

CHAPTER III

Diploma in Pharmacy (Part-III) (Practical Training)

20. Period and other conditions of Practical Training :

(1) After having appeared in Part-II examination of Diploma in Pharmacy conducted by Board/University or other approved Examination Body or any other course accepted as being equivalent by the Pharmacy Council of India, a candidate shall be eligible to undergo practical training in one or more of the following institutions namely :

- (i) Hospitals/Dispensaries run by Central/State Government/Municipal Corporation/Central Government Health Scheme and Employees State Insurance Scheme.
- (ii) A Pharmacy, Chemist and Druggist licensed under the Drugs and Cosmetics Act, 1940 & Rules made thereunder.

(2) The institutions referred in sub-regulation (1) shall be eligible to impart training subject to the condition that the number of student pharmacists that may be taken in any hospital, pharmacy, chemist and druggist and drugs manufacturing unit licensed under the Drugs and Cosmetics Rules, 1945 made under the Drugs and Cosmetics Act, 1940 shall not exceed two where there is one registered pharmacist engaged in the work in which the student pharmacist is under going practical training, where there is more than one registered pharmacist similarly engaged, the number shall not exceed one for each additional such registered pharmacist.

(3) Hospital and Dispensary other than those specified in sub-regulation (1) for the purpose of giving practical training shall have to be recognised by Pharmacy Council of India on fulfilling the conditions specified in Appendix D to these regulations.

(4) In the course of practical training, the training shall have exposure to :

- (i) Working knowledge of keeping of records required by various Acts concerning the profession of Pharmacy; and
- (ii) Practical experience in :
 - (a) the manipulation of pharmaceutical apparatus in common use.

- (b) the reading, translation and copying of prescription including checking of doses;
- (c) the dispensing of prescriptions illustrating the commoner methods of administering medicaments; and
- (d) the storage of drugs and medical preparations.

(5) The practical training shall be not less than five hundred hours spread over a period of not less than three months, provided that not less than two hundred and fifty hours are devoted to actual dispensing of prescriptions.

21. Procedure to be followed prior to commencing of the training:

(1) The Head of an academic training institution, on application, shall supply in triplicate 'Practical Training Contract Form for Qualification as a Pharmacist' (hereinafter referred to as the Contract Form) to a candidate eligible to undertake the said practical training. The Contract Form shall be as specified in Appendix-E to these regulations.

(2) The Head of an academic training institution shall fill section-I of the Contract Form. The trainee shall fill section II of the said Contract Form and the Head of the institution agreeing to impart the training (here in after referred to as the Apprentice Master) shall fill section III of the said Contract Form.

(3) It shall be the responsibility of the trainee to ensure that one copy (hereinafter referred to as the first copy of the Contract Form) so filled is submitted to the Head of the academic training institution and the other two copies (hereinafter referred to as the second copy and the third copy) shall be filed with the Apprentice Master (if he so desires) or with the trainee pending completion of the training.

22. Certificate of passing Diploma in Pharmacy(Part-III) : On satisfactory completion of the apprentice period, the Apprentice Master shall fill Section IV of the second copy and third copy of the Contract Form and cause it to be sent to the Head of the academic training institution who shall suitably enter in the first copy of the entries from the second copy and third copy and shall fill Section V of the three copies of Contract Form and thereafter hand over both the second copy and third copy to the trainee.

This, if completed in all respects, shall be regarded as a certificate of having successfully completed the course of Diploma in Pharmacy (Part-III)

CHAPTER IV

23. Certificate of Diploma in Pharmacy : A certificate of Diploma in Pharmacy shall be granted by the Examining Authority to a successful candidate on producing certificate of having passed the Diploma in Pharmacy Part-I and Part-II and satisfactory completion of practical training for Diploma in Pharmacy (Part-III).

24. Miscellaneous : No course of training in pharmacy shall be considered for approval under regulation 18 unless it satisfies all the conditions prescribed under these regulations.

25. Repeal and Savings :

(1) The Education Regulations, 1981 (hereinafter referred to as the said regulations) published by the Pharmacy Council of India vide No. 14-55/79-Pt.I/PCI/4235-4650 dt. 8th July, 1981 is hereby repealed.

