EDUCATION REGULATIONS 1991

Education (Amendment) Regulations 1994

as notified by the
Pharmacy Council of India

Syllabus for the
Diploma Course in Pharmacy

Price : **Rs 20/-**

EDUCATION REGULATIONS 1991

Education (Amendment) Regulations 1994

For the Diploma Course in Pharmacy

(Regulations framed under Section 10
of the Pharmacy Act, 1948)

ducation Regulations 1991 as approved by the Govt. of India, inistry of Health & F. W. vide letter No.V.13016/1/89-PMS dt. .8.1991 and notified by the Pharmacy Council of India in Gazette f India, Part III, Section 4, No. 28 dt. 11th July 1992.

and

Education (Amendments) Rgulations 1994 approved by Govt. of India, Ministry of Health & F. W. vide letter No. V. 13012/1/93 PMS dt. 1.11.1993 and subsequent letters dt. 12.11.1993; 4.3.94; and 31.5.1994 and published by the Pharmacy Council of India in the Gazette of India, Part III, Section 4, No.28 dated 9th July, 94.

Pharmacy Council of India
Combined Councils' Building
Temple Lane, Kotla Road,
New Delhi-110 002

PHARMACY COUNCIL OF INDIA

(Constituted Under the Pharmacy Act, 1948)

elegram : `Farmcouncil'
elephone : `331 9184'

Combined Councils Building
Temple Lane, Kotla Road
New Delhi - 110 002

No. 14-55/87(Part)-PCI/2484-2887 *Dated:* 24th June 1992

Regd.

Manager,
. Of India Press,
labad.

Sub. : Pharmacy Act, 1948—Notification of Eductation Regulations framed under section 10 of the :—

I am directed to forward you herewith two copies of the ation Regulations 1991, both in English and Hindi versions framed e Pharmacy Council of India and duly approved by the Central in the Ministry of Health and F.W., New Delhi vide letter No. 1016/1/89-PMS dated 2.8..91 for publication in Part-III, Section- Gazette of India for notification urgently.

It is further requested that ten copies each of the English Hindi versions of Gazette Notification in which Education Regulations ublished may kindly be supplied to this office against cost.

Kindly acknowledge its receipt.

Yours faithfully
Sd/-
(Devinder K Jain)
Secretary-cum-Registrar

As above

py with a copy of the above notification to Union Ministry of alth and F.W., to State Govts., Examining Authorities, Institutions d all others concerned.

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New Delhi - 110 002.

Ref. No. 14-55/93(Pt. I)-PCI/2447-2981 *Dated:* 28th June 1994

Regd.

The Manager,
Govt. Of India Press,
Faridabad.

Sub. : Pharmacy Act, 1948—Notification of amendements to Eductation Regulations 1991 framed under section of the—

Sir,

I am directed to forward you herewith two copies of the amendments to the Education Regulations 1991 both in English and Hindi framed by the Pharmacy Council of India and duly approved by the Central Govt. in the Ministry of Health and F.W., New Delhi vide letter No. V. 13012/1/93-PMS dated 1.11.93 and subsequent letters dated 12.11.93, 4.3.94 and 31.5.94 for publication in Part-III, Section-4 of Gazette of India for notification urgently.

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Contents

No 14-55/87 (Part) PCI/2484-2887—In exercise of the powers conferred by Section 10 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government, hereby makes the following regulations namely :—

CHAPTER I

1. Short title and commencement :

(1) These regulations may be called the Education Regulations 1991.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. Qualification for Pharmacists : The minimum qualification required for registration as a pharmacist shall be a pass in Diploma in Pharmacy (Part-I & Part-II) and satisfactory completion of Diploma in Pharmacy (Part-III).

Or

Any other qualification approved by the Pharmacy Council of India as equivalent to the above.

3. Diploma in Pharmacy Part-I and Part-II shall consist of a certificate of having passed the course of study prescribed in Chapter II of these regulations.

4. Diploma in Pharmacy Part-III shall consist of a certificate of having satisfactorily completed course of practical training as prescribed in Chapter III of these regulations.

Note : Published in Gazette of India, Part III, Section 4, No 28, dated July 11, 1992. and amendments published on 9th July 1994

CHAPTER II

Diploma in Pharmacy (Part-I and Part-II)

5. Minimum qualification for admission to Diploma in Pharmacy Part-I course : A pass in any of the following examination with Physics, Chemistry and Biology [1]* * * [2][or Mathematics].

(1) Intermediate examination in science,

(2) The first year of the three year degree course in science,

(3) 10+2 examination (academic stream) in science,

(4) Pre-degree examination *or*

(5) Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examination.

[3][Provided that there shall be reservation of seats for Scheduled Caste and Scheduled Tribe candidates in accordance with the instructions issued by the Central Govt./State Govts./Union Territory Administration., as the case may be, from time to time.]

6. Duration of the course : The duration of the course shall be for two academic years, with each academic year spread over a period of not less than one hundred and eighty working days in addition to 500 hours practical training spread over a period of not less than 3 months.

7. Course of study : The course of study for Diploma in Pharmacy Part-I and Diploma in Pharmacy Part-II shall include the subjects as given in the Tables I & Table II below. The number of hours devoted to each subject for its teaching in Theory and Practical, shall not be less than that noted against it in columns 2 and 3 of the Tables below.

[1]The words, "with 60% marks in aggregate of the above subjects:" omitted by s. 2 of the Education (Amendment) Regulations 1994 and published in the Gazette of India, Part III, Section 4, No. 28 dated July 9, 1994.

[2]Inserted by s. 2 *ibid.* (w.e.f. 9.7.1994)

[3]Ins. by s. 2, *ibid.* (w.e.f. 9.7.1994)

TABLE I

Diploma in Pharmacy (Part-I)

Subject	*No. of hours of theory*	*No. of hours of practical*
Pharmaceutics-I	75	100
Pharmaceutical Chemistry-I	75	75
Pharmacognosy	75	75
Biochemistry & Clinical Pathology	50	75
Human Anatomy & Physiology	75	50
Health Education & Community Pharmacy	50	—
Total	400	375 = 775

TABLE II

Diploma in Pharmacy (Part-II)

Subject	*No. of hours of theory*	*No. of hours of practical*
Pharmaceutics-II	75	100
Pharmaceutical Chemistry-II	100	75
Pharmacology & Toxicology	75	50
Pharmaceutical Jurisprudence	50	—
Drug Store and Business Management	75	—
Hospital and Clinical Pharmacy	75	50
Total	450	275 = 725

8. The syllabi for each subject of study in the said Tables shall be as specified in Appendix A to these regulations.

9. Approval of the authority conducting the course of study: The course of regular academic study prescribed under regulation 7 shall be conducted in an institution, approved by the Pharmacy Council of India under sub-section (1) of Section 12 of the Pharmacy Act, 1948.

