.5.6(D)	Salient Features of IP 2018 (8th Edition)	1-25

Chapter 2 : Packaging Materials**2-1 to 2-10**

Syllabus : Types, selection criteria, advantages and disadvantages of glass, plastic, metal, rubber as packaging materials.

2.0	Glossary	2-1
2.1	Introduction to Packaging Materials	2-1
2.1.1	Selection Criteria of Packaging Materials.....	2-1
2.2	Containers.....	2-2
2.2.1	Classification of Containers.....	2-2
2.2.2	Ideal Properties of Good Container.....	2-3
2.2.3	Selection Criteria of Containers	2-3
2.2.4	Levels of Packaging of Containers	2-3
2.2.5	Materials Used for the Construction of Containers	2-4
2.2.5(A)	Glass.....	2-4
2.2.5(B)	Plastic.....	2-5
2.2.5(C)	Metals.....	2-6
2.2.5(D)	Paper and Board.....	2-7
2.3	Closures.....	2-7
2.3.1	Functions of Closures	2-7
2.3.2	Types of Closures	2-7
2.3.3	Materials used for the Construction of Closures	2-8
2.4	Liners (Closure Liners)	2-8
2.4.1	Types of Liners	2-8
2.4.2	Selection Criteria of Closure Liner.....	2-9
2.5	Rubber as Packaging Material	2-9
2.5.1	Types of Rubber.....	2-9

Chapter 3 : Pharmaceutical Aids**3-1 to 3-11**

Syllabus : Organoleptic (Colouring, flavouring, and sweetening) agents, Preservatives - Definition, types with examples and uses

3.0	Glossary	3-1
3.1	Introduction to Pharmaceutical Aids	3-1
3.1.1	Classification of Pharmaceutical Aids	3-1
3.2	Organoleptic Agents	3-4
3.2.1	Coloring Agents.....	3-4

3.2.1(A) Classification of Colouring Agents	3-4	4.1.2 Applications of Size Reduction	4-2
3.2.1(B) Criteria for Selection of Colouring Agents.....	3-5	4.1.3 Factors Affecting Size Reduction	4-3
3.2.1(C) Applications of Colouring Agents	3-5	4.1.4 Mechanism of Size Reduction	4-3
3.2.1(D) List of Colouring Agents used in Pharmaceutical Industry	3-5	4.1.5 Equipments Used for Size Reduction	4-4
3.2.2 Flavoring Agents.....	3-5	4.1.5(A) Hammer Mill.....	4-4
3.2.2(A) Classification of Flavouring Agents	3-6	4.1.5(B) Ball Mill	4-5
3.2.2(B) Criteria for Selection of Flavouring Agents	3-6	4.2 Size Separation.....	4-7
3.2.2(C) Applications of Flavouring Agents.....	3-7	4.2.1 Objectives.....	4-7
3.2.2(D) List of Flavouring Agents used in pharmaceutical Industry	3-7	4.2.2 Applications of Size Separation.....	4-7
3.2.3 Sweetening Agents	3-7	4.2.3 Factors Affecting Size Separation.....	4-7
3.2.3(A) Classification of Sweetening Agents.....	3-7	4.2.4 Classification of Powders According to Indian Pharmacopoeia	4-7
3.2.3(B) Criteria for Selection of Sweetening Agents.....	3-8	4.2.5 Principles of Mechanical Size Separation.....	4-8
3.2.3(C) Applications of Sweetening Agents	3-8	4.2.6 Equipments Used for Size Separation	4-9
3.2.3(D) List of Sweetening Agents used in Pharmaceutical Industry	3-9	4.2.6(A) Cyclone Separator	4-9
3.3 Pharmaceutical Preservatives	3-9	4.2.6(B) Sieves	4-10
3.3.1 Classification of Preservatives	3-9	4.3 Mixing	4-12
3.3.1(A) Based on the Mechanism of Action.....	3-9	4.3.1 Objectives.....	4-12
3.3.1(B) Based on the Source.....	3-10	4.3.2 Applications of Mixing	4-12
3.3.2 Applications of Preservatives.....	3-10	4.3.3 Types of Mixtures.....	4-12
Chapter 4 : Unit Operations 4-1 to 4-44		4.3.4 Mechanisms of Mixing	4-12
<p>Syllabus : Definition, objectives or applications, principles, construction and workings of :</p> <p>Size reduction : Hammer mill and ball mill</p> <p>Size separation : Classification powder according to I.P., Cyclone separator, Sieves and standards of sieves</p> <p>Mixing : Double cone blender, Turbine mixer, Triple roller mill and Silverson mixer homogenizer</p> <p>Filtration : Theory of filtration, membrane filter and sintered glass filter</p> <p>Drying : Working of fluidized bed dryer and process of freeze drying</p> <p>Extraction : Definition, Classification, method and applications</p>		4.3.5 Mixing of States of Matter	4-13
		4.3.6 Equipments Used for Mixing	4-14
		4.3.6(A) Double Cone Blender.....	4-14
		4.3.6(B) Turbine Mixer	4-15
		4.3.6(C) Triple Roller Mill	4-16
		4.3.6(D) Silverson Mixer Homogenizer.....	4-17
		4.4 Filtration.....	4-18
		4.4.1 Objectives.....	4-18
		4.4.2 Applications of Filtration	4-19
		4.4.3 Theory of Filtration	4-19
		4.4.4 Factors Affecting Filtration	4-19
		4.4.5 Mechanism of Filtration.....	4-20
		4.4.6 Types of Filtration	4-20
		4.4.7 Filter Media.....	4-21
		4.4.7(A) Characteristics of an Ideal Filter Media	4-21
4.4.7(B) Types of Filter Media.....	4-21		
4.4.8 Filter Aids.....	4-25		
4.0 Glossary.....	4-1		
4.1 Size Reduction	4-2		
4.1.1 Objectives.....	4-2		