(2) Notwithstanding such repeal,—

- (a) anything done or any action taken under the said regulations shall be deemed to have been done or taken under the corresponding provisions of these regulations.
- (b) a person who was admitted as a student under the said regulations to the course of training for Diploma in Pharmacy and who had not passed the examination at the commencement of these regulations shall be required to pass the examination in accordance with the provisions of the said regulations as if these regulations had not come into force :

Provided, however, the Examining Authority in a particular State may fix a date after which the examinations under the said Regulations shall not be conducted.

APPENDIX A : SYLLABUS

Diploma in Pharmacy, Part-I (First Year)

1.1 PHARMACEUTICS-I

THEORY (75 hours)

1. Introductions of different dosage forms. Their classification with example—their relative applications. Familiarisation with new drug delivery systems.
2. Introduction to Pharmacopoeias with special reference to the Indian Pharmacopoeia.
3. Metrology—Systems of weights and measures. Calculations including conversion from one to another system. Percentage calculations and adjustment of products. Use of alligation method in calculations. Isotonic solutions.
4. Packaging of Pharmaceuticals—Desirable features of a container, types of containers. Study of glass and plastics as materials for containers and rubber as a material for closures—their merits and demerits. Introduction to aerosol packaging.
5. Size reduction—Objectives, and factors affecting size reduction, methods of size reduction—Study of Hammer mill, Ball mill, Fluid energy mill and Disintegrator.
6. Size separation—Size separation by sifting. Official standards for powders. Sedimentation methods of size separation. Construction and working of cyclone separator.
7. Mixing and Homogenisation—Liquid mixing and powder mixing, mixing of semisolids. Study of Silverson Mixer—Homogeniser, Planetary Mixer, Colloid Mill and Hand Homogeniser. Double Cone Mixer.
8. Clarification and Filtration—Theory of filtration, Filter media; Filter aids and selection of filters. Study of the following filtration equipments—Filter Press, Sintered Filters, Filter Candles, Metafilter.
9. Extraction and Galenicals — (a) Study of percolation and maceration and their modifications, continuous hot extraction —

Applications in the preparation of tinctures and extracts. (b) Introduction to Ayurvedic dosage forms.

10. Heat processes—Evaporation—definition, factors affecting evaporation. Study of evaporating still and evaporating pan.

11. Distillation—Simple distillation and Fractional distillation; Steam distillation and vacuum distillation. Study of vacuum still, preparation of purified water I.P. and water for Injection I.P. Construction and working of the still used for the same.

12. Introduction to drying processes—Study of Tray Dryers: Fluidized Bed Dryer, Vacuum Dryer and Freeze Dryer.

13. Sterilization—Concept of sterilization and its difference from disinfection. Thermal resistance of microorganisms. Detailed study of the following sterilisation processes:

- (i) Sterilization with moist heat;
- (ii) Dry heat sterilization;
- (iii) Sterilization by radiation;
- (iv) Sterilization filtration; and
- (v) Gaseous sterilization.

Aseptic techniques—Application of sterilization processes in hospitals particularly with reference to surgical dressings and intravenous fluids. Precautions for safe and effective handling of sterilization equipment.

14. Processing of Tablets—Definition, different types of compressed tablets and their properties. Processes involved in the production of tablets; tablets excipients; defects in tablets; evaluation of tablets; Physical standards including disintegration and dissolution. Tablet coating—sugar coating; film coating; enteric coating and microencapsulation (Tablet coating may be dealt in an elementary manner).

15. Processing of Capsules—Hard and soft gelatin capsules; different sizes of capsules; filling of capsules; handling and storage of capsules. Special applications of capsules.

16. Study of immunological products like sera, vaccines, toxoids and their preparations.

Preparation (minimum number stated against each) of the following categories illustrating different techniques involved.

1. Aromatic waters	3
2. Solutions	4
3. Spirits	2
4. Tinctures	4
5. Extracts	2
6. Creams	2
7. Cosmetic preparations	3
8. Capsules	2
9. Tablets	2
10. Preparations involving sterilisation	2
11. Ophthalmic preparations	2
12. Preparations involving aseptic techniques	2

Books Recommended : (Latest editions)

1. Remington's Pharmaceutical Sciences.
2. The Extra Pharmacopoeia—Martindale.

1.2 PHARMACEUTICAL CHEMISTRY-I

THEORY (75 hours)

1. General discussion on the following inorganic compounds including important physical and chemical properties, medicinal and pharmaceutical uses, storage conditions and chemical incompatibility.

