Pharma Unit

Pharmacy Law & Ethics

1 Marks Questions with Answers

According to New Syllabus ER 2020-21

2nd Year D. Pharmacy

List of Schedules as per Drugs and Cosmetics Act 1940

1) Schedule A: Includes forms used for licence applications, granting licences, and sending official memorandums.
2) Schedule B: Specifies the fees for tests or analysis conducted by central drug laboratories or government analysts.
3) Schedule C: Contains a list of biological and special products regulated by special provisions for import, manufacture, and sale.
4) Schedule C1: Covers other specific products governed by special rules for import, manufacturing, and sale.
5) Schedule D: Lists drugs exempted from certain provisions related to drug imports.
6) Schedule E: List of Ayurvedic, Siddha, and Unani poisonous substances.
7) Schedule F: Provisions applicable to blood bank requirements and licensing to process blood components.
8) Schedule F(I): Provisions applicable to the production of bacterial and viral vaccines, sera, and diagnostic agents.
9) Schedule F(II): Standards for surgical dressings.
10) Schedule F(III): Standards for umbilical tapes.
11) Schedule FF: Standards for ophthalmic preparations.
12) Schedule G: List of substances required to be taken only under the supervision of an RMP (Registered Medical Practitioner).
13) Schedule H: Prescription drugs that are required to be sold by retail only on the Rx of an RMP.
14) Schedule J: List of diseases or ailments that a drug may not claim to prevent or cure.
15) Schedule M(I): Factory requirements for homeopathic medicines.
16) Schedule M(II): Factory requirements for cosmetics.
17) Schedule M(III): Factory requirements for medical devices.
18) Schedule T: Factory and hygiene requirements for Ayurvedic, Siddha, and Unani medicines.
19) Schedule N: Minimum equipment for pharmacies.
20) Schedule O: Standards for disinfectants.
21) Schedule P: Drug shelf life.
22) Schedule P1: Drug pack sizes.
23) Schedule Q: List of coal tar colours permitted to be used in cosmetics and soaps.
24) Schedule V: Standards for patent and proprietary medicines.
25) Schedule R: Requirements for condoms made of rubber latex intended for single use.
26) Schedule S: Standards for cosmetics.
27) Schedule U: It prescribes the particulars to be shown in the manufacturing records of drugs.
28) Schedule U(I): It prescribes the particulars to be shown in the manufacturing records of cosmetics.
29) Schedule V: It prescribes standards for patent and proprietary medicines.
30) Schedule W: It prescribes the list of drugs which are marketed under generic names only.
31) Schedule X: It prescribes the list of habit-forming narcotic drugs and psychotropic substances for the import, manufacture, distribution, and sale of which requires a license.
32) Schedule Y: It prescribes requirements and guidelines on clinical trials for the import and manufacture of new drugs.

List of All the Important Definitions of Pharmacy Law and Ethics

1) Define Central Council

Ans. Refers to the Pharmacy Council of India constituted under Section 3 of the Pharmacy Act, 1948.

2) Define State Council

Ans. Refers to the State Pharmacy Council constituted under Section 19. It also includes the Joint State Pharmacy Council constituted under Section 20.

3) Define Registered Pharmacist

Ans. A person whose name is, for the time being, entered in the register of pharmacists of the state where they are residing or carrying on their profession or business of pharmacy.

4) Define Displaced Person

Ans. Refers to Any person who, due to the setting up of the dominions of India and Pakistan, or due to civil disturbances or fear of such disturbances in areas now forming Pakistan, has left their residence after March 1, 1947, and has since been residing in India. Any person who, due to civil disturbances or fear of such disturbances in areas now forming Bangladesh, has left their residence after April 14, 1957, but before March 25, 1971, or has been displaced from such place of his residence and since then residing in India.

5) Define Repatriate

Ans. Refers to any person of Indian origin who, due to civil disturbances in any area now forming the part of Burma, Sri Lanka, Uganda, or any other country, has left their residence after March 14, 1957, or has been displaced from such place of residence and has since been residing in India.

6) Define First Register

Ans. Refers to the register of pharmacists prepared under Chapter IV of the Pharmacy Act by the state government before the constitution of the state council.

