

KATHMANDU UNIVERSITY
End Semester Examination
March/April, 2022

Level : B. Pharm.
Year : IV
Time : 2 hrs. 30 mins.

Course : PHAR 416
Semester : II
F.M. : 55

SECTION "B"

[5Q × 3 = 15 marks]

Attempt *ANY FIVE* questions.

1. Lists the regulation made under Drug Act 2035. Why those regulations are made by Government of Nepal?
2. As per Drug Act 2035, what qualifications are required to be dispenser, prescriber, Inspector and Analyst.
3. On what basis drugs are classified as per Drug Act 2035.
4. What are rights of consumers?
5. Write down powers of Inspector and Administrator as per Drug Act 2035.
6. Write down the objectives of Drug Act 2035.
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. Enumerate the procedure for standardization of drugs which are not included in any of pharmacopoeias.
9. What is the role of Pharmacists for ethical promotion of medicine?
10. Write down constitution of Drug Advisory Committee.
11. Please point out factors which affect for effective implementation of drug regulation.
12. Define Narcotic Substance as per Narcotic Substances Control Act. How would relate Drug Act 2035 and Narcotic Substances Control Act 2033?
13. Discuss the role of pharmacists in the present context.
14. Briefly write down different organizations related to pharmaceutical fields.

SECTION "D"

[2Q × 7.5 = 15 marks]

Attempt *ANY TWO* questions.

15. Please write down the brief history of pharmaceutical development in Nepal with special focus to pharmaceutical industry and education.
16. What are provisions and processes that are in place in Nepal to ensure safe, effective and quality medicines?
17. Enumerate briefly strategies and achievement of National Drug Policy 1995?



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Registration No.:

Date :

SECTION "A"
[20Q × 1 = 20 marks]

Encircle the most appropriate option.

1. Drugs Act of Nepal is concerned with the following EXCEPT:
a. Efficacy b. Safety c. Abuse d. Availability
2. As per Drug Act 2035, "Misuse and Abuse" of drug is in section ...
a. 18 b. 19 c. 13 d. 12
3. Which of the following is not the component of GMP?
a. Premises b. Advertisement c. Self-audit d. Documentation
4. The combinations of antibiotics are not banned by Government of Nepal except the following Antibiotics
a. Penicillin and Sulphonamide b. Rifampicin and Isoniazid
c. Nalidixic Acid and Metronidazole d. Ofloxacin and Sulphonamide
5. Department of Drug Administration was first established under....
a. Ministry of Health b. Ministry of Industry
c. Ministry of Home d. Ministry of Forest
6. As per Drug Act, the following categories Health Professionals are authorized to sale and distribute all categories of medicine except
a. Certificate Level in Pharmacy b. MD in Pharmacology
c. Vyabasai d. Pharmacists
7. The following is the required qualification to be appointed as analyst as per drugs act except...
a. Bachelor in Pharmacy b. Certificate in Pharmacy
c. Master in Chemistry d. Bachelor in Chemistry with experience
8. National Drug Policy emphasizes on which of the following
a. Quality, Safety and Efficacy
b. Quality, Safety, Availability and Efficacy
c. Quality, Safety, Availability, Affordability and Efficacy
d. Quality, Safety and Availability
9. The pharmacy registration license becomes void if not renewed within ...
a. 35 days of expiration b. Three months after expiration
c. One year after expiration d. Five years after expiration
10. Who is eligible to be an investigation officer as per Drug Act, 2035?
a. Chemists
b. Personnel from CDO Office
c. At least Inspector appointed as per Drug Act
d. Police Inspector

11. 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
12. 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
13. 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
14. 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
15. 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
16. 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
17. All of the followings are regulated by Drug act except:
 - a. Patent Right
 - b. Clinical Trial
 - c. Drug Advertisement
 - d. Price control
18. Code on Drug production (Ausadhi Utpadan Sanghita) is
 - a. Equivalent to GMP guidelines
 - b. Just Quality Control document
 - c. Describes the production documents
 - d. Instructs for inventory record
19. 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 Department of Health Services
20. As per Drug Act 2035, Pethidine is grouped under:
 - a. Ka
 - b. Kha
 - c. Ga
 - d. Gha