4.4.9	Clarification and Filtration	4-26
4.5	Drying	4-26
4.5.1	Objectives	4-26
4.5.2	Applications of Drying	4-27
4.5.3	Theory of Drying	4-27
4.5.4	Factors Affecting Drying Process	4-28
4.5.5	Categories of Drying	4-29
4.5.6	Equipments Used in Drying	4-30
4.5.6(A)	Fluidized Bed Dryer	4-30
4.5.6(B)	Freeze Drying	4-31
4.6	Extraction	4-33
4.6.2	Objectives	4-33
4.6.3	Applications of Extraction	4-33
4.6.4	Factors Affecting the Extraction Process	4-34
4.6.5	Classification of Extraction Process	4-34
4.6.6	Methods of Extraction	4-36

Chapter 5 : Tablets **5-1 to 5-22**

Syllabus : Coated and uncoated, various modified tablets (sustained release, extended-release, fast dissolving, multi-layered etc.

5.0	Glossary	5-1
5.1	Tablets	5-1
5.1.1	Definition	5-1
5.1.2	Classification of Tablets	5-1
5.1.2(A)	Tablets Ingested Orally	5-2
5.1.2(B)	Tablets used in Oral Cavity	5-4
5.1.2(C)	Tablets Administered by Other Routes	5-4
5.1.2(D)	Tablets used for Solution	5-5
5.1.3	Tablet Ingredients or Adjuvant (Excipients or Additives)	5-5
5.1.4	Ideal Characteristics of Tablets	5-7
5.1.5	Advantages of Tablets	5-7
5.1.6	Disadvantages of Tablets	5-7
5.2	Granulation Techniques	5-8
5.2.1	Wet Granulation	5-8
5.2.2	Dry Granulation	5-10
5.2.3	Direct Compression Method	5-12
5.3	Coating of Tablets	5-14

5.4	Tablet Machines (Tablet Punching or Compression)	5-15
5.4.1	Single Punch Machine	5-15
5.4.2	Multi-station Rotary Tablet Machine	5-16
5.5	Manufacturing Defects in Tablets	5-17
5.6	Evaluation of Tablets	5-19