7) Define Subsequent Register

Ans. Refers to the register of pharmacists prepared under Chapter IV of the Pharmacy Act by the state council after the first register.

8) Define Central Register

Ans. Refers to the register of pharmacists maintained by the Central Council.

9) Define UGC

Ans. Refers to the University Grants Commission, established under Section 4 of the University Grants Commission Act, 1956.

10) Define What is Pharmacy Council of India (PCI)

Ans. The Pharmacy Council of India (PCI) was constituted under **Section 3** of the **Pharmacy Act, 1948**. The first Pharmacy Council of India was constituted by the **Central Government** in **1949**. The council is reconstituted every **5 years**.

11) Define Drug

Ans. Includes, all medicines for internal or external use of human beings or animals, and substances intended for diagnosis, treatment, mitigation, or prevention of diseases or disorders in humans or animals, including preparations applied to the human body to repel insects like mosquitoes. Substances (other than food) intended to affect the structure or function of the human body or for the destruction of vermin or insects causing diseases in humans or animals. All substances intended for use as components of drugs, including empty gelatin capsules. Devices intended for internal or external use in diagnosis, treatment, mitigation, or prevention of diseases or disorders in humans or animals.

12) Define Ayurvedic, Siddha, and Unani Drugs

Ans. Includes medicines for internal or external use for diagnosis, treatment, mitigation, or prevention of diseases or disorders in humans or animals and manufactured according to formulae described in books of Ayurveda, Siddha, and Unani systems of medicine as specified in the first schedule of the Drugs and Cosmetics Act, 1940.

13) Define Homeopathic Medicines

Ans. Includes drugs recorded in homeopathic literature, whose therapeutic efficacy has been established through long clinical experience and which are prepared according to homeopathic techniques but does not include medicines for parenteral use.

14) Define Manufacture

Ans. Refers to any process or part of the process for making, altering, ornamenting, finishing, labeling, or breaking up any drug or cosmetic for sale and distribution, but does not include compounding or dispensing of drugs or the packing of drugs in the ordinary course of retail business.

15) Misbranded Drug

Ans. Refers to a drug that Is coloured, coated, powdered, or polished to conceal damage or make it appear of better therapeutic value than it is, Is not labelled as prescribed, Has a false or misleading label or makes a false claim.

16) Adulterated Drug

Ans. A drug is considered adulterated if It consists, in whole or in part, of any filthy, putrid, or decomposed substance, It has been prepared, packed, or stored under insanitary conditions likely to make it injurious to health, It is packed in containers composed of poisonous substances, It contains an unapproved colour. It contains harmful or toxic substances that may render it injurious to health. Any substance has been mixed with it to reduce its quality or strength.

17) Define Spurious Drug

Ans. A drug is spurious if it is imported under the name of other drugs, It is an imitation or substitute for another drug, It resembles another drug in a way that may cause deception, It bears a fictitious manufacturer's name or a name of a non-existent manufacturer, It is claimed to be the product of a manufacturer but is not.

18) Define Drug Inspector

Ans. In relation to Ayurvedic, Siddha, or Unani drugs, it refers to an inspector appointed by the central or state government under Section 33 G of the Act.
In relation to other drugs and cosmetics, it refers to an inspector appointed by the central or state government under Section 21 of the Act.

19) Define Government Analyst

Ans. In relation to Ayurvedic, Siddha, or Unani drugs, it refers to a person appointed under Section 33 F.
In relation to other drugs and cosmetics, it refers to a person appointed by the central or state government under Section 20 of the Act.

20) Define chemist and druggist?

Ans. Refers to premises licensed for the sale of drugs requiring the services of a qualified person, but where drugs are not compounded against the prescription of a Registered Medical Practitioner (RMP).

21) Define Cosmetics?

Ans. Refers to any article intended to be applied to any part of the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of a cosmetic.

22) Define Misbranded Cosmetic?

Ans. Refers to a cosmetic that Contains an unapproved colour., Is not labelled in the prescribed manner., Makes false or misleading claims.

23) Define Spurious cosmetics?

Ans. Refers to a cosmetic that: Imported under the name of another cosmetic, An imitation or substitute for another cosmetic, Resembles another cosmetic in a way that may cause deception, Bears the name of a non-existent manufacturer, Is claimed to be the product of a manufacturer but is not.

