

KATHMANDU UNIVERSITY
End Semester Examination
May/June, 2023

Marks Scored:

Level : B.Pharm.

Year : IV

Exam Roll No. :

Time: 30 mins.

Course : PHAR 416

Semester : II

F. M. : 20

Registration No.:

Date : *June-02-2023*

SECTION "A"

[20Q. × 1 = 20 marks]

Encircle the most appropriate alternative from each set of choices.

- Which of the following section of Drug Act has provision of prohibition of sale and distribution of drug not confirming the prescribed standard?
a. 12 b. 13 c. 14 d. 25
- As per Drug Act 2035, "Misuse and Abuse" of drug is in section
a. 18 b. 19 c. 13 d. 12
- The pharmacy registration license becomes void if not renewed within
a. 35 days of expiration c. One year after expiration
b. Three months after expiration d. Five years after expiration
- Which regulation/codes classifies drugs in groups/sub-groups?
a. Drug Registration Regulation
b. Drug Standard regulation
c. Codes on Sale and Distribution of drugs
d. Codes on Drug Manufacture
- Under which section of drug act 2035, Department of Drug Administration was established?
a. 3 b. 4 c. 5 d. 6
- The combinations of antibiotics are banned by Government of Nepal except
Antibiotics.
a. Penicillin and Sulphonamide c. Nalidixic Acid and Metronidazole
b. Rifampicin and Isoniazid d. Ofloxacin and Sulphonamide
- Department of Drug Administration was first established under
a. Ministry of Health c. Ministry of Home
b. Ministry of Industry d. Ministry of Forest
- The bodies which advise Government of Nepal on the basic principles and administrative matters relating to drugs is
a. Drug Advisory Committee c. Nepal Pharmacy Council
b. Drug Consultative Council d. Nepal Health Research Council
- The function, duties and power of Drug Consultative Council does not cover to
a. Uplift the quality of pharmacy education
b. Fix the price of drugs
c. Prohibit sale of drug
d. Transportation of Drugs

10. Which of the following is not the jurisdiction of Nepal Pharmacy Council?
 - a. Make policy related to pharmacy profession
 - b. Cancel the license of a pharmacist
 - c. Act for the availability of medicine
 - d. Inspection of examination conducted by universities
11. As per Pharmacy Council Act, Pharmacy Profession is defined as except
 - a. Those involved Quality Control of Medicines
 - b. Those involved in Pharmaceutical Industry
 - c. Those involved in Community Pharmacy
 - d. Those involved in Hospital Pharmacy
12. Schedule 4Kha is related with
 - a. Application for Sales Registration Certificate
 - b. Sales Registration Certificate
 - c. Application for Import Registration Certificate
 - d. Import Registration Certificate
13. List drugs that have been approved for use on the basis of therapeutic and economic considerations is
 - a. Therapeutic drug list
 - b. Narcotic List
 - c. Investigational drug list
 - d. Formulary
14. What is the maximum penalty against the sale of antibiotics without prescription, if there is chances of injury to health with the use of such antibiotics?
 - a. Up to life imprisonment and fine
 - b. Up to 10 years imprisonment and fine
 - c. Up to 5 years imprisonment and fine
 - d. Up to 3 years imprisonment and/or fine up to Rs. 25000
15. All of the followings are regulated by Drug act except
 - a. Patent Right
 - b. Clinical Trial
 - c. Drug Advertisement
 - d. Price control
16. Code on Drug production (AusadhiUtpadanSanghita) is
 - a. Equivalent to GMP guidelines
 - b. Just Quality Control document
 - c. Describes the production documents
 - d. Instructs for inventory record
17. The chairman of "Drug Advisory Committee" is
 - a. Hon Minister of Health
 - b. Director General of DDA
 - c. Secretary of Ministry of Health
 - d. DG of Dept of Health Services
18. As per Drug Act 2035, Pethidine is grouped under
 - a. Ka
 - b. Kha
 - c. Ga
 - d. Gha
19. The provision of management for narcotic drugs is in Section ... of Drug Act 2035.
 - a. Section 27
 - b. Section 33
 - c. Section 17
 - d. Section 28
20. Which one is not mentioned in Drug Act?
 - a. Drug Consultative Council
 - b. Department of Drug Administration
 - c. Drug Advisory Committee
 - d. Nepal Pharmacy Council

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Time : 2 hrs. 30 mins.

SECTION "B"

[5Q. × 3 = 15 marks]

Attempt *ANY FIVE* questions.

1. List the regulations made under Drug Act 2035. Why those regulations are made by the Government of Nepal?
2. List the Pharmacopoeias recognized by the Government of Nepal.
3. What is the main aim of introducing codes for drug sale and distribution?
4. What are consumer rights?
5. Write down the powers of Inspector and Administrator as per Drug Act 2035.
6. Which organization is responsible for the implementation of drug act and when it is established?
7. List the Narcotic and Psychotropic Drugs used in pharmaceutical dosage form as per Narcotic Control Substances Act 2033.

SECTION "C"

[5Q. × 5 = 25 marks]

Attempt *ANY FIVE* questions.

8. What is the basis of drug classification as per drug act with examples?
9. What is the role of Pharmacists for ethical promotion of medicine?
10. Write down about the constitution of Drug Advisory Committee.
11. Point out factors which affect the effective implementation of drug regulation.
12. What qualifications are required to be a dispenser, prescriber, inspector and analyst?
13. Discuss the roles of pharmacists in the present context.
14. Briefly write down about the different organizations related to the pharmaceutical field.

SECTION "D"

[2Q. × 7.5 = 15 marks]

Attempt *ANY TWO* questions.

15. Write down about the preamble of Drug Act 2035. Enumerate the process for marketing authorization in Nepal. What is the provision for Pharmacy Practice as per Drug Act and Regulation made under?
16. Explain the process for forming the Nepal Pharmacy Council (NPC). Elaborate power, function and duties of NPC. Write down the process for registration of Pharmacists as per the NPC act.
17. Enumerate briefly the objectives, strategies and achievement of the National Drug Policy 1995?