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 August 2024)

Ceylon Medical College Council
1st Floor, UCFM Tower,
Faculty of Medicine, Maradana Road,
Colombo 08, Sri Lanka.

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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 basedtraining 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 profession.

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 counseling and all other relevant areas in line with the updated syllabus of the Ceylon Medical College Council for the External Pharmacists' Examination.

1.3 Admission requirements

Apprenticeship shall commence upon 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

Individuals successful at the General Certificate of Education (Ordinary Level) Examination of Sri Lanka or an equivalent Examination including a pass in English language

and

Successful at one and the same General Certificate of Education (Advanced Level) Examination of Sri Lanka or an equivalent examination with a pass in **Chemistry** and at least two passes in Biology, Botany, Zoology, Physics, Agriculture or other similar **Biological science** subject 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 signing the indenture.

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 purchase procure the training record book, complete it, and present it at the practical test and *viva voce*. The training records should be presented to any Ceylon Medical College Council Examiner 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 are mandatory. 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 purposes after inspection.

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, 1st Floor, UCFM tower, Faculty of Medicine, Maradana 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 (5) years after the first attempt at the examination.

2.2 Written Examination (3 hours)

Written papers
Part I – MCQ 50 Questions 50% Marks
Part II – Essay 5 Questions 50% Marks

Candidates with a score 40% and above in the written papers shall be called for practical and *viva voce* tests.

2.3 Practical Component (2 hours)

Shall be in the form of an Objective Structured Practical Examination (OSPE) with about 40 items and 2 rest stations.

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 pharmacology, regulatory affairs, patient care and counseling.

2.5 Marking Scheme

	Written	**Practical**	***Viva voce***	**Total**
Contribution%	**50%**	**40%**	**10%**	**100%**
Pass mark*	**40%**	**30%**	**30%**	**50%**

* The interpretation here is that the written, practical and *viva* components are given 100 marks and the candidate must score at least 30% or above in each.
Candidates should complete all components in one and the same examination and achieve an overall average of 50% marks.

2.6 Results

Results shall be published in the cmcc.lk website.

2.7 Re-correction

Candidates may appeal for re-correction of answer scripts 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. Written Examination (Part I) fee – Rs.15,000/-
2. OSPE and *Viva voce* examination (Part II) fee – Rs. 10,000/-
3. Efficiency Certificate fee – Rs. 5000/-
4. Transcript fee – Rs. 10,000/-
5. Re-correction fee – Rs. 3,000/- Regulations and syllabus booklet
6. Grading letter fee – Rs. 2,000/-

7. Apprentice Ttraining Rrecord Bbook – Rs. 2,000/-
8. Any other fees that may be authorized by the Ceylon Medical College Council

Part II – SYLLABUS

1. PHARMACY PRACTICE

1.1 1.1 Forensic Pharmacy

Laws applicable to pharmacy practice with emphasis on: National Medicines Regulatory Authority Act No. 05 of 2015 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 Medicines Quality Assurance Laboratory, Medical Supplies Division, National Medicines 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 Medical 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, labeling and storage of drugs.
Labeling 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 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. None – 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, labeling and dispensing of parenteral preparations.
Solvents for injections.

Intravenous infusions.
Eye preparations.
External preparation for open wounds.

2.4 Devices

A basic knowledge of sutures, ligatures, catheters, syringes, needles, intravenous administration sets, surgical dressing, 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, pK_a, pK_b, solubility, ionization, buffers and colligative properties.

2.7 Unit processes in pharmacy

Basic principles and pharmaceutical applications of the following.

i. Trituration, mixing
ii. Temperature and humidity control
iii. Extraction, maceration, percolation
iv. Filtration
v. Drying, freeze-drying
vi. Comminution, sieving
vii. Evaporation, distillation
viii. Centrifugation and clarification

3. MICROBIOLOGY AND IMMUNOLOGY

3.1 Microbiology

Principles of aseptic procedures, test for sterility and pyrogens, and sterilization processes in the preparation of pharmaceutical product and medical devices.
Principles of preservation against microbial contamination
Microorganisms of pharmaceutical interest
Disinfectants and antiseptics
Preservatives and 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.

i. Nomenclature of drugs and pharmaceuticals – chemical name, international nonproprietary names (INN), generic names, brand / proprietary names.
ii. 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, and 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 test

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
National Medicines Regulatory Authority Act No. 05 of 2015, the amendments and the Regulations No 38 of 1984 its regulations
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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1st August 2024