



CEYLON MEDICAL COLLEGE COUNCIL SRI LANKA

REGULATIONS FOR THE EXTERNAL PHARMACISTS' APPRENTICE COURSE AND EXAMINATION FOR THE AWARD OF CERTIFICATE OF EFFICIENCY IN PHARMACY (Effective 1st July 2004)

Part I - REGULATIONS

1. PROGRAMME OUTLINE

1.1 Introduction

The apprentice pharmacists' training is an on the job training programme lasting for not less than two years according to the requirements laid down by the Medical Ordinance. It is a broad based training programme to prepare the prospective pharmacist to sit for the examination which qualifies him/her for registration as a pharmacist and thereafter to practice the profession of pharmacy.

1.2 Objective of the apprenticeship

The programme is aimed at making the candidate self-sufficient and competent in running a retail pharmacy. The training covers the Good Dispensing Practices (GDP) requirements applicable to retail pharmacy practice, dispensing over the counter drugs (OTC), prescription only medicine (POM), extemporaneous and prefabricated medicines, reconstitution techniques, Latin abbreviations, surgical items, devices, forensic pharmacy, patient counselling and all other relevant areas in line with the updated 2004 syllabus of the Ceylon Medical College Council for the External Pharmacists' Examination.

1.3 Admission requirements

Apprenticeship shall commence on completing the indenture form available with the Sri Lanka Medical Council. It shall be kept with the apprentice. The candidate should be not less than 18 years of age on the day of signing the indenture and commencing apprenticeship.

1.4 Qualifications

- 1) Individuals successful at the General Certificate of Education (Ordinary Level) Examination of Sri Lanka or an equivalent Examination of a foreign country including a pass in English Language.

and

Successful at one and the same General Certificate of Education (Advance Level) Examination of Sri Lanka or an equivalent examination of a foreign country with a pass in Chemistry and at least two passes in Biology, Botany, Zoology, Physics, Agriculture, Applied Mathematics, Combined Mathematics, Pure Mathematics or such other similar science subject acceptable to the Council.

or

- 2) Individuals with a General or Special Bachelor's Degree of any recognized University in Sri Lanka or abroad in the following: Science, Biology, Biochemistry and Molecular Biology, Physical Science, Applied Science, Health Promotion, Food Science and Nutrition, Food Science and Technology, Agriculture Technology and Management, Agriculture or an equivalent General or Special bachelor's Degree in Science acceptable to the Council.

1.5 Duration

From the date of signing the indenture the two year apprenticeship shall commence immediately. The prescribed training record book should be maintained by the candidate. The candidate is eligible to sit for the examination two calendar years after such date.

1.6 Place of training

The apprenticeship must be undertaken at the registered pharmacy situated at the address appearing under section 2 (a) of the indenture. The registered pharmacy should be equipped to cater to the requirements set out under section 1.2 above.

1.7 Inspection

The apprentice should procure the training record book and present it at the viva voce. The training records should be presented to any Ceylon Medical College Council Examiner of this examination or any officer authorized by the Ceylon Medical College Council for assessment during the two or more years apprentice period.

Training

Training shall be provided by the master pharmacist whose name appears in the indenture. The training records of immediate two years prior to the examination is required. It should be certified by the master pharmacist and produced at the time of practical examination.

The Ceylon Medical College Council may inspect the pharmacy named in the indenture to determine its suitability for training and may declare the pharmacy unacceptable for training purpose of the examination.

1.8 Fees Payable (See Annex)

1.9 Frequency of examination

The examination shall be usually held once or twice a year as determined by the Ceylon Medical College Council.

1.10 Correspondence

All correspondence should be addressed to the Registrar, Ceylon Medical College Council, Faculty of Medicine, Kynsey Road, Colombo 8.

2. EXAMINATION AND THE AWARD OF THE CERTIFICATE

2.1. Examination

The External Pharmacists' Examination is conducted by a Board of Examiners appointed by the registrar of the Ceylon Medical College Council.

The candidate is permitted a maximum of five attempts within five years after the first attempt at the examination.

2.2 Written Examination (3 hours)

Written papers

Part I - MCQ 40 Questions 60% Marks

Part II - Essay 5 Questions 40% Marks

Candidates with a score 40% and above shall be called for practical and viva voce tests.

2.3 Practical Component (3 hours)

Shall consist of the preparation of 3 extemporaneously compounded products dispensing of prescriptions and spot identification tests. It may be conducted in the form of objective structured practical examination (OSPE).

2.4 Viva Voce Component

Evaluation of apprentice training records.

Prefabricated dosage forms, cosmetics and devices

Questions pertaining to all aspects of retail pharmacy practice and syllabus including regulatory affairs, patient care and counselling.

2.5 Marking Scheme

	Written	Practical	Viva	Total
Contribution %	60%	20%	20%	100%
Pass mark*	40%	40%	40%	50%

- * The interpretation here is that the written, practical and viva components are given 100 marks and the candidate must score at least 40% or above in each.

Candidates should complete all components in one and the same examinations and achieve an overall average of 50% marks.