- (A) Acids, bases and buffers—Boric acid*, Hydrochloric acid, Strong ammonium hydroxide, Calcium hydroxide, Sodium hydroxide and official buffers.
- (B) Antioxidants—Hypophosphorous acid, Sulphur dioxide, Sodium bisulphite, Sodium meta-bisulphite, Sodium thiosulphate, Nitrogen and Sodium nitrite.

(C) Gastrointestinal agents —

- (i) Acidifying agent—Dilute hydrochloric acid;
- (ii) Antacids—Sodium bicarbonate, Aluminium hydroxide gel, Aluminium phosphate, Calcium carbonate, Magnesium carbonate, Magnesium trisilicate, Magnesium oxide, combinations of antacid preparations.
- (iii) Protectives and Adsorbents—Bismuth subcarbonate and Kaolin.
- (iv) Saline cathartics—Sodium potassium tartrate and Magnesium sulphate.

(D) Topical Agents—

- (i) Protectives—Talc, Zinc oxide, Calamine, Zinc stearate, Titanium dioxide, Silicone polymers.
- (ii) Antimicrobials and astringents—Hydrogen peroxide*, Potassium permanganate, Chlorinated lime, Iodine, Solutions of iodine, Povidone - Iodine, Boric acid, Borax, Silver nitrate, Mild silver protein, Mercury, Yellow mercuric oxide, Ammoniated mercury.
- (iii) Sulphur and its compounds—Sublimed sulphurs, Precipitated sulphur, Selenium sulphide.
- (iv) Astringents : Alum and Zinc sulphate.

(E) Dental Product—Sodium fluoride, Stannous fluoride, Calcium carbonate, Sodium meta phosphate, Dicalcium phosphate, Strontium chloride, Zinc chloride.

(F) Inhalants—Oxygen, Carbon dioxide, Nitrous oxide.

(G) Respiratory stimulants—Ammonium carbonate.

(H) Expectorants and Emetics—Ammonium chloride*, Potassium iodide, Antimony potassium tartrate.

(I) Antidotes—Sodium nitrite.

2. Major Intra- and Extra-cellular Electrolytes —

(A) Electrolytes used for replacement therapy—Sodium chloride and its preparations, Potassium chloride and its preparations.

(B) Physiological acid-base balance and electrolytes used—Sodium acetate, Potassium acetate, Sodium bicarbonate injection, Sodium citrate, Potassium citrate, Sodium lactate injection, Ammonium chloride and its injection.

(C) Combination of oral electrolyte powders and solutions.

3. Inorganic official compounds of Iron, Iodine, and Calcium ferrous sulfate and Calcium gluconate.

4. Radio Pharmaceuticals and Contract Media—Radio Activity-Alpha, Beta and Gamma radiations, Biological effects of radiations, Measurement of radio Activity G.M. Counter. Radio isotopes—their uses, storage and precautions with special reference to the official preparations. Radio opaque contract media—Barium sulfate.

5. Quality Control of Drugs and Pharmaceuticals—Importance of quality control, significant errors, methods used for quality control, sources of impurities in pharmaceuticals. Limit tests for arsenic, chloride, sulfate, iron and heavy metals.

6. Identification tests for cations and anions as per Indian Pharmacopoeia.

PRACTICALS (75 hours)

1. Identification tests for inorganic compounds particularly drugs and pharmaceuticals.
2. Limit test for chloride, sulfate, arsenic, iron and heavy metals.
3. Assay of inorganic pharmaceuticals involving each of the following methods of compounds marked with (*) under theory.
 - (a) Acid-Base titrations (at least 3)
 - (b) Redox titrations (One each of permanganometry and iodimetry).
 - (c) Precipitation titrations (at least 2)
 - (d) Complexometric titrations (Calcium and magnesium).

Books recommended (Latest editions)

1. Indian Pharmacopoeia.

1.3 PHARMACOGNOSY

THEORY (75 hours)

1. Definition, history and scope of Pharmacognosy including indigenous system of medicine.
2. Various systems of classification of drugs of natural origin.
3. Adulteration and drug evaluation; significance of pharmacopoeial standards.

4. Brief outline of occurrence, distribution outline of isolation, identification tests, therapeutic effects and pharmaceutical applications of alkaloids, terpenoids, glycosides, volatile oils, tannins and resins.

5. Occurrence, distribution, organoleptic evaluation, chemical constituents including tests wherever applicable and therapeutic efficacy of following categories of drugs.