Provided that the Pharmacy Council of India shall not approve any institution under this regulation unless it provides adequate arrangements for teaching in regard to building, accommodation, equipment and teaching staff as specified in Appendix-B to these regulations.

10. Examination : There shall be an examination for Diploma in Pharmacy (Part-I) to examine students of the first year course and an examination for Diploma in Pharmacy (Part-II) to examine students of the second year course. Each examination may be held twice every year. The first examination in a year shall be the annual examination and the second examination shall be supplementary examination of the Diploma in Pharmacy (Part-I) or Diploma in Pharmacy (Part-II), as the case may be. The examinations shall be of written and practical (including oral) nature, carrying maximum marks for each part of a subject, as indicated in Table III and IV below :

TABLE III

Diploma in Pharmacy (Part-I) Examination

Subject	*Maximum marks for Theory*			*Maximum marks for Practical*		
	Exami-naton	**Sess-ional*	*Total*	*Exami-naton*	*Sess-ional*	*Total*
Pharmaceutics-I	80	20	100	[4]80	[5]20	100
Pharma. Chemistry-I	80	20	100	[4]80	[5]20	100
Pharmacognosy	80	20	100	[4]80	[5]20	100
Biochemistry & Clinical Pathology	80	20	100	[4]80	[5]20	100
Human Anatomy & Physiology	80	20	100	[4]80	[5]20	100
Health Education & Community Pharmacy	80	20	100	—	—	—
Total			600		+	500 = 1100

*Internal assessment

[4]subs. for 70 by s. 3, Education (Amendment) Regulations 1994 (w.e.f. 9th July 1994).

[5]subs. for 20 by s. 3, *ibid.* (w.e.f. 9th July 1994)

TABLE IV

Diploma in Pharmacy (Part-II) Examination

Subject	*Maximum marks for Theory*			*Maximum marks for Practical*		
	Exami-naton	**Sess-ional*	*Total*	*Exami-naton*	*Sess-ional*	*Total*
Pharmaceutics-II	80	20	100	[4]80	[5]20	100
Pharm. Chemistry-II	80	20	100	[4]80	[5]20	100
Pharmacognosy & Toxicology	80	20	100	[4]80	[5]20	100
Pharmaceutical Jurisprudence	80	20	100	—	—	—
Drugs Store & Business Mgt.	80	20	100	—	—	—
Hospital & Clinical Pharmacy	80	20	100	[4]80	[5]20	100
Total			600		+	400 = 1000

*Internal assessment

11. Eligibility for appearing at the Diploma in Pharmacy Part-I examination : Only such candidates who produce certificate from the Head of the academic institution in which he/she has undergone the Diploma in Pharmacy Part-I course, in proof of his/her having regularly and satisfactorily undergone the course of study by attending not less than 75% of the classes held both in theory and in practical separately in each subject shall be eligible for appearing at the Diploma in Pharmacy (Part-I) examination.

12. Eligibility for appearing at the Diploma in Pharmacy Part-II examination : Only such candidates who produce certificate from the Head of the academic institution in which he/she has undergone the Diploma in Pharmacy Part-II course, in proof of his/her having regularly and satisfactorily undergone the Diploma in Pharmacy Part-II course by attending not less than 75% of the classes held both in theory and practical separately in each subject, shall be eligible for appearing at the Diploma in Pharmacy (Part-II) examination.

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) Not withstanding 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—Evaparation—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 techinques—Application of sterilization processes in hospitals particularly with reference to surgical dressings and intravenous fluids. Precaustions for safe and effective handling of sterilization equipment.

14. Processing of Tablets—Definition, different types of compressed tablets and their properties. Processes involoved 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.

PRACTICALS (100 hours)

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 techinques	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 Contrast 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 contrast 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. Indentification 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, Nux vomica.

(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, Guargum, Gelation.

(u) Miscellaneous—Liquorice, Garlic, Picrorhiza, Dioscorea, Linseed, Shatavari, Shankhupushpi, Pyrethrum, Tobacco.

6. Collection and preparation of crude drugs for the market as examplified by 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 morpholicocal 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 constitutents 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, small, 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 heamoglobin 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.

Diploma in Pharmacy, Part-II (Second Year)

2.1 PHARMACEUTICS-II

THEORY (75 hours)

1. **Dispensing Pharmacy :**

(i) **Prescriptions**—Reading and understanding of prescriptions; Latin terms commonly used (Detailed study is not necessary), Modern methods of prescribing, adoption of metric system. Calculations involved in dispensing.

(ii) **Incompatibilities in prescriptions**—Study of various types of incompatibilities—physical, chemical and therapeutic.

(iii) **Posology**—Dose and dosage of drugs. Factors influencing dose. Calculations of doses on the basis of age, sex and surface area. Veterinary doses.

2. **Dispensed Medications :**

(*Note* : A detailed study of the following dispensed medication is necessary. Methods of preparation with theoretical and practical aspects, use of appropriate containers and closures. Special labelling requirements and storage conditions should be highlighted)

(i) **Powders**—Types of powders, advantages and disadvantages of powders, Granules, Cachets and Tablet triturates. Preparation of different types of powders encountered in prescriptions.

Weighing methods, possible errors in weighing, minimum weighable amounts and weighing of a material below the minimum weighable amount, geometric dilution and proper usage and care of dispensing balance.

(ii) **Liquid Oral Dosage Forms** :

(a) **Monophasic**—Theoretical aspects including commonly used vehicles, essential adjuvant like stabilizers, colourants and flavours, with examples.

Review of the following monophasic liquids with details of formulation and practical methods.

Liquids for Internal Administration	*Liquids for External Administration or Used on Mucas Membranes*
Mixtures and concentrates	Gargles
Syrups	Mouth washes
	Throat-paints
	Douches
Elixirs	Ear drops
	Nasal Drops & Sprays
	Liniments
	Lotions

(b) **Biphasic Liquid Dosage Forms** :

(i) *Suspensions (elementary study)*—Suspensions containing diffusible solids and liquids and their preparations. Study of the adjuvants used like thickening agents, wetting agents, their necessity and quantity to be incorporated. Suspensions of precipitate forming liquids like tinctures, their preparations and stability. Suspensions produced by chemical reaction. An introduction to flocculated/non-flocculated suspension system.

