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KATHMANDU UNIVERSITY
End Semester Examination
July/August, 2018

Level : B. Pharm.

Year : IV

Course : PHAR 416

Semester: II

Exam Roll No. :

Time: 30 mins.

F. M. : 20

Registration No.:

Date **JUL 31 2018**

SECTION "A"

[20 Q × 1 = 20 marks]

Tick (✓) the correct answer.

- The first institution to start the Bachelor of Pharmacy course in Nepal is
 - Kathmandu University
 - Tribhuvan University
 - Pokhara University
 - Purbanchal University
- Preamble of Drugs Act 2035 covers the following *except*
 - Efficacy
 - Safety
 - Abuse
 - Availability
- According to Drug Act 2035, Vyabasai (Professionalist) as Medicine Dispenser in pharmacy outlet is recognized by
 - Drug Advisory Committee
 - Nepal Pharmacy Council
 - Drug Consultative Council
 - Department of Drug Administration
- Pharmacopoeias recognized by Government of Nepal are all *except*
 - JP
 - USSRP
 - Int. P
 - Chinese Pharmacopoeia
- Following combinations of antibiotics are not banned by Government of Nepal *except*
 - Penicillin and Sulphonamide
 - Nalidixic Acid and Metronidazole
 - Amoxycillin and Cloxacillin
 - Ciprofloxacin and Sulphonamide
- The chairman of "Drug Advisory Committee" is
 - Honorable Minister of Health
 - Director General of DDA
 - Secretary of Ministry of Health
 - Director General of Dept. of Health Services
- As per Narcotic Drug Control Act, 2033 Narcotic is defined as the following substances *except*
 - Lorazepam
 - Buprenorphine
 - Codiene
 - Codeine Syrup containing 3mg/5ml not exceeding 60 ml pack size
- Code on Drug production (Ausadhi Utpadan Sanghita) is
 - Equivalent to GMP guidelines
 - Just Quality Control document
 - Describes the production documents
 - Instructs for inventory record
- Quality of medicines in general refers to
 - Therapeutic excellence
 - Increment of Sale Volume
 - Consumer Satisfaction
 - Safety, Efficacy and potency
- Nepal Pharmacy Council Act was promulgated in the year
 - 2052 BS
 - 2057 BS
 - 2059 BS
 - 2035 BS

11. All of the following are regulated by Drug Act *except*
 - a. Patent Right
 - b. Clinical Trial
 - c. Drug Advertisement
 - d. Price control
12. As per Drug Act 2035, Pethidine is grouped under schedule
 - a. Ka
 - b. Kha
 - c. Ga
 - d. Gha
13. APPON (Association of Pharmaceutical Producers of Nepal) was established in theyear
 - a. 1995 AD
 - b. 1990 AD
 - c. 1997 AD
 - d. 1992 A
14. Which of the following does not meet the required qualification to be appointed as inspector as per Drug Act?
 - a. Bachelor in Pharmacy
 - b. Certificate in Pharmacy
 - c. Certificate Level in Pharmacy with five years' experience
 - d. Master in Pharmacy
15. 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
16. The pharmacy registration license becomes void if not renewed within
 - a. 35 days of expiration
 - b. One year after expiration
 - c. Three months after expiration
 - d. Five years after expiration
17. 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
18. The functions, duties and powers of Drug Consultative Council do 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
19. 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
20. As per Pharmacy Council Act, Pharmacy Profession is defined as all of the following *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

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SECTION "B"

[5 Q. × 3 = 15 marks]

Answer *ANY FIVE* of the following questions.

1. What is preamble of Drug Act 2035? When and for what Department of Drug Administration was established?
2. On what basis different types of drug regulations made under drug act 2035 were formulated?
3. As per Drug Act 2035, what qualifications are required to be dispenser, prescriber, Inspector and Analyst?
4. What are rights of consumers?
5. Write down powers of Inspector and Administrator as per Drug Act 2035.
6. Write down legal provision and process for standardization of drugs manufactured in Nepal.
7. List the Narcotic and Psychotropic Drugs used in pharmaceutical dosage form as per Narcotic Control Substances Act 2033.

SECTION "C"

[5 Q. × 5 = 25 marks]

Answer *ANY FIVE* of the following questions.

8. Comment and give your suggestions for the constitution of Nepal Pharmacy Council.
9. Discuss on the role of Pharmacists for ethical promotion of medicine.
10. Discuss the powers, roles and responsibilities of Drug Advisory Committee.
11. Point out strategies related to pharmaceutical field mentioned in National Health Policy.
12. Define Narcotic Substance as per Narcotic Substances Control Act. How would you relate Drug Act 2035 and Narcotic Substances Control Act 2033?
13. At the time of inspection, Drug Inspector found that unqualified person as per Drug Act 2035 at Community Pharmacy named as XYZ Pharmacy situated in ABC Hospital sold and stored Analgin Tablet and Morphine Injection. Is it illegal as per Drug Act? If so, how inspector proceed this case in the court? What maximum penalties will be charged to the person?
14. Briefly write down different organizations related to pharmaceutical fields.

SECTION "D"
[2 Q. × 7.5=15 marks]

Answer *ANY TWO* of the following questions.

15. Outline the development of pharmaceutical education in Nepal, its present status relating to quality pharmacy human resources production. Discuss the strengths and weakness of pharmacy human resources engaged in national pharmaceutical industries for the production of quality medicines.
16. Discuss the role of Drug Act 2035 and regulation and codes made thereunder for making availability of safe, effective and quality medicine in Nepal?
17. Enumerate briefly objectives, policies and strategies of National Drug Policy?