24) Define Psychotropic Substances

Ans. Any substance (natural or synthetic) or its salt or preparation, which is included in the list of psychotropic substances in the relevant schedule. Examples include mescaline, diazepam, nitrazepam, phenobarbitone, chlordiazepoxide, and amphetamine.

25) Define Narcotic Drugs

Ans. Includes coca leaf, cannabis, opium, poppy straw, and all manufactured drugs.

26) Define Advertisement

Ans. It refers to Any notice, circular, label, wrapper, or other document. Any announcement made orally or through the production or transmission of light, sound, or smoke.

27) Define Magic Remedy

Ans. It includes talismans, mantras, kavachas, and other charms of any kind that claim to possess miraculous powers for the diagnosis, cure, mitigation, treatment, or prevention of diseases in human beings or animals or for altering any organic function of human or animal bodies.

28) Define poison?

Ans. The term refers to all substances that have been notified as poisons under the Poison Act, 1919. The substances are categorized as follows - List A Morphine, atropine, arsenic, heroin, potassium cyanide, belladonna, coca, strychnine, barbituric acid, cyanide, ecgonine, lead, aconite digitalis, aconine, ergot. List B Chloroform, zinc chloride, oxalic acid, carbolic acid, barium sulphate.

29) Define Active Pharmaceutical Ingredient

Ans, It refers to any pharmaceutical, chemical, biological, or plant product, including its salts, esters, isomers, analogues, and derivatives, that conforms to the standards specified in the Drugs and Cosmetics Act, 1940

30) Define Ceiling Price

Ans. It refers to the price fixed by the government for scheduled formulations in accordance with the provisions of the relevant order.

31) Define Ethics

Ans. Ethics means rules by which a profession regulates actions and sets standards for all its members.

32) Define CDSCO

Ans. The Central Drugs Standards Control Organization (CDSCO) is Indian National Regulatory body for drugs, cosmetics, medical and diagnostic devices and clinical trials.

33) Define NDA (New Drug Application)

Ans. The NDA is a crucial step in the drug approval process, required to be submitted to the USFDA before a drug can be commercially marketed.

34) Define ANDA (Abbreviated New Drug Application)

Ans. An ANDA includes data that, when submitted to the FDA's Office of Generic Drugs, facilitates the review and approval of a generic drug product.

35) Define IND (Investigational New Drug Application)

Ans. An IND is a submission made to the FDA seeking permission to begin clinical trials of a new drug product.

36) Define bioethics?

Ans. Bioethics is the field of study that addresses the ethical issues arising from advancements in biology and medicine.

37) Define Medical device?

Ans. A medical device is an instrument, apparatus, in vitro reagent, implant, or similar article intended for use in diagnosing a disease or condition, or for affecting the structure or function of the body. It achieves its primary intended purposes without relying on chemical action within or on the body.

Important Full form of Pharmacy Law and Ethics

1) DEC - Drug Enquiry Committee
2) CDL - Central Drug Laboratory
3) DTAB - Drug Technical Advisory Board
4) DCC - Drugs Consultative Committee
5) PCI - Pharmacy Council of India
6) NPPA - National Pharmaceutical Pricing Authority
7) DPEA - Drug Price Equalization Account
8) DPCO - Drug Price Control Order
9) NELM - National List of Essential Medicines
10) MAPE - Maximum Allowable Post Manufacturing Expenses
11) WPI - Wholesale Price Index
12) CPCSEA - Committee for the Purpose of Control and Supervision of Experiments on Animals
13) IAEC - Institutional Animal Ethical Committee
14) FSSAI - Food Safety and Standards Authority of India
15) IPC - Indian Pharmacopoeia Commission
16) CDSCO - Central Drugs Standard Control Organization
17) CLAA - Central Licensing Approval Authority
18) GRPs - Good Regulatory Practices
19) GPP - Good Pharmacy Practice
20) PMRs - Patient Medication Records
21) GMP - Good Manufacturing Practice
22) GDP - Good Documentation Practice
23) BCS - Biopharmaceutical Classification System
24) NDA - New Drug Application
25) ANDA - Abbreviated New Drug Application
26) INDA - Investigational New Drug Application
27) FDA - Food and Drug Administration
28) IPRs - Intellectual Property Rights
29) TRIPS - Trade Related Aspects of Intellectual Property Rights
30) WTO - World Trade Organization
31) EUA - Emergency Use Authorization
32) NDCT - New Drugs and Clinical Trials
33) BMW - Biomedical Waste
34) ICMR - Indian Council of Medical Research
35) EC - Ethics Committee
36) SDMA - State Disaster Management Authority
37) DDMA - District Disaster Management Authority
38) NDMA - National Disaster Management Authority
39) IMDRA - Indian Medical Devices Regulation Act