(ii) *Emulsions*—Types of emulsions, identification of emulsion systems, formulation of emulsions, selection of emulsifying agents. Instabilities in emulsions, Preservation of emulsions.

(iii) *Semi-Solid Dosage Forms* :

(*a*) Ointments—Types of ointments, classification and selection of dermatological vehicles. Preparation and stability of ointments by the following processes : (*i*) Tricuration (*ii*) Fusion (*iii*) Chemical reaction (*iv*) Emulsification.

(*b*) *Pates*—Differences between ointments and pastes. Bases of pastes. Preparation of pastes and their preservation.

(*c*) *Jellies*—An introduction to the different types of jellies and their preparation.

(*d*) *Poultices*—An elementary study of poultice.

(*e*) *Suppositories and pessaries*—Their relative merits and demerits, types of susppositories, suppository bases, classification, properties. Preparation and packing of suppositories. Use of suppositories for drug absorption.

(iv) **Dental and Cosmetic Preparations** : Introduction to Dentrifices, Facial cosmetics, Deodorants, Antiperspirants, Shampoos, Hair dressings and Hair removers.

(v) Sterile Dosage Forms :

(*a*) Parenteral dosage forms—Definition, general requirements for parenteral dosage forms. Types of parenteral formulations, vehicles, adjucants, processing, personnel, facilities and quality control. Preparation of intravenous fluids and admixtures—Total parenteral nutrition, Dialysis fluids.

(b) Sterility testing, particulate matter mointoring. Faulty seals, packaging.

(c) Ophtalmic Products—Study of essential characteristics of different opthalmic preparations. Formulation additives, special precautions in handling and storage of opthalmic products.

PRACTICAL (100 hours)

Dispensing of at least 100 products covering a wide range of preparations such as mixtures, emulsions, lotions, liniments, E.N.T. preparations, ointments, suppositories, powders, incompatible prescription etc.

Books recommended : (Latest editions)

1. Indian Pharmacopoeia
2. British Pharmacopoeia
3. National Formularies (N.F.I., B.N.F.)
4. Remington's Pharmaceutical Sciences
5. Martindale's Extra Pharmacopoeia

2.2 PHARMACEUTICAL CHEMISTRY-II

THEORY (100 hours)

1. Introduction to the nomenclature of organic chemical systems with particular reference to hetero-cyclic system containing upto 3 rings.

2. The chemistry of following pharmaceutical organic compounds covering their nomenclature, chemical structure, uses and the important physical and chemical properties (Chemical structure of only those compounds marked with asterisk (*).

The stability and storage conditions and the different type of pharmaceutical formulations of these drugs and their popular brand names.

Antiseptics and Disinfectants—Proflavine*, Benzalkonium chloride, Cetrimide, Chloro cresol*, Chloroxylene, Formaldehyde solution, Hexachlorophene, Liquified phenol, Nitro furantoin.

Sulfonamides—Sulfadiazine*, Sulfaguanidine*, Phthalyl sulfathiazole, Succinyl sulfathiazole, Sulfadimethoxine, Sulfadimethoxine, Sulfamethoxy pyridazine, Sulfa methoxazole, Co-trimoxazole, Sulfacetamide*.

Antileprotic Drugs—Clofazimine, Thiambutosine, Dapsone*. Solapsone.

Antitubercular Drugs—Isoniazid*, PAS*, Streptomycin, Rifampicin, Ethambutol*, Thiacetazone, Ethionamide, Cycloserine, Pyrazinamide*.

Antiamoebic and Anthelmintic Drugs—Emetine, Metronidazole*, Halogenated hydroxygquinolines, Diloxamide furoate, Paromomycin Piperazine*. Mebendazole, D.E.C.*.

Antibiotics—Benzyl penicillin*. Phenoxy methyl penicillin*, Benzathine penicillin, Ampicillin*, Cloxacillin, Carbenicillin, Gentamycin, Neomycin, Erythromycing, Tetracyline, Cephalexin, Cephaloridine, Cephalothin, Griseofulvin, Chloramphenicol. Antifungal agents—Undecylenic acid, Tolnaftate, Nystatin, Amphoterecin, Hamycin.

Antimalarial Drugs—Cloroquine*, Amodiaquine, Primaquine, Proguanil, Pyrimethamine*, Quinine, Trimethoprim.

Tranquilizers—Chlorpromazine*, Prochlor Perazine, Trifluo, Perazine, Thiothixene, Haloperidol*, Triperidol, Oxypertine, Chloridiazepoxide, Diazepam*, Lorazopam, Meprobamate.

Hypnotics—Phenobarbitone*, Butobarbitone, Cyclobarbitone, Nitrazepam, Glutethimide*, Methyprylon, Paraldehyde. Triclofossodium.

General Anaesthetics—Halothane*, Cyclopropane*, Diethyl ether*, Metho-hexital sodium, Thiopental sodium, Trichloro ethylene.

Antidepressent Drugs—Amitriptyline, Nortryptyline, Imipramine*, Phenelzine, Tranyl cypromine.

Analeptics—Theophylline, Caffeine*, Dextro-amphetamine.

Adrenergic Drugs—Adrenaline*, Noradrenaline, Isoprenaline*, Phenylephrine, Salbutamol, Terbutaline, Ephedrine*, Pseudo ephedrine.

Adrenergic Antagonist—Tolazoline, Propranolol*, Practalol.

Cholinergic Drugs—Neostigmine*, Pyridostigmine, Pralidoxine, Pilocarpine, Physiostigmine*.

Cholinegric Antagonists—Atropine*, Hyoscine, Homatropine, Propantheline*, Benztropine, Tropicamide, Biperiden*.

Diuretic Drugs—Furosemide*, Chlorothiazide, Hydrochlorothiazide*, Benzthiazide, Urea*, Mannitol*, Ethacrynic acid.

Cardiovascular Drugs—Ethyl nitrite*, Glyceryl trinitrate, Alpha methyl dopa, Guanethidine, Clofibrate, Quinidine.

Hypoglycemia Agents—Insulin, Chlorpropamide*, Tolbutamide, Glibenclamide, Phenformir*, Metformin.

Coagulants and Anti coagulants—Heparin, Thrombin, Menadione*, Bishydroxycoumarin, Warfarin Sodium.

Local Anaesthetics—Lignocaine*, Procaine*, Benzocaine.