Chapter 6 : Capsules **6-1 to 6-14**

Syllabus : Hard and soft gelatin capsules

6.0	Glossary	6-1
6.1	Capsules	6-1
6.1.1	Definition	6-1
6.1.2	Advantages of Capsules	6-1
6.1.3	Disadvantages of Capsules	6-2
6.1.4	Composition of Gelatin	6-2
6.2	Types of Capsules	6-2
6.2.1	Hard Gelatin Capsules	6-2
6.2.1(A)	Manufacturing of Hard Gelatin Capsules	6-3
6.2.1(B)	Methods of Filling the Hard Gelatin Capsules	6-4
6.2.1(C)	Excipients used in formulation of Hard Gelatin Capsules	6-6
6.2.1(D)	Advantages of Hard Gelatin Capsules	6-7
6.2.1(E)	Disadvantages of Hard Gelatin Capsules	6-7
6.2.1(F)	Applications of Hard Gelatin Capsules	6-7
6.2.1(G)	Storage of Hard Gelatin Capsules	6-7
6.2.2	Soft Gelatin Capsules	6-8
6.2.2(A)	Manufacture of Soft Gelatin Capsules	6-8
6.2.2(B)	Advantages of Soft Gelatin Capsules	6-9
6.2.2(C)	Disadvantages of Soft Gelatin Capsules	6-10
6.2.2(D)	Applications of Soft Gelatin Capsules	6-10
6.2.2(E)	Difference between Hard Gelatin Capsules and Soft Gelatin Capsules	6-10
6.3	Quality Control Tests for Capsules	6-11
6.4	Packaging and Storage of Capsules	6-12
6.5	Special Applications of Capsules	6-12

Chapter 7 : Liquid Oral Preparations **7-1 to 7-23**

Syllabus : Solution, syrup, elixir, emulsion, suspension, dry powder for reconstitution

7.0	Glossary.....	7-1	7.5.6	Identification Tests for Different Types of Emulsions	7-11
7.1	Liquid Oral Preparations	7-1	7.5.7	Instabilities in Emulsions.....	7-13
7.2	Solutions	7-1	7.5.8	Ideal Properties of Emulsion.....	7-14
7.2.1	Definition.....	7-1	7.5.9	Evaluation of Emulsions	7-14
7.2.2	Method of Preparation	7-1	7.5.10	Advantages of Emulsion	7-14
7.2.3	Formulation Ingredients of Solution	7-2	7.5.11	Disadvantages of Emulsion	7-14
7.2.4	Formulations of Solutions.....	7-2	7.5.12	Applications of Emulsions	7-14
7.2.5	Advantages of Solutions.....	7-2	7.6	Suspension	7-15
7.2.6	Disadvantages of Solutions.....	7-2	7.6.1	Definition	7-15
7.2.7	Applications of Solutions.....	7-3	7.6.2	Purpose of Suspension	7-15
7.3	Syrups	7-3	7.6.3	Type of Suspension	7-15
7.3.1	Definition.....	7-3	7.6.4	Classification of Suspensions	7-16
7.3.2	Classification of Syrups	7-3	7.6.5	Preparation of Suspensions	7-16
7.3.3	Ideal Characteristics of Syrups	7-3	7.6.6	Formulation Ingredients of Suspensions	7-17
7.3.4	Method of Preparation	7-4	7.6.7	Formulations of Suspensions	7-18
7.3.5	Formulation Ingredients of Syrup.....	7-4	7.6.8	Stability of Suspensions	7-18
7.3.6	Formulations of Syrup	7-5	7.6.9	Ideal Properties of Pharmaceutical Suspension ...	7-19
7.3.7	Advantages of Syrups.....	7-5	7.6.10	Advantages of Suspensions.....	7-19
7.3.8	Disadvantages of Syrups.....	7-5	7.6.11	Disadvantages of Suspensions.....	7-19
7.3.9	Applications of Syrups.....	7-5	7.6.12	Applications of Pharmaceutical Suspensions.....	7-19
7.4	Elixirs	7-6	7.7	Dry Powder for Reconstitution	7-20
7.4.1	Definition.....	7-6	7.7.1	Definition	7-20
7.4.2	Types of Elixirs	7-6	7.7.2	Dry Powder for Reconstitution is formulated to Overcome.....	7-20
7.4.3	Method of Preparation	7-6	7.7.3	Types of Dry Powder for Reconstitution.....	7-21
7.4.4	Formulation Ingredients of Elixirs.....	7-6	7.7.4	Ideal Properties of Dry Powder	7-21
7.4.5	Formulations of Elixir	7-7	7.7.5	Formulation Ingredients of Dry Powder	7-21
7.4.6	Advantages of Elixirs.....	7-7	7.7.6	Method of Preparation	7-22
7.4.7	Disadvantages of Elixirs.....	7-7	7.7.7	Preparation of Dry Powder for Reconstitution	7-22
7.4.8	Difference between Syrup and Elixir.....	7-7	7.7.8	Advantages of Dry Powder.....	7-22
7.5	Emulsions.....	7-8	7.7.9	Disadvantages of Dry Powder	7-22
7.5.1	Definition.....	7-8	7.7.10	Applications of Dry Powder	7-22
7.5.2	Types of Emulsion.....	7-8	<hr/>		
7.5.3	Classification of Emulsions	7-9	Chapter 8 : Topical Preparations 8-1 to 8-30		
7.5.3(A)	Emulsifying Agent.....	7-9	Syllabus : Ointments, creams, pastes, gels, liniments and lotions, suppositories and pessaries		
7.5.3(B)	Classification of Emulsifying Agents.....	7-10			
7.5.3(C)	Ideal Properties of Emulsifying Agent.....	7-10			
7.5.4	Method of Preparation of Emulsions.....	7-10	8.0	Glossary	8-1
7.5.5	Formulations of Emulsions.....	7-11			