2.6 Results

Results shall be published in the news papers and displayed at the office of the Registrar for the Ceylon Medical College Council, Faculty of Medicine, Kynsey Road, Colombo 8, subject to confirmation by the Ceylon Medical College Council.

2.7 Rescrutiny

Candidates may appeal for rescrutiny after paying the prescribed fee (annex)

2.8 Award of Certificate of Efficiency in Pharmacy

The Candidate may be awarded the "*Certificate of Efficiency in Pharmacy*" by the Ceylon Medical College Council, provided that he/she has fulfilled all of the following.

- 2.8.1 carried out the apprenticeship according to the terms of the Sri Lanka Medical Council indenture.
- 2.8.2 submitted the completed apprenticeship training records to the satisfaction of examiners.
- 2.8.3 met the examination criteria successfully.
- 2.8.4 paid the Certificate of efficiency fees and
- 2.8.5 paid such fees or other dues prescribed and met any other criteria prescribed by the Ceylon Medical College Council.

Annex - 1. Examination fees Rs. 5,000/-

- 2. Efficiency certificate fees Rs. 500/-
- 3. Provisional certificate fees Rs. 500/-
- 4. Rescrutiny fees Rs. 1,500/-
- 5. Regulations and syllabus booklet
Apprentice training record book } Rs. 500/-
- 6. Any other fees that may be authorized by the Ceylon Medical College Council.

Part II - SYLLABUS

1. PHARMACY PRACTICE

1.1 Forensic Pharmacy

Laws applicable to pharmacy practice with emphasis on: Cosmetics, Devices and Drugs Act No. 27 of 1980 with amendments and Regulations thereof.

Poisons, Opium and Dangerous Drugs Ordinance.

Medical Ordinance - Registration of Pharmacists.

Food Act - permitted dyes and pigments.

International control of narcotic drugs. International Narcotic Control Board, Conventions on Narcotic and Psychotropic Drugs. National control of narcotic drugs in relation to schedule III drugs - National Dangerous Drugs Control Board.

Pricing of drugs.

Knowledge on the function of State Pharmaceuticals Corporation, State Pharmaceuticals Manufacturing Corporation, National Drugs Quality Assurance Laboratory, Medical Supplies Division, Cosmetics, Devices and Drugs Regulatory Authority and World Health Organization in relation to pharmaceuticals.

1.2 Professional conduct and ethics

The concept of a "Profession", and their Regulatory Councils; professional responsibilities; standards of conduct and practice including the "code of ethics" of the profession.

Working knowledge of the ethical criteria for drug promotion with reference to the World Health Organization Criteria of Ethical Drug Promotion.

Sri Lanka Medical Association (SLMA): Ethical Criteria for the Promotion of Medicinal Drugs and Devices in Sri Lanka.

International Federation of Pharmaceutical Manufacturers Association (IFPMA) code.

Code of Conduct for Medical Representatives of the Sri Lanka Chamber of Pharmaceutical Industry.

1.3 Principles and techniques

Supply of medicine based on pharmaceutical knowledge, legislation and ethical criteria. Identifying authenticity of prescriptions, interpretation of same and avoiding medication errors.

Knowledge of Latin terms.

Sources of reliable pharmaceutical information and communication of information to patients.

Pharmacopoeial, regulatory and in-house standards of raw materials, finished products and packaging material.

Posology

- Weights, measures, strengths, units and their conversions.
- Potency calculations involving active ingredient chemistry.
- Reducing and enlarging formulae, percentage strengths and ratio strengths.
- Alligation.
- Standard dosages, their adoption to paediatric and geriatric dosages, and drugs in pregnancy.

1.4 Labelling of Drugs

Packaging, labelling and storage of drugs.

Labelling requirements.

Product information leaflets.

Storage temperatures.

Hazardous pharmaceuticals.

1.5 Related healthcare products

Herbal preparations, Homeopathic medicines, veterinary drugs, insect and rodent control products, cosmetics, diagnostic kits, contraceptive items, convalescent foods, and sanitary products.

1.6 Pharmacy management

Inventory control, flow of stock, zoning stock within the store; storage at uncontrolled room temperature, storage at controlled room temperature and controlled humidity; cold storage; secure storage.

Stock Classification - Therapeutic or pharmacological category of clinical indication, or alphabetical order, level of use, dosage form, stock storage and handling.

Packaging specification.

Shelving, housekeeping, cleaning and pest control.

Inspection, stock verification, disposal of expired or damage stock.

Fire precautions and security.

Condemned items, inventory control.

Community pharmacy practice; stores management.

2. PHARMACEUTICS

2.1 Formulations

Stability and shelf-life. Non-sterile pharmaceutical preparations.

Extemporaneous preparations - excipients, active ingredients, synonyms and pharmaceutical incompatibilities.

Oral solid dosages - formulation principles of different varieties of tablets and capsules; excipients; methods of granulation;

Oral and other powders.

Oral liquid dosages - solutions, suspensions and emulsions.

Powder for reconstitution, syrups, elixirs; suspending and emulsifying agents.

External preparations - suppositories, enemas, lotions, liniments, creams, ointments, ointment and cream bases and finished preparations.