Histamine and Antihistaminic Agents—Histamine, Diphen Hydramine*, Promethazine, Cyproheptadine, Mepyramine, Pheniramine Chlorpheniramine*.

Analgesics and Anti-pyretics—Morphine, Pethidine*, Codeine, Methadone, Aspirin*, Paracetamol*, Analgin, Dextropropoxyphene, Pentazocine.

Non-steriodal Anti-inflammatory Agents—Indomethacin*, Phenylbutazone*, Oxyphen Butazone, Ibuprofen.

Thyroxine and Antithyroids—Thyroxine*, Methimazole, Methyl thiouracil, Propylthiouracil.

Diagnostic Agents—Iopanoic acid, Propyliodone, Sulfobromophthalein, sodium, Indiogotindisulfonate sodium (Indigo Carmine), Evans Blue, Congo Red, Fluorescein sodium.

Anticonvulsants, cardiac glycosides, Antiarrhythmic antihypertensives and Vitamins.

Steriodal Drugs—Betamethazone, Cortisone, Hydrocortisone, Prednisolone, Progesterone, Testosterone, Oestradiol Nandrolone.

Anti-Neoplastic Drugs—Actinomycins, Azathioprine, Busulphan, Chlorambucil Cisplatin Cyclophosphamide, Daunorubicin, Hydrochloride, Fluorouracil, Mercaptopurine, Methotrexate, Mytomycin.

Books Recommended : (Latest editions)

1. Pharmacopoeia of India.
2. British Pharmaceutical Codex.
3. Martindale's Extra Pharmacopoeia.

PRACTICAL (75 hours)

1. Systematic qualitative testing of organic drugs involving solubility determination, melting point and/or boiling point, detection of elements and functional groups (10 compounds).

2. Official identification tests for certain groups of drugs included in the I.P. like barbiturates, sulfonamides, phenothiazines, antibiotics etc. (8 compounds).

3. Preparation of three simple organic preparations.

2.3 PHARMACOLOGY & TOXICOLOGY

THEORY (75 hours)

1. Introduction to pharmacology, scope of pharmacology.

2. Routes of administration of drugs, their advantages and disadvantages.

3. Various processes of absorption of drugs and the factors affecting them. Metabolism, distribution and excretion of drugs.

4. General mechanism of drugs action and the factors which modify drugs Action.

5. Pharmacological classification of drugs. The discussion of drugs should emphasise the following aspects :

(i) Drugs acting on ~~autonomic~~ central nervous system:

(a) General anaesthetics, adjunction to anaesthesia, intraveuous anaesthetics.

(b) Analgesic and non-steroidal anti-inflammatory drugs, Narcotic analgesics. Antirheumatic and antigout remedies. Sedatives and Hypnotics, Psychopharmacological agents, Anti—convulsants, analeptics.

(c) Centrally acting muscle relaxants and antiparkinsonism agents.

(ii) Local anaesthetics.

(iii) Drugs acting on autonomic nervous system.

(a) Cholinergic drugs, anticholinergic drugs, anticholinesterase drugs.

(b) Adrenergic drugs and adrenergic recepter blockers.

(c) Neurone blockers and ganglion blockers.

(d) Neuromuscular blockers, drugs used in myasthenia gravis.

(iv) Drugs acting on eye, mydriatics, drugs used in glaucoma.

(v) Drugs acting on respiratory system—Respiratory stimulants Bronchodilators, Nasal decongestants, Expectorants and Antitussive agents.

(vi) Antacids, Physiological role of histamine and serotonin, Histamine and Antihistamines, Prostaglandins.

(vii) Cardiovascular drugs, Cardiotonics, Antiarrhythmic agents, Antianginal agents, Antihypertensive agents, Peripheral vasodilators and drugs used in atherosclerosis.

(viii) Drugs acting on the blood and blood forming organs. Haematinics, Coagulants and anticoagulants, Haemostatics, Blood substitutes and plasma expanders.

(ix) Drugs effecting renal function—Diuretics and antidiuretics.

(x) Harmones and hormone antagonists—Hypoglycemic agents, Antithyroid drugs, sex harmones and oral contraceptives, corticosteroids.

(xi) Drugs acting on digestive system—Carminatives, digestants bitters, antacids and drugs used in peptic ulcer, Purgatives and laxatives, antidiarrhoeals, antispamo lics.

6. Chemotherapy of microbial disease—Urinary antiseptics, Sulphonamides, Penricillins, Streptomycin, Tetracyclines and other

antibiotics. Antitubercular agents, antifungal agents, antiviral drugs, antileprotic drugs.

7. Chemotherapy of protozoal diseases. Anthelmintic drugs.

8. Chemotherappy of cancer.

9. Disinfectants and antiseptics.

A detailed study of the action of drugs on each organ is not necessary.

PRACTICAL (50 hours)

The first six of the following experiments will be done by the students while the remaining will be demonstrated by the teacher.

1. Effect of K^+, Ca^{++}, acetyl choline and adrenaline on frog's heart.

2. Effect of acetyl choline on rectus abdominis muscles of frog and guinea pig ileum.

3. Effect of spasmogens and relaxants of rabbits intestine.

4. Effect of local anaesthetics on rabbit cornea.

5. Effect of mydriatics and miotics on rabbits eye.

6. To study the action of strychnine on frog.

7. Effect of digitalis on frog's heart.

8. Effect of hypnotics in mice.

9. Effect of convulsants and anticonvulsant in mice or rats.

10. Test for pyrogens.

11. Taming and hypnosis potentiating effect of chlorpromazine in mice/rats.

12. Effect of diphenhydramine in experimentally produced asthama in guinea pigs.

2.4 PHARMACEUTICAL JURISPRUDENCE

THEORY (50 hours)

1. Origin and nature of pharmaceutical legislation in India, its scope and objectives. Evolution of the "Concept of Pharmacy" as an integral part of the health care system.

2. Principles and significance of Professional Ethics. Critical study of the code of Pharmaceutical Ethics drafted by Pharmacy Council of India.

3. Pharmacy Act, 1948—The general study of the Pharmacy Act with special reference to Education Regulations, working of State and Central Councils, constitution of these councils and functions. Registration procedures under the Act.

4. The Drugs and Cosmetics Act, 1940—General study of the Drugs and Cosmetics Act and Rules thereunder. Definitions and salient features related to retail and wholesale distribution of drugs. The powers of Inspectors, the sampling procedures and the procedure and formalities in obtaining licences under the rule. Facilities to be provided for running a Pharmacy effectively. General study of the schedules with special reference to schedule C, C_1, F, G, J, H, P and X and salient features of labelling and storage conditions of drugs.