8.1	Topical Preparations.....	8-1	8.4.5	Preparation of Paste.....	8-14
8.1.1	Structure of Skin.....	8-2	8.4.6	General Excipients used in the Preparation of Paste.....	8-14
8.1.2	Drug Absorption through the Skin.....	8-3	8.4.7	Formulations of Paste.....	8-15
8.1.3	Factors Affecting the Drug Absorption through Skin.....	8-3	8.4.8	Advantages of Paste.....	8-15
8.1.4	Excipients used in the Preparation of Topical Preparations.....	8-3	8.4.9	Disadvantages of Paste.....	8-16
8.2	Ointments.....	8-4	8.4.10	Applications of Paste.....	8-16
8.2.1	Definition.....	8-4	8.4.11	Difference between Pastes and Ointments.....	8-16
8.2.2	Ideal Properties of Ointments.....	8-4	8.5	Gels.....	8-16
8.2.3	Types of Ointments.....	8-4	8.5.1	Definition.....	8-16
8.2.4	Ointment Bases.....	8-4	8.5.2	Ideal Properties of Gel.....	8-16
8.2.4(A)	Classification of Ointment Bases.....	8-5	8.5.3	Types of Gel.....	8-17
8.2.5	Method of Preparation of Ointments.....	8-7	8.5.4	Preparation of Gel.....	8-17
8.2.6	Advantages of Ointments.....	8-10	8.5.5	General Ingredients used in the Preparation of Gel.....	8-17
8.2.7	Disadvantages of Ointments.....	8-10	8.5.6	Formulations of Gel.....	8-18
8.2.8	Applications of Ointments.....	8-10	8.5.7	Advantages of Gel.....	8-18
8.3	Creams.....	8-10	8.5.8	Disadvantages of Gel.....	8-18
8.3.1	Definition.....	8-10	8.5.9	Applications of Gel.....	8-18
8.3.2	Ideal Properties of Creams.....	8-10	8.6	Liniments.....	8-19
8.3.3	Types of Cream.....	8-11	8.6.1	Definition.....	8-19
8.3.4	Method of Preparation of Creams.....	8-11	8.6.2	Ideal Properties of Liniments.....	8-19
8.3.5	Common Excipients used in the Preparation of Creams.....	8-11	8.6.3	Types of Liniment.....	8-19
8.3.6	Formulations of Cream.....	8-12	8.6.4	Preparation of Liniment.....	8-19
8.3.7	Evaluation of Cream.....	8-12	8.6.5	Formulations of Liniment.....	8-19
8.3.8	Advantages of Cream.....	8-13	8.6.6	Advantages of Liniment.....	8-20
8.3.9	Disadvantages of Cream.....	8-13	8.6.7	Disadvantages of Liniment.....	8-20
8.3.10	Applications of Cream.....	8-13	8.6.8	Applications of Liniment.....	8-20
8.3.11	Difference between Creams and Ointments.....	8-13	8.7	Lotions.....	8-21
8.4	Pastes.....	8-13	8.7.1	Definition.....	8-21
8.4.1	Definition.....	8-14	8.7.2	Ideal Properties of Lotion.....	8-21
8.4.2	Ideal Properties of Pastes.....	8-14	8.7.3	Types of Lotion.....	8-21
8.4.3	Types of Paste.....	8-14	8.7.4	Preparation of Lotion.....	8-21
8.4.4	Types of Bases used in the Preparation of Paste.....	8-14	8.7.5	Excipients used in the Preparation of Lotion.....	8-21