Application of polymeric systems in drug delivery.

2.2 Special products

Aerosols, metered dose inhalers and inhalations.

Modified and sustained release dosage forms - tablets capsules, injections.

2.3 Sterile preparations

An understanding of basic manufacture, strengths, stability, labelling and dispensing of parenteral preparations.

Solvents for injections.

Intravenous infusions.

Eye preparations.

External preparations for open wounds.

2.4 Devices

A basic knowledge of sutures, ligatures, catheters, syringes, needles, intravenous administration sets, surgical dressings, urine incontinence aids, devices applicable to the eye.

2.5 Packaging technology

Understanding of different kinds of packages and packaging material.

2.6 Physical pharmacy

Basic concepts of pH, pKa, pKb, solubility, ionization, buffers and colligative properties.

2.7 Unit processes in pharmacy

Basic principles and pharmaceutical applications of the following.

Trituration, mixing.

Temperature and humidity control.

Extraction, maceration, percolation.

Filtration.

Drying, freeze drying.

Comminution, sieving.

Evaporation, distillation.

Centrifugation and clarification.

3. MICROBIOLOGY AND IMMUNOLOGY

3.1 Microbiology

Principles of aseptic procedures, tests for sterility and pyrogens, sterilization processes in the preparation of pharmaceutical products and medical devices.

Principles of preservation against microbial contamination.

Microorganisms of pharmaceutical interest.

Disinfectants and antiseptics.

Preservatives, physical methods of preservation.

3.2 Immunology

Principles of immunology; passive and active immunization.

Antigens, antibodies.

Hypersensitivity reactions.

Vaccines, sera and biological preparations.

Immunization programme in Sri Lanka.

Maintenance of cold chain.

4. BASICS OF QUALITY CONTROL AND QUALITY ASSURANCE

Official compendial requirements.

Friability and disintegration tests.

Dissolution test.

Assay and potency determination.

Limit test for by-products.

Contaminants.

Particulate matter.

Basic laboratory tests.

Visible signs of quality failure.

5. NATURAL PRODUCTS IN PHARMACY PRACTICE (PHARMACOGNOSY)

Chemical classification of crude drugs.

Pharmacognostic features of medicinal plants.

Pharmaceutical agents derived from natural products with special reference to senna, digitalis, opium, ipecacuanha, cinchona, vinca rosea, belladonna, clove, cinnamon, castor, dill, cascara, colchocum, ginger, cardamom, coca, glycyrrhiza, peppermint, artemisia, agar, gelatin, gum acacia, tragacanth, cotton, cocoa starches, celluloses, fixed and volatile oils and waxes.

Flavours and colouring agents.

Other popular extracts and tinctures in use.

Drugs derived from petroleum and minerals.

Natural substances in the development of modern medicine.

6. PHARMACOLOGY AND THERAPEUTICS

The meaning of the terms and knowledge of the following. Nomenclature of drugs and pharmaceuticals - chemical name, international nonproprietary names (INN), generic names, brand / proprietary names. Pharmacokinetics and Pharmacodynamics - main steps in the pharmacokinetic process and alterations in drug handling in the neonate, and with ageing and disease.

A basic understanding of human anatomy and physiology related to the study of pharmacy - gastrointestinal tract, respiratory tract, urinary system, circulatory system, autonomic central nervous system, reproductive organs and the skin. Comprehensive knowledge of the mechanism of action, indications, adverse effects, special storage conditions, interactions, precautions and contraindications of schedule I and II A drugs registered in Sri Lanka.

A basic knowledge of the mechanism of action, indications, common and serious adverse effects, special storage conditions, interactions, precautions and contraindications of the drugs in the Essential Drug List (EDL).

A knowledge of the therapeutic category, different formulations of registered drugs available for use in Sri Lanka.

Knowledge of common methods of poisoning and the antidotes, methods of prevention of poisoning, and emergency treatment of poisoning, A basic understanding of laboratory diagnostic test reports.

7. PRACTICAL

Prescription reading, calculation, preparation and labelling of extemporaneously dispensed products.
Spot identification tests.
Paediatric dosages.
Dispensing prefabricated drugs.

8. RECOMMENDED READING MATERIALS

List of Essential Drugs - Ministry of Health, Sri Lanka
British Pharmacopoeia by Her Majesty's Stationary Office
British National Formulary - The Pharmaceutical Press. A recent edition.
Pharmaceutical Practice - D M Collet, M E. Aulton
Clinical Pharmacology - Lawrence & Benette
Manual on Management of Drugs - Ministry of Health, Sri Lanka
Management of Drug Supplies - World Health Organization
Drug Regulatory Authority of Sri Lanka - publications and circulars
Poisons, Opium and Dangerous Drugs Ordinance
Cosmetics, Devices and Drugs Act. No 27 of 1980, the amendments and the Regulations No 38 of 1984
Other relevant acts, gazette notifications and official circulars
Good Manufacturing Practices by the World Health Organization
Physical Pharmacy by Alfred, James and Arthur
Textbook of Pharmacognosy by Trease and Evans

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