- (a) Laxatives—Aloes, Rhuburb, Castor oil, Ispaghula, Senna.
- (b) Cardiotonics—Digitalis, Arjuna.
- (c) Carminatives & G.I. regulators—Umbelliferous fruits. Coriander, Fennel, Ajowan, Cardamom, Ginger, Black pepper, Asafoetida, Nutmeg, Cinnamon, Clove.
- (d) Astringents—Catechu.
- (e) Drugs acting on nervous system—Hyoscyamus, Belladonna, Aconite, Ashwagandha, Ephedra, Opium, Cannabis, Nuxvomica.
- (f) Antihypertensives—Rauwolfia.
- (g) Antitussives—Vasaka, Tolu balsam, Tulsi.
- (h) Antirheumatics - Guggul, Colchicum.
- (i) Antitumour—Vinca.
- (j) Antileprotics—Chaulmoogra Oil.
- (k) Antidiabetics—Pterocarpus, Gymnema, Sylvestro.
- (l) Diuretics—Gokhru, Punarnava.
- (m) Antidysenterics—Ipecacuanha.
- (n) Antiseptics and disinfectants—Benzoin, Myrrh, Nim, Curcuma.
- (o) Antimalarials—Cinchona.
- (p) Oxytocics—Ergot
- (q) Vitamines—Shark Liver Oil and Amla
- (r) Enzymes—Papaya, Diastase, Yeast
- (s) Perfumes and flavouring agents—Peppermint oil, Lemon oil, Orange oil, Lemon Grass oil, Sandalwood.
- (t) Pharmaceutical aids—Honey, Arachis oil, Starch, Kaolin, Pectin, Olive oil, Lanolin, Beeswax, Acacia, Tragacanth, Sodium alginate, Agar, Guar gum, Gelation.
- (u) Miscellaneous—Liquorice, Garlic, Picrorhiza, Dioscorea, Linseed, Shatavari, Shankhpushpi, Pyrethrum, Tobacco.

6. Collection and preparation of Ergot, Opium, Rauwolfia, Digitalis, Senna.

7. Study of source, preparation and identification of fibres used in sutures and surgical dressings—cotton, silk, wool and regenerated fibres.

8. Gross anatomical studies of—Senna, Datura, Cinnamon, Cinchona, Fennel, Clove, Ginger, Nuxvomica and Ipecacuanha.

PRACTICAL (75 hours)

1. Identification of drugs by morphological characters.
2. Physical and chemical tests for evaluation of drugs wherever applicable.
3. Gross anatomical studies (t.s.) of the following drugs — Senna, Datura, Cinnamon, Cinchona, Coriander, Fennel, Clove, Ginger, Nuxvomica, Ipecacuanha.
4. Identification of fibres and surgical dressings.

1.4 BIOCHEMISTRY & CLINICAL PATHOLOGY

THEORY (50 hours)

1. Introduction to Biochemistry.
2. Brief chemistry and role of proteins, polypeptides and amino acids, classification, qualitative tests, biological value, deficiency diseases.
3. Brief chemistry and role of carbohydrates. Classification, qualitative tests. Diseases related to carbohydrate metabolism.
4. Brief chemistry and role of Lipids. Classification, qualitative tests. Diseases related to lipids metabolism.
5. Brief chemistry and role of vitamins and coenzyme.
6. Role of minerals and water in life processes.
7. Enzymes : Brief concept of enzymic action. Factors affecting it. Therapeutic and pharmaceutical importance.
8. Brief concept of normal and abnormal metabolism of proteins, carbohydrates and lipids.
9. Introduction to pathology of blood and urine.

- (a) Lymphocytes and Platelets, their role in health and disease.
- (b) Erythrocytes—abnormal cells and their significance.
- (c) Abnormal constituents of urine and their significance in diseases.

PRACTICAL (75 hours)

1. Detection and identification of proteins, amino acids, carbohydrates and lipids.
2. Analysis of normal and abnormal constituents of blood and urine (Glucose, Urea, Creatine, Creatinine, Cholesterol alkaline phosphatase, Acid phosphatase, Bilirubin, SGPT, SGOT, Calcium, Diastase, Lipase).
3. Examination of sputum and faeces (microscopic and staining).
4. Practice in injecting drugs by intramuscular, subcutaneous and intravenous routes. Withdrawal of blood samples.