8.7.6	Formulations of Lotion.....	8-22
8.7.7	Evaluation of Lotion.....	8-23
8.7.8	Advantages of Lotion.....	8-23
8.7.9	Disadvantages of Lotion.....	8-23
8.7.10	Applications of Lotion.....	8-23
8.7.11	Difference between Lotions and Liniments.....	8-23
8.8	Suppositories and Pessaries.....	8-23
8.8.1	Definition.....	8-24
8.8.2	Classification of Suppositories.....	8-24
8.8.3	Types of Suppository Bases.....	8-25
8.8.4	Preparation of Suppositories.....	8-25
8.8.5	Formulation of Boric Acid Suppository.....	8-26
8.8.6	Ideal Characteristics of Suppository Base.....	8-27
8.8.7	Displacement Value.....	8-27
8.8.8	Advantages of Suppositories.....	8-28
8.8.9	Disadvantages of Suppositories.....	8-28
8.8.10	Applications of Suppositories.....	8-28
8.8.11	Packing and Storage.....	8-28
8.8.12	Evaluation of Suppositories.....	8-29

Chapter 9 : Nasal and Ear Preparations 9-1 to 9-14

Syllabus : Nasal preparations, ear preparations

9.0	Glossary.....	9-1
9.1	Nasal Preparations.....	9-1
9.1.1	Definition.....	9-1
9.1.2	Anatomy and Physiology of Nasal Cavity.....	9-2
9.1.3	Mechanism of Drug Absorption through Nasal Cavity.....	9-3
9.1.4	Nasal Preparations.....	9-4
9.1.4(A)	Liquid Nasal Preparations.....	9-4
9.1.4(B)	Powder Nasal Preparations.....	9-5
9.1.4 (C)	Nasal Pressurized Metered Inhalers.....	9-6
9.1.4 (D)	Nasal Gels.....	9-6
9.1.4 (E)	Nasal Vaccines.....	9-7

9.1.5	General Formulation Additives for Nasal Preparations.....	9-7
9.1.6	Advantages of Nasal Preparations.....	9-8
9.1.7	Disadvantages of Nasal Preparations.....	9-8
9.1.8	Applications of nasal Preparations.....	9-8
9.2	Ear Preparations.....	9-8
9.2.1	Definition.....	9-8
9.2.2	Anatomy and Physiology of Ear.....	9-8
9.2.3	Mechanism of Drug Absorption through Ear.....	9-10
9.2.4	Ear Preparations.....	9-10
9.2.4(A)	Ear Solutions.....	9-10
9.2.4(B)	Ear Suspensions.....	9-11
9.2.4(C)	Ear Powders.....	9-11
9.2.5	General Formulation Additives of Ear Preparations.....	9-12
9.2.6	Advantages of Ear Preparations.....	9-12
9.2.7	Disadvantages of Ear Preparations.....	9-12
9.2.8	Applications of Ear Preparations.....	9-13

Chapter 10 : Powders and Granules 10-1 to 10-12

Syllabus : Insufflations, dusting powders, effervescent powders and effervescent granules