5. The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954—General study of the Act, objectives, special reference to be laid on advertisements, magic remedies and objectionable and permitted advertisements—diseases which cannot be claimed to be cured.

6. Narcotic Drugs and Psychotropic Substances Act, 1985—A brief study of the Act with special reference to its objectives, offences and punishment.

7. Brief introduction to the study of the following Acts :

(1) Latest Drugs (Price Control) Order in force.

(2) Poisons Act 1919 (as amended to date)

(3) Medicinal and Toilet Preparations (Excise Duties) Act, 1955 (as amended to date)

(4) Medical Termination of Pregnancy Act, 1971 (as amended to date)

Books Recommended (Latest edition) :

Bare Acts of the said laws published by the Government.

2.5 DRUG STORE & BUSINESS MANAGEMENT

THEORY (75 hours)

Part I : Commerce (50 hours)

1. Introduction—Trade, industry and commerce, functions and subdivisions of commerce, Introduction to elements of economics and management.

2. Forms of Business Organisations.

3. Channels of Distribution.

4. Drug House Management—Selection of site, space lay-out and legal requirements.

Importance and objectives of purchasing, Selection of suppliers, credit information, tenders, contracts and price determination and legal requirements thereto.

Codification, handling of drug stores and other hospital supplies.

5. Inventory Control—Objects and importance, modern techniques like ABC, VED analysis, the lead time, inventory carrying cost, safety stock, minimum and maximum stock levels, economic order quantity, scrap and surplus disposal.

6. Sale promotion, market research, salesmanship, qualities of a salesman, advertising and window display.

7. Recruitment, training, evaluation and compensation of the pharmacist.

8. Banking and Finance—Service and functions of bank, finance planning and sources of finance.

Part II : Accountancy (25 hours)

1. Introduction to the accounting concepts and conventions. Double entry, book keeping, different kinds of accounts.

2. Cash Book.

3. General Ledger and Trial Balance.

4. Profit and Loss Account and Balance Sheet.

5. Simple techniques of analysing financial statements.

6. Introduction to Budgetting.

Books Recommended (Latest editions) :

1. Remingtons Pharmaceutical Sciences.

2.6 HOSPITAL & CLINICAL PHARMACY

THEORY (75 hours)

Part I : Hospital Pharmacy

1. Hospitals—Definition, function, classifications based on various criteria, organisation, management and health delivery system in India.

2. Hospital Pharmacy :

(a) Definition

(b) Functions and objectives of hospital pharmaceutical services.

(c) Location, layout, flow chart of materials and men.

(d) Personnel and facilities requirements including equipments based on individual and basic needs.

(e) Requirements and abilities required of hospital pharmacists.

3. Drug Distribution System in Hospitals :

(a) Out-patient services

(b) In-patient services : (i) types of services (ii) detailed discussion of Unit dose system, Floor ward stock system, Satellite pharmacy services, Central sterile services, Bed side pharmacy.

4. Manufacturing :

(a) Economical considerations, estimation of demand.

(b) Sterile manufacture—large and small volume parenterals, facilities, reqrirements, layout, production planning, man-power requirements.

(c) Non-sterile manufacture—Liquid orals, externals, Bulk concentrates.

(d) Procurement of stores and testing of raw materials.

5. Nomenclature and uses of surgical instruments and hospital equipments and health accessories.

6. P.T.C (Pharmacy Therapeutic Committee), Hospital formulary system and their organisation, functioning, composition.

7. Drug information service and Drug information bulletin.

8. Surgical dressings like cotton, gauze, bandages and adhesive tapes including their pharmacopoeial tests for quality. Other hospital supply e.g. I.V. sets, B.G. sets, Ryals tubes, Catheters, Syringes etc.

9. Application of computers in maintenance of records, inventory control, medication monitoring, drug information and data storage and retrieval in hospital and retail pharmacy establishments.

Part II : Clinical Pharmacy

1. Introduction to clinical pharmacy practice—Definition, scope.

2. Modern dispensing aspects—pharmacists and patient counselling and advice for the use of common drugs, medication history.

3. Common daily terminology used in the practice of medicine.

4. Disease, manifestations and pathophysiology including salient symptoms to understand the disease like Tuberculosis, Hepatitis, Rhenumatoid Arthritis, Cardio-vascular diseases, Epilepsy, Diabetes, Peptic Ulcer, Hypertension.

5. Physiological parameters with their significance.

6. Drug interactions :

(a) Definition and introduction.

(b) Mechanism of drug interaction.

(c) Drug—Drug interaction with reference to analgesies, diuretics, cardio vasular drugs, Gastro-intestinal agent, Vitamins and Hypoglycemic agents.

(d) Drug-food interaction.

7. Adverse Drug Reactions :

(a) Definition and significance.

(b) Drug-induced diseases and teratogenicity.

8. Drugs in Clinical Toxicity—Introduction, general treatment of poisoning, systematic antidotes. Treatment of insecticide poisoning, heavy metal poison, Narcotic drugs, Barbiturate, Organophosphorus poisons.

9. Drug dependenes, drug abuse, addictive drugs and their treatment, complications.

10. Bio-availability of drugs, including factors affecting it.

Books Recommended (Latest editions) :

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

PRACTICAL (50 hours)

1. Preparation of transfusion fluids.
2. Testing of raw materials used in (1).
3. Evaluation of surgical dressings.
4. Sterilization of surgical instruments, glassware and other hospital supplies.
5. Handling and use of data processing equipments.

APPENDIX B

(See Regulation 9)

CONDITIONS TO BE FULFILLED BY THE ACADEMIC TRAINING INSTITUTION

Any authority in India applying to the Pharmacy Council of India for approval of courses of study for Pharmacists under sub-section (1) of section 12 of the Pharmacy Act, 1948 shall provide:

(A) Accommodation

Suitable and sufficient accommodation with adequate ventilation, lighting and other hygienic conditions should be provided to the rooms for Principal/Head of the department, office, class room, library, staff common room, students common room, museum, store etc.

At least four laboratories specified below should be provided for :

1. Pharmaceutics Lab.
2. Pharm. Chemistry Lab.
3. Physiology, Pharmacology and Pharmacognosy Lab.
4. Biochemistry, Clinical Pathology, Hospital and Clinical Pharmacy Lab.

In addition to the laboratories, balance room, aseptic room or cabinet, animal house, a machine room are also to the provided for.

