ANNEXURE - I
ER-2020 (AS PER PHARMACY COUNCIL OF INDIA)
PHARMACY

SECTION I

PHARMACEUTICS

1. **Pharmacopoeia:** Introduction to IP, BP, USP, NF and Extra Pharmacopoeia. Salient features of Indian Pharmacopoeia
2. **Packaging materials**: Types, selection criteria, advantages and disadvantages of glass, plastic, metal, rubber as packaging materials
3. **Pharmaceutical aids**: Organoleptic (Colouring, flavouring, and sweetening) agents, Preservatives**:** Definition, types with examples and uses
4. **Unit operations:** Definition, objectives/applications, principles, construction, and workings of:
   - **Size reduction**: hammer mill and ball mill
   - **Size separation**: Classification of powders according to IP, Cyclone separator, Sieves and standards of sieves
   - **Mixing**: Double cone blender, Turbine mixer, Triple roller mill and Silverson mixer homogenizer
   - **Filtration**: Theory of filtration, membrane filter and sintered glass filter
   - **Drying:** working of fluidized bed dryer and process of freeze drying
   - **Extraction**: Definition, Classification, method, and applications,
5. **Tablets** – coated and uncoated, various modified tablets (sustained release, extended-release, fast dissolving, multi- layered, etc.)
   - **Capsules** - hard and soft gelatine capsules
   - **Liquid oral preparations** - solution, syrup, elixir, emulsion, suspension, dry powder for reconstitution
   - **Topical preparations** - ointments, creams, pastes, gels, liniments and lotions, suppositories, and pessaries
   - Nasal preparations, Ear preparations,
   - **Powders and granules** - Insufflations, dusting powders, effervescent powders, and effervescent granules
   - **Sterile formulations** – Injectable, eye drops and eye ointments
   - **Immunological products**: Sera, vaccines, toxoids, and their manufacturing methods., Basic structure, layout, sections, and activities of pharmaceutical manufacturing plants Quality control and quality assurance: Definition and concepts of quality control and quality assurance, current good manufacturing practice (cGMP), Introduction to the concept of calibration and validation.

HOSPITAL PHARMACY

1. **Different Committees in the Hospital**
    - Pharmacy and Therapeutics Committee - Objectives, Composition, and functions
    - Hospital Formulary - Definition, procedure for development and use of hospital formulary
    - Infection Control Committee – Role of Pharmacist in preventing Antimicrobial Resistance.

2. **Supply Chain and Inventory Control**
    - Preparation of Drug lists - High Risk drugs, Emergency drugs, Schedule H1 drugs, NDPS drugs, reserved antibiotics
    - Procedures of Drug Purchases – Drug selection, short term, long term, and tender/e-tender process, quotations, etc.
    - Inventory control techniques: Economic Order Quantity, Reorder Quantity Level, Inventory Turnover etc.
    - Inventory Management of Central Drug Store – Storage conditions, Methods of storage, Distribution, Maintaining Cold Chain, Devices used for cold storage (Refrigerator, ILR, Walk-in-Cold rooms).
    - FEFO, FIFO methods.
    - Expiry drug removal and handling, and disposal. Disposal of Narcotics, cytotoxic drugs
    - Documentation - purchase and inventory.

3. **Drug distribution**:
    - Drug distribution (in- patients and out - patients) – Definition, advantages and disadvantages of individual prescription order method, Floor Stock Method, Unit Dose Drug Distribution Method, Drug Basket Method.
    - Distribution of drugs to ICCU/ICU/NICU/Emergency wards. Automated drug dispensing systems and devices.
    - Distribution of Narcotic and Psychotropic substances and their storage

4. **Compounding in Hospitals**. Bulk compounding, IV admixture services and incompatibilities,
   Total parenteral nutrition.

5. **Radio Pharmaceuticals -** Storage, dispensing and disposal of Radiopharmaceuticals.

PHARMACY LAW AND ETHICS:

1. **Pharmacy Act-1948 and Rules:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils, Registration of Pharmacists, Offences and Penalties.
   Pharmacy Practice Regulations-2015**.**
2. **Drugs and Cosmetics Act 1940 and Rules 1945 and New Amendments**
   Objectives, Definitions, Legal definitions of schedules to the Act and Rules

- Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit.
- Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and
  repacking license. Study of schedule C and C1, G, H, H1, K, P, M, N, and X. Sale of Drugs – Wholesale, Retail sale and Restricted license, Records to be kept in a pharmacy Drugs Prohibited for manufacture and sale in India
- Administration of the Act and Rules – Drugs Technical Advisory Board, Central Drugs Laboratory, Drugs Consultative Committee, Government analysts, licensing authorities, controlling authorities, Drug Inspectors.

3. **Narcotic Drugs and Psychotropic Substances Act 1985** and Rules Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties.
4. **Drugs and Magic Remedies (Objectionable Advertisements) Act 1954** Objectives, Definitions, Prohibition of certain advertisements, Classes of exempted-advertisements, Offences and Penalties.
5. **Poisons Act-1919:** Introduction, objective, definition, possession, possession for sales and sale of any poison, import of poisons
6. **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO) - 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, Pharmaceutical Policy 2002, National List of Essential Medicines (NLEM)
7. **Code of Pharmaceutical Ethics:** Definition, ethical principles, ethical problem solving, registration, code of ethics for Pharmacist in relation to his job, trade, medical
   profession and his profession, Pharmacist's oath.
8. **Medical Termination of Pregnancy Act and Rules:** basic understanding, salient features, and Amendments
9. **Role of all the government pharma regulator bodies** – Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)
10. **Good Regulatory practices** (documentation, licenses, renewals, e-governance) in Community Pharmacy, Hospital pharmacy, Pharma Manufacturing, Wholesale business**,** inspections, import, export of drugs and medical devices
11. **Medical Devices :** Categorization, basic aspects related to manufacture and sale