10.0	Glossary.....	10-1
10.1	Powders and Granules.....	10-1
10.1.1	Definition.....	10-2
10.1.2	Classification of Powders.....	10-2
10.1.2	Methods of Preparation.....	10-5
10.1.3	Geometric Dilution.....	10-6
10.1.4	Packing of Powders.....	10-6
10.2	Powders and Granules Preparations.....	10-7
10.2.1	Insufflations.....	10-7
10.2.2	Dusting Powders.....	10-7
10.2.3	Effervescent Powders.....	10-8
10.2.4	Effervescent Granules.....	10-8
10.2.5	Dentifrices.....	10-10
10.2.6	Advantages of Powders and Granules.....	10-10

10.2.7	Disadvantages of Powder and Granules	10-10
10.2.8	Applications of Powder and Granules.....	10-10
10.2.9	Advantage of Granules over Powders.....	10-11

Chapter 11 : Sterile Formulations 11-1 to 11-18

Syllabus : Injectables, eye drops and eye ointments		
11.0	Glossary	11-1
11.2	Introduction	11-1
11.2.1	Classification of Sterile Formulations.....	11-2
11.2.2	Ideal characteristics of Sterile Formulations	11-2
11.2.3	Advantages of Sterile Formulations	11-2
11.2.4	Disadvantages of Sterile Formulations	11-3
11.2.5	Applications of Sterile Formulations.....	11-3
11.2.6	Processing of Sterile Formulations	11-3
11.3	Injectables	11-3
11.3.1	Definition	11-3
11.3.2	Advantages of Injectables.....	11-3
11.3.3	Disadvantages of Injectables.....	11-3
11.3.4	Types of Presentation of Injections	11-4
11.3.5	Routes of Administration of Injections	11-5
11.3.6	Excipients used in Injection Formulations.....	11-6
11.3.7	Water for Injection I.P (WFI)	11-7
11.3.8	Difference between water for injection and purified water	11-8
11.3.9	Injection Preparations.....	11-8
11.3.10	Quality Control Tests for Injections.....	11-9
11.4	Ophthalmic or Ocular Drug Delivery.....	11-11
11.4.1	Anatomy and Physiology of Eye	11-11
11.4.2	Ophthalmic Dosage Forms	11-12
11.4.3	Routes of Drug Administration to Eye.....	11-13
11.4.4	Excipients used in Ophthalmic Preparations	11-13
11.4.5	Advantages and Disadvantages of Ophthalmic Dosage Disadvantages.....	11-15
11.4.6	Eye Drops.....	11-15
11.4.7	Eye Ointment	11-17
11.4.8	Packaging.....	11-17
11.4.9	Labelling.....	11-17

Chapter 12 : Immunological Products 12-1 to 12-22

Syllabus : Sera, vaccines, toxoids and their manufacturing methods		
12.0	Glossary.....	12-1
12.1	Introduction	12-1
12.1.1	Immunity	12-2
12.1.2	Types of Immunity	12-3
12.1.2(A)	Innate / Non-Adaptive Immunity	12-3
12.1.2(B)	Acquired or Adaptive Immunity	12-4
12.2	Immunological Products	12-5
12.2.1	Definition.....	12-5
12.2.2	Characteristics of Immunological Products.....	12-5
12.2.3	Factors Affecting Immunological Products.....	12-5
12.2.4	Advantages of Immunological Products.....	12-5
12.2.5	Disadvantages of Immunological Products.....	12-5
12.2.6	Applications of Immunological Products.....	12-5
12.3	Classification of Immunological Products	12-6
12.4	Preparations Producing Active Immunity.....	12-7
12.4.1	Vaccine.....	12-7
12.4.2	Types of Vaccines	12-7
12.4.3	General Method of Preparation of Bacterial Vaccine.....	12-9
12.4.4	General Method of Preparation of Viral Vaccine	12-10
12.4.4(A)	Preparation of Living Bacterial Vaccine.....	12-10
12.4.4(B)	Preparation of Killed Bacterial Vaccine.....	12-11
12.4.4(C)	Preparation of Living Virus Vaccine.....	12-13
12.4.4(D)	Preparation of Living/Killed/Subunit Bacterial Vaccine.....	12-14
12.4.4(E)	Preparation of Typhus Vaccine (Killed Rickettsia).....	12-15
12.4.4(F)	Preparation of vaccine containing toxoid.....	12-15
12.5	Preparations Producing Passive Immunity	12-17
12.5.1	Preparation of Diphtheria Vaccine (Antitoxin).....	12-17
12.6	Diagnostic Preparations.....	12-18
12.6.1	Diagnostic Preparations containing Bacterial Toxins.....	12-18