Floor area of the laboratory should not be less than 30 square feet per student required to work in the laboratory at any given time subject to a minimum of 500 square feet.

Laboratories should be fitted and constructed in a manner that these can be kept reasonably clean. Gas and water fittings, shelves, fume cuboards be provided wherever necessary.

(B) Staff

Principal/Director/Head of the department may be engaged in teaching upto eight hours a week, and the work load of other teaching staff should not be more than 16 hours per week.

Staff student ratio should not exceed 1 : 60 in theory classes and 1 : 20 in practical classes. There should be two teachers for a batch of 30 students in practicals.

According to the above norms, the following staff is required for an intake of 60 students :

*Professor/Reader	— One
Senior Lecturers/Lecturers	— Seven

The minimum qualification of the the Principal/Director/Head of the Institution/Department, and the teachers be as given below :

Principal/Director/Head of Institution/Department (Professor/Reader)	Basic degree in pharmacy and Post-graduate in any discipline of Pharmaceutical Sciences with not less than 5 years experience in teaching.
Lecturers	M.Pharm. *or* B.Pharm. with 3 years teaching/ professional experience.
[8][Lecturers (1) Anatomy and Physiology (2) Biochemistry and Clinical pathology	M. Pharm *or* B Pharm with 3 years teaching/ professional experience *or* M.B.B.S.]

Provided that the above qualifications shall not apply to the incumbents appointed under the repealed Education Regulations.

[9][The pay scale of teaching staff shall be as prescribed by the All India Council for Technical Education for teaching staff of Polytechincs from time to time.]

List of Non-Teaching staff for the D. Pharm. course

1. Laboratory Technician (Qualification — Diploma in Pharmacy)	2	
2. Laboratory Attendant	4	contd.

*He may also work as Principal or Head of the Department, as the case may be

[8]Ins. by Education (Amendment) Regulations 1994. (w.e.f. 9th July 1994)

[9]Ins. by *ibid.* (w.e.f. 9th July 1994)

3. Office superintendent		1
4. Clerk-cum-Accountant		1
5. Store-keeper		1
6. Typist		1
7. Asstt. Librarian		1
8. Peons		2
9. Cleaners/Sweepers		4
10. Gardener		1

(C) Equipments for various laboratries

1. Pharmaceutics Laboratory

A. Special equipment and instruments	*Numbers required for* 60	*120 students*
1. Continuous hot extraction equipment	5	10
2. Conical percolators	20	40
3. Tincture Press	1	1
4. Hand grinding mill	5	5
5. Disintegrator	1	1
6. Ball mill	1	1
7. Hand operated Tablet machines	3	3
8. Tablet coating pan unit with hot air blower (Laboratory size)	1	1
9. Polishing Pan (Laboratory size)	1	1
10. Tablet Hardness Tester (Monsanto Type)	3	3
11. Tablet Hardness Tester (Pfizer type)	3	3
12. Disintegration Test Unit	2	2
13. Dissolution Rate Test Apparatus	1	1
14. Granulating sieve sets	20	40
15. Tablet counter (small size)	5	5
16. Friability Tester	1	1
17. Collapsible Tube filling and sealing equipments	2	2

Special equipment and instruments	*Numbers required for* 60	*120 students*
18. Capsule filling machine (Laboratory size)	2	2
19. Prescription balance	40	60
20. Balance [Torsion type with removable glass pan sensitivity (30 mgm.)]	5	5
21. Distillation equipment for distilled water	2	2
22. Water deionization unit	1	2
23. All glass distillation unit for making water for injection	2	4
24. Ampoule washing machine	1	1
25. Ampoule filling and sealing machine	1	1
26. Sintered glass filters for bacteria proof filtration (4 different grades)	20	20 each grade
27. Millipore filters (3 grades)	2	2 each grade
28. Autoclaves	2	2
29. Pressure cookers	5	10
30. Hot air sterlizer	2	3
31. Incubators	2	2
32. Aseptic cabinet	2	3
33. Rabbit cages and holders	10	10
34. Ampoule clarity test equipments	2	2
35. Blender	2	3
36. Sieves Set (Pharmacopoeial standards)	10	10
37. Laboratory centrifuge	2	3
38. Ointment slabs	40	40
39. Ointment spatulas	40	40
40. Pestle and mortar (Porcelain)	40	40
41. Pestle and mortar (glass)	10	10
42. Suppository moulds (of 3 sizes)	20	30 each
43. Refrigerator	1	1

B. General glassware	Adequate	
C. Chemicals, appliances and laboratory facilities.	Adequate	

2. Pharmaceutical Chemistry Laboratory

A. Special equipment and instruments	*Numbers required for* 60	*120 students*
1. Refractometer	1	1
2. Polarimeter	1	1
3. Photo Electric Colorimeter	1	1
4. pH meter	2	2
5. Atomic model sets	10	10
6. Analytical balances and weight box sets	10	15
7. Physical balances & weight box sets	5	5
8. Platform balance	2	2
9. Periodic Table chart	2	2
B. General Glassware	Adequate	
C. Miscellaneous appliances, chemicals and laboratory facilities	Adequate	

3. Physiology and Pharmacology Laboratory

A. Special equipment and instruments	*Numbers required for* 60	*120 students*
1. Haemoglobinometer	20	30
2. Haemocytometer	10	20
3. Student's Organ bath	5	10
4. Sherrington rotating drum	5	10
5. Frog Boards	10	20
6. Trays (dissecting)	10	20
7. Frontal writing levers	15	30
8. Aeration tube	20	40
9. Telethermometer	1	2

Special equipment and instruments	*Numbers required for* 60	*120 students*
10. Pole climbing apparatus	1	2
11. Histamine chamber	1	2
12. Simple levers	15	30
13. Starling heart levers	10	20
14. ECG Machine		
15. Aerators	5	10
16. Histological slides	25	25
17. Sphygmomanometer (B.P. appratus)	5	5
18. Stethoscope	5	5
19. First aid equipments	5	5 sets
20. Contraceptive device	5	5 sets
21. Dissecting (Surgical) instruments	20	30 sets
22. Operation table (small)	2	2
23. Balance for weighing small animals	1	2
24. Kymograph paper	Adequate	
25. Activity cage (Actophotometer)	1	1
26. Analgesiometer	1	1
27. Thermometers	20	20
28. Distilled water stills	2	2
29. Plastic animal cages	10	10
30. Double unit organ bath with thermostat	1	1
31. Refrigerator	1	1
32. Single pan balance	1	1
33. Charts	Adequate	
34. Human Skeleton	1	1
35. Anatomical Specimen (Heart, brain, eye, ear, reproductive system etc.)	1	1 set
36. Electro-convulsometer	1	1
37. Stop watches	10	10

