STATE BOARD OF TEX TELANGANA

DIPLOMA EXAMINATION (ER-2020) ER2020-APR-2023

II Year, PHARMACY END EXAM

ER20-26T PHARMACY LAW & ETHICS



10206

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Exam Date: 01-05-2023

Define Code of Pharmaceutical Ethics.

16.

Duration: 3 Hours [10:00 AM To 01:00 PM]

PART-A

Carl Sans		a learning questions.	$20 \times 1 = 20$	
	Instructions:	 Answer the following questions. Each question carries ONE mark. 		
			of	
1,	Nominated or elected member of PCI shall hold office for a term of			
2.	What is the main obje	ective of Drugs and Cosmetic Act 1940?		
3.	tarbat is the role of Cu	What is the role of Custom Collector?		
	Drugs and magic remedies act was passed in FSSAI has issued an advisory banning the use of which material for wrapping and packaging of food items.			
€ <u>4</u> 5?				
6.	How many human vol	unteers are selected for Phase I Chincal Trial	31	
क	Pharmaceutical legislation covers both and			
8.	To Manufacture drugs for the purpose of examination, test or anlysis has to obtain license in zo form and the application to issue a license in form.			
€9.	What does DTAB stand	What does DTAB stands for?		
10.		includes notices, circulars, labels, wra	pper or	
	smoke.	rally or by producing/transmitting light, sour	id or	
11.	Phooka or doom dev includes process of Expand ANDA.			
12.				
13.	Define Registered Phar	Define Registered Pharmacist. 3		
14,	What is the minimum area specification required for Wholesale of drugs premises?			
15:	Bioethics was improved from four fronts namely			

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- Which application form to be submitted for retail sale of drugs other than schedule-x drugs?
- 18. When application for a renewal of license to be made under FSSAI, 2006?
- Digitalis and Ergot Preparations are covered under _______
 Schedule.
- Human anatomical wastes are categorized under biomedical waste management as
 - a. Blue
 - b. Yellow
 - c. Red
 - d. White

PART-B

Instructions: 1. Answer any TEN questions.

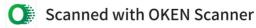
 $10 \times 3 = 30$

2. Each question carries THREE marks.

- Define Medical Practitioner.
 - What is Schedule FF, Schedule J, Schedule V as per Drugs and Cosmetics Act1940?
 - 23. What are the functions of Drugs Consultative Committee?
 - What are the offences and penalties under Medical termination of Pregnancy act?
 - Write the objectives of Institutional Animals Ethics Committee.
 - As per BCS system of classification how the drugs are classified?
 - 27. Write about recommendations of Drug Enquiry Committee.
 - 28. How do State Government regulate possession for sale and sale of any poison?
 - Write a note on E-Governance required in import of drugs and medical devices.
 - 30. Mention the Government Pharma Regulator Bodies?Write the role of these bodies.
 - 31. What is the role of National Executive Committee under Disaster Management act?

PART-C





Instructions: 1. Answer any SIX questions. 6 X 5 = 30

2. Each question carries FIVE marks.

- Explain the procedure of preparation of first register. 32.
- What are the conditions required for grant of a Loan Licence? 33.
- Discuss the penalities for manufacturing and sale of drugs in contravention of D&C Act, 1940.
- Write about a) the constitution and functions of Narcotic and Psychotropic consultative Committee. ...
 - b) Functions of Officers of Central Government.
- Briefly describe any two general steps involved in biomedical waste managaement.
- Explain E-governance in hospital pharmacy and pharma manufacturing. 37.
- Enlist the functions of Blood bank. Explain any three functions.

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