1.5 HUMAN ANATOMY & PHYSIOLOGY

THEORY (75 hours)

1. Scope of anatomy and physiology. Definition of various terms used in anatomy.
2. Structure of cell, function of its components with special reference to mitochondria and microsomes.
3. Elementary tissues of the body, *i.e.* epithelial tissue, muscular tissue, connective tissue and nervous tissue.
4. Structure and function of skeleton. Classification of joints and their function, joint disorder.
5. Composition of blood, functions of blood elements. Blood group and coagulation of blood. Brief information regarding disorders of blood.
6. Name and functions of lymph glands.
7. Structure and functions of various parts of the heart. Arterial and venous system with special reference to the names and positions of main arteries and veins. Blood pressure and its recording. Brief information about cardiovascular disorders.

8. Various parts of respiratory system and their functions. Physiology of respiration.

9. Various parts of urinary systems and their functions, Structure and functions of kidney. Physiology of urine formation. Pathophysiology of renal diseases and oedema.

10. Structure of skeletal muscle. Physiology of muscle contraction. Names, positions, attachments and functions of various skeletal muscles. Physiology of neuromuscular junction.

11. Various parts of central nervous system, brain and its parts, functions and reflex action. Anatomy and physiology of autonomic nervous system.

12. Elementary knowledge of structure and functions of the organs of taste, smell, ear, eye and skin. Physiology of pain.

13. Digestive system. Names of the various parts of digestive system and their functions. Structure and functions of liver, physiology of digestion and absorption.

14. Endocrine glands and hormones. Location of the glands, their hormones and functions.

Pituitary, Thyroid, Adrenal and Pancreas.

15. Reproductive system—Physiology and anatomy of reproductive system.

PRACTICAL (50 hours)

1. Study of the human skeleton.
2. Study with the help of charts and models of the following systems and organs :
 - (a) Digestive system
 - (b) Respiratory system
 - (c) Cardiovascular system
 - (d) Urinary system
 - (e) Reproductive system
 - (f) Nervous system
 - (g) Eye
 - (h) Ear

3. Microscopic examination of epithelial tissue, cardiac muscle, smooth muscle, skeletal muscle. Connective tissue and nervous tissues.
4. Examination of blood films for TLC, DLC and malarial parasite.
5. Determination of clotting time of blood, erythrocyte sedimentation rate and haemoglobin value.
6. Recording of body temperature, pulse, heart rate, blood pressure and ECG.

1.6 HEALTH EDUCATION AND COMMUNITY PHARMACY

THEORY (50 hours)

1. Concept of health—Definition of physical health, mental health, social health, spiritual health—determinants of health, indicators of health, concept of disease, natural history of diseases, the disease agents, concept of prevention of diseases.
2. Nutrition and health—Classification of foods, requirements, diseases induced due to deficiency of proteins, vitamins and minerals - treatment and prevention.
3. Demography and family planning—Demography cycle, fertility, family planning, contraceptive methods, behavioural methods, natural family planning method, chemical method, mechanical methods, hormonal contraceptives, population problem of India.
4. First aid - Emergency treatment in shock, snake-bite, burns, poisoning, heart disease, fractures and resuscitation methods. Elements of minor surgery and dressings.
5. Environment and health—Sources of water supply, waterpollution, purification of water, health and air, noise, light. Solid waste disposal and control. Medical entomology, arthropod borne diseases and their control, rodents, animals and diseases.
6. Fundamental principles of microbiology—Classification of microbes, isolation, straining techniques of organisms of common diseases.
7. Communicable diseases—Causative agents, mode of transmission and prevention.
 - (a) Respiratory infections—Chicken pox, measles, influenza, diphtheria, whooping cough and tuberculosis.

- (b) Intestinal infections—Poliomyelitis, hepatitis, cholera, typhoid, food poisoning, hookworm infection.
- (c) Arthropod borne infections—Plague, malaria, filariasis.
- (d) Surface infections—Rabies, trachoma, tetanus, leprosy.
- (e) Sexually transmitted diseases—Syphilis, gonorrhoea, AIDS.

8. Non-communicable diseases—Causative agents, prevention, care and control : Cancer, diabetes, blindness, cardiovascular diseases.

9. Epidemiology—Its scope, methods, uses, dynamics of disease transmission. Immunity and immunisation: Immunological products and their dose schedule. Principles of disease control and prevention, hospital acquired infection, prevention and control. Disinfection, types of disinfection, disinfection procedures, for faeces, urine, sputum, room, linen, dead-bodies, instruments.