Special equipment and instruments	*Numbers required for* 60	*120 students*
38. Clamp, Bossheds, Screw clips	Adequate	
39. Symes' Cannula	20	40
B. General glassware	Adequate	
C. Chemical and miscellaneous laboratory/apparatus and appliances (needles, thread, plasticin, tubing, burners, polythene, tubes, syringes etc.).	Adequate	

4. Biochemistry and Clinical Pathology Laboratory

A. Special equipment and instruments	*Numbers required for* 60	*120 students*
1. Colorimeter	2	2
2. Microscopes	20	20
3. Permanent slides (Skin, Kidney, pancreas, Smoothmuscle, liver etc.)	Adequate	
4. Watch glasses	25	50
5. Centrifuge	1	1
6. Microscope with oil immersion	5	5
B. General glassware	Adequate	
C. Biochemical reagents for analysis of normal and pathological constituents of urine, blood and facilities	Adequate	

5. Pharmacognosy Laboratory

A. Special equipment and instruments	*Numbers required for* 60	*120 students*
1. Dissecting Microscope	20	20
2. Charts (different types)	100	100
3. Models (different types)	50	50
4. Permanent slides	100	100
5. Slides and cover slips	Adequate	

B. General glassware	Adequate
C. Miscellaneous appliances, chemicals and laboratory facilities.	Adequate

6. Hospital and Clinical Pharmacy Practicals Laboratory

	Quantity
1. Water Still	1
2. Mixing Vat with stirrer	2
3. Filtration equipment	2
4. Filling machine	1
5. Sealing machine	1
6. Autoclave sterilizer	1
7. Membrane filter	1 unit
8. Sintered glass funnel with complete filtering assembly	10 units
9. Small disposable membrane filters for IV admixture filtration	Adequate
10. Laminar air flow bench	1
11. Vacuum pump	1
12. Ovens	2
13. Surgical dressing	2
14. Incubator	1
15. Karl Fischer apparatus for moisture content determination	1
16. Flame photometer	1
17. pH meter	1
18. Dissolution apparatus	1
19. Disintegration test apparatus	1
20. Hardness tester	1
21. Centrifuge	1
22. Magnetic stirrer	1
23. Thermostatic bath	1
24. Experimental Animals	Adequate

7. General List of Equipments

	Numbers required for 60	*120 students*
1. Distilled water still	2	2
2. Vacuum pump	2	3
3. Refrigerator	1	2
4. General filling equipment for the museum	Adequate	
5. Compound microscopes	20	20
6. Oil immersion microscope	1	2
7. Over head projector	1	1
8. Slide cum strip projector	1	1
9. Projection screen	1	1

Museum

Every institution shall maintain a museum of crude drugs, harbarium sheets, botanical specimens of the drugs and plants mentioned in the course. In addition, the following are recommended :—

1. Coloured slides of medicinal plants;
2. Display of popular patent medicines; and
3. Containers of common usage in medicines.

Library

Every institution shall maintain a library which should contain books mentioned in the syllabus and also the current pharmaceutical journals. There should be adequate place in the library for students and staff to refer books.

Note **: The above requirements are the minimum requirements and the Institute is free to provide more physical and teaching facility.**

APPENDIX C

(See Regulation 18)

CONDITIONS TO BE FULFILLED BY THE EXAMINING AUTHORITY

1. The Examining Authority shall be either a statutory Indian University or a body constituted by the Central or State Government. It shall ensure that discipline and decorum of the examinations are strictly observed at the examination centres.

2. It shall permit the inspector or inspectors of the Pharmacy Council of India to visit and inspect the examinations.

3. It shall provide :

(a) Adequate rooms with necessary furniture for holding written examinations;

(b) Well-equipped laboratories for holding practical examinations;

(c) An adequate number of qualified and responsible examiners and staff to conduct and invigilate the examination; and

(d) Such other facilities as may be necessary for efficient and proper conduct of examinations.

4. It shall, if so required by a candidate, furnish the statement of marks secured by a candidate in the examinations after payment of prescribed fee, if any, to the Examining Authority.

5. It shall appoint examiners whose qualifications should be similar to those of the teachers in the respective subjects as shown in Appendix-B.

6. In pursuance of sub-section (3) of section 12 of the Pharmacy Act, 1948, the Examining Authority shall communicate to the Secretary, Pharmacy Council of India not less than six weeks in advance the dates fixed for examinations, the time-table for such examinations, so as to enable the Council to arrange for inspection of the examination.

[10][7. The Chairman and at least one expert member of Examining Committee of the Examining Authority concerned with appointment of examiners and conduct of pharmacy examination should be persons possessing pharmacy qualifications.]

[10]Ins. by Education (Amendment) Regulations 1994. (w.e.f. 9th July 1994)

APPENDIX D

[See Regulation 20 (3)]

CONDITIONS TO BE FULFILLED BY THE INSTITUTION TO BE RECOGNISED FOR GIVING PRACTICAL TRAINING

1. The institution, where practical training is give to student pharmacists, shall from time to time, if required, furnish such information as may be needed by the Pharmacy Council of India about the staff, accommodation and equipment of the institution concerned and its working.

2. The institution shall permit the Inspectors of the Pharmacy Council of India to inspect the premises at any reasonable time while the work is proceeding therein.

3. The institution shall entrust some member or members of its staff, who shall be registered pharmacist(s), to look after the student pharmacist(s). Such members of the staff shall be responsible in this behalf to the Head of the Institution concerned.

4. The institution shall provide such opportunity, accommodation, apparatus, materials and books of reference, as may be required, to enable the student pharmacists to undergo the practical training properly.

5. The number of student pharmacists that may be taken in any hospital, pharmacy and chemist and druggist and a drugs manufacturer licensed under the Drugs and Cosmetics Rules, 1945 made under the Drug and Cosmetics Act, 1940 shall not exceed two where there is one registered pharmacist engaged in the working in which the student pharmacist is undergoing practical training; where there is more than one registered pharmacist similarly engaged, the number shall not exceed one for each additional such registered pharmacist.

6. The institution wishing to be recognised under regulation 20 shall apply in writing to the Secretary, Pharmacy Council of India stating its desire, to be so recognised.

7. Having satisfied that the institution shall follow the conditions laid down in these rules, the Pharmacy Council of India shall grant such recognition.