12.6.2	Sera.....	12-19
12.6.3	Difference between Vaccine and Sera	12-20
12.6.4	Difference between Exotoxin and Endotoxin ...	12-20
12.7	Storage of Immunological Products.....	12-21

Chapter 13 : Pharmaceutical Mfg. Plants & Concept of QC & QA 13-1 to 13-40

Syllabus : Basic structure, layout, sections and activities of pharmaceutical manufacturing plants, Quality control and quality assurance : Definition and concepts of quality control and quality assurance, current good manufacturing practice (cGMP), Introduction to concept of calibration and validation

13.0	Glossary	13-1
13.1	Pharmaceutical Plant Layout	13-2
13.1.1	Characteristics of a Good Pharmaceutical Plant	13-2
13.1.2	Factors Influencing Pharmaceutical Plant Layout.....	13-2
13.2	Tablet Manufacturing Plant.....	13-3
13.2.1	Structure of Tablet Manufacturing Plant.....	13-3
13.2.2	Layout of Tablet Manufacturing Plant.....	13-4
13.2.3	Sections and Activities	13-7
13.3	Capsule Manufacturing Plant.....	13-12
13.3.1	Structure of Capsule Manufacturing Plant	13-12
13.3.2	Layout of Capsule Manufacturing Plant.....	13-13
13.3.3	Sections and Activities	13-14
13.4	Sterile Manufacturing Plant (Injection).....	13-17
13.4.1	Structure of Sterile Manufacturing Plant.....	13-17
13.4.2	Layout of Sterile Manufacturing Plant (Injection).....	13-18
13.4.3	Sections and Activities	13-19
13.5	Quality Control (QC) and Quality Assurance (QA).....	13-22
13.5.1	Quality Control (QC).....	13-23
13.5.2	Quality Assurance (QA)	13-24

13.5.3	Difference between Quality Control and Quality Assurance	13-26
13.6	Current Good Manufacturing Practice (cGMP)	13-26
13.6.1	Why cGMP is Important?	13-27
13.6.2	Significance of cGMP	13-27
13.6.3	Basic Components of cGMP	13-27
13.7	Introduction to Calibration.....	13-34
13.7.1	Definition.....	13-34
13.7.2	Concept of Calibration.....	13-34
13.7.3	Basic Requirements for a Calibration.....	13-35
13.7.4	Parameters to be determined to check the Performance.....	13-35
13.8	Introduction to Validation.....	13-36
13.8.1	Definition.....	13-36
13.8.2	Concept of Validation	13-36
13.8.3	Characteristics of Validation	13-36
13.8.4	Concept of Qualification.....	13-37
13.8.5	Difference between Calibration and Validation.....	13-38

Chapter 14 : Novel Drug Delivery Systems 14-1 to 14-9

Syllabus : Introduction, Classification with examples, advantages and challenges

14.0	Glossary.....	14-1
14.1	Introduction to Drug Delivery System (DDS)	14-1
14.2	Novel Drug Delivery Systems (NDDS).....	14-1
14.2.1	Classification of NDDS.....	14-2
14.2.1(A)	Rate Pre-programmed DDS.....	14-3
14.2.1(B)	Activation-modulated DDS	14-4
14.2.1(C)	Feedback-regulated DDS.....	14-7
14.2.1(D)	Site-targeted DDS	14-7
14.2.2	Advantages of NDDS	14-8
14.2.3	Disadvantages or Challenges of NDDS	14-8
14.2.4	Applications of NDDS.....	14-8