Important Year for Pharmacy Law and Ethics

1) 1931 - DEC appointed under the chairmanship of Col. R.N. Chopra
2) 1811 - First chemist shop opened in Calcutta by Mr. Bathgate
3) 1937 - 'Import of Drugs Bill' introduced in the legislative assembly to control the import of drugs
4) 1930 - The Drug Bill introduced
5) 2010 - The sixth edition of the Indian Pharmacopoeia published
6) 1923 - The Pharmaceutical Society of India established
7) 1903 - Prof. T.K. Gajjar initiated a small factory at Parel (Bombay)
8) 1948 - The Pharmacy Act came into force
9) 1949 - First Pharmacy Council of India (PCI) constituted
10) 1948 - PCI constituted under Section III of the Pharmacy Act
11) 1948 - First register prepared by the state government under Chapter IV of the Pharmacy Act
12) 1940 - The Drugs and Cosmetics Act passed
13) 1985 - The Narcotic Drugs and Psychotropic Substances Act passed
14) 1930 - The Dangerous Drugs Act passed
15) 1924 - The second International Opium Conference held
16) 1972 - The Geneva Convention held on Narcotic Drugs
17) 1954 - The Magic Remedies Act passed
18) 1960 - The Prevention of Cruelty to Animals Act passed
19) 1919 - The Poison Act passed
20) 1968 - The Insecticide Act passed
21) 1954 - The Food and Adulteration Act passed
22) 2006 - The Food Safety and Standards Act passed
23) 1997 - The NPPA constituted
24) 1971 - The Medical Termination of Pregnancy (MTP) Act passed
25) 1948 - The Indian Pharmaceutical Committee appointed
26) 2004 - The Indian Pharmacopoeia Commission (IPC) established
27) 1940 - The Trademark Act passed in India
28) 1970 - The Patent Act in India implemented
29) 1972 - The Patent Act in India enforced
30) 1995 - The WTO (World Trade Organization) established
31) 2019 - The "New Drugs and Clinical Trials" Rules notified by the Ministry of Health and Family Welfare
32) 1856 - The Patent System first introduced in India
33) 1986 - The Consumer Protection Act passed
34) 2005 - The Disaster Management Act passed
35) 2009 - The IMDRA (Indian Medical Devices Regulation Act) came into force

Extra Questions

1) Who maintains the central register of pharmacists?
Answer: Registrar
2) What is the penalty for failure to surrender the certificate of registration?
Answer: ₹50
3) What is the minimum age limit for registration as a pharmacist?
Answer: 18
4) What is the total area required for a retail and wholesale drug store together?
Answer: 15 (sq.m.)
5) How many copies of the register must each State Pharmacy Council supply to the central council?
Answer: 5
6) How many persons does the Registration Tribunal for the first register consist of?
Answer: 3
7) Within how many days can a person aggrieved by the decision of the Registration Tribunal appeal?
Answer: 60 days
8) What is the minimum age for pharmacist registration?
Answer: 18
9) Where are antisera tested?
Answer: Izzatnagar
10) Where are biologicals tested?
Answer: Kasauli
11) Where is the Central Drug Laboratory located?
Answer: Calcutta
12) What is the Chairman of DTAB?
Answer: Director (General Health Services)
13) Who is the pioneer/father of the blood bank?
Answer: Charles Richard Drew

All The Best For Your Exam

Very Imp Note:

- Please Read All the chapters very carefully before Pharmacy Law and Ethics Exam.
- These questions are only for the reference purpose.