8. In the event of any question arising as to the interpretation or observance of these conditions the decision of the Pharmacy Council of India shall be final.

APPENDIX E

[See Regulation 21 (1)]

PRACTICAL TRAINING CONTRACT FORM FOR PHARMACISTS

SECTION I

This form has been issued to _____
(Name of student pharmacist)

son of/daughter of _____

residing at _____ who has produced evidence before me that he/she is entitled to receive the Practical Training as set out in the Education Regulations framed under section 10 of the Pharmacy Act, 1948.

Date :

The Head of the Academic Training Institution

SECTION II

I _____ accept
(Name of the student pharmacist)

_____ of _____
(Name of the Apprentice Master) (Name of the institution)

_____ as my Apprentice Master
(Hospital or Pharmacy)

for the above training and agree to obey and respect him/her during the entire period of my training.

_____
(Student Pharmacist)

SECTION III

I, _____ accept

(name of the Apprentice Master)

_____ as the trainee and

(Name of the student pharmacist)

I agree to give him/her training facilities in my organisation so that during his/her training he/she may acquire:—

1. Working knowledge of keeping of records required by the various Acts affecting the profession of pharmacy; and

2. Practical experience in—

(a) the manipulation of pharmaceutical apparatus in common use;

(b) the reading, translation and copying of prescriptions including the checking of doses;

(c) the dispensing of prescriptions illustrating the commoner methods of administering medicaments; and

(d) the storage of drugs and medicinal preparations.

I also agree that a Registered Pharmacist shall be assigned for his/her guidance.

(Apprentice Master)

(Name and address of the Institution)

SECTION IV

I certify that _____

(Name of the student pharmacist)

has undergone _____ hours training spread over _____ months in accordance with the details enumerated in Section III.

_____

(Head of the Organisation or Pharmaceutical Division)

SECTION V

I certify that _____ has

(Name of the student pharmacist)

completed in all respect his practical training under regulation 20 of the Education Regulations framed under section 10 of the Pharmacy Act, 1948. He had his practical training in an Institution approved by the Pharmacy Council of India.

Date : _____

(Head of the Academic Institution)

Notified by

Sd/-

(Devinder K. Jain)

Secretary-cum-Registrar

Pharmacy Council of India,

New Delhi - 110002

Notification in the Gazzette of India
Part-III Section 4 No. 28 dated 9th July 1994

PHARMACY COUNCIL OF INDIA

New Delhi-110 002, the 28th June 1994

*Ref. No.*14-55/93 (Part-I)/PCI/2447-2981—*In exercise of the powers conferred by Section 10 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government, hereby makes the following amendments in the Education Regulations 1991, namely :—*

1. (1) These Regulations may be called the Education (Amendment) Regulations 1994.

(2) They shall come into force from the date of their publication in the official gazette.

2. In the Education Regulations 1991 (hereinafter referred to as the said regulations) for regulation 5, the following regulation shall be substituted, namely:—

"5. Minimum qualification for admission to Diploma in Pharmacy Part-I course : A pass in any of the following examination with Physics, Chemistry and Biology or Mathematics.

(1) Intermediate examination in science,

(2) The first year of the three year degree course in science,

(3) 10+2 examination (academic stream) in science,

(4) Pre-degree examination *or*

(5) Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examination."

"Provided that there shall be reservation of seats for Scheduled Caste and Scheduled Tribe candidates in accordance with the instructions issued by the Central Govt./State Govts./Union Territory Administration., as the case may be, from time to time."

3. In the said regulations, in regulation 10 for Table III and Table IV, the following tables shall be substituted, namely—

"TABLE III—**Diploma in Pharmacy (Part-I) Examination**

Subject	*Maximum marks for Theory*			*Maximum marks for Practical*		
	Examinaton	**Sessional*	*Total*	*Examinaton*	*Sessional*	*Total*
Pharmaceutics-I	80	20	100	80	20	100
Pharma. Chemistry-I	80	20	100	80	20	100
Pharmacognosy	80	20	100	80	20	100
Biochemistry & Clinical Pathology	80	20	100	80	20	100
Human Anatomy & Physiology	80	20	100	80	20	100
Health Education & Community Pharmacy	80	20	100	—	—	—
Total			600		+	500
						= 1100

*Internal assessment

TABLE IV—**Diploma in Pharmacy (Part-II) Examination**

Subject	*Maximum marks for Theory*			*Maximum marks for Practical*		
	Examinaton	**Sessional*	*Total*	*Examinaton*	*Sessional*	*Total*
Pharmaceutics-II	80	20	100	80	20	100
Pharm. Chemistry-II	80	20	100	80	20	100
Pharmacognosy & Toxicology	80	20	100	80	20	100
Pharmaceutical Jurisprudence	80	20	100	—	—	—
Drugs Store & Business Mgt.	80	20	100	—	—	—
Hospital & Clinical Pharmacy	80	20	100	80	20	100
Total			600		+	400
						= 1000

*Internal assessment"

4. In the said regulations, for the regulation 14, the following regulation shall be substituted, namely—

"14. Award of sessional marks and maintenance of records :

(1) A regular record of both theory and practical class work and examinations conducted in an institution imparting training for Diploma in Pharmacy Part-I and Diploma in Pharmacy Part-II courses, shall be maintained for each student in the institution and 20 marks for each theory and 20 marks for each practical subject be allotted as sessionals.

(2) There shall be at least two periodic sessional examinations during each academic year. The highest aggregate of any two performances shall form the basis of calculating sessional marks.

(3) The sessional marks in practicals shall be allotted on the following basis :

(*i*) Actual performance in the sessional examination — 10 marks.

(*ii*) Day to day assessment in the practical class work — 10 marks."

5. In the said regulations, in APPENDIX-B, in paragraph (B), under the heading STAFF, the followin entries shall be added, namely—

"Lecturers	
(1) Anatomy and Physiology (2) Biochemistry and Clinical pathology	M. Pharm *or* B Pharm with 3 years teaching/ professional experience *or* M.B.B.S.

The pay scale of teaching staff shall be as prescribed by the A India Council for Technical Education for teaching staff of Polytechir from time to time."

6. In the said regulations, in APPENDIX-C after paragraph the following paragraph shall be added, namely :—

"7. The Chairman and at least one expert member of Examin Committee of the Examining Authority concerned with appointm of examiners and conduct of pharmacy examination should persons possessing pharmacy qualifications."

DEVINDER K. JA
Secretary-cum-Regis