UNIVERSITY OF JAFFNA BACHELOR OF PHARMACY

SECOND YEAR SECOND SEMESTER EXAMINATION – JULY 2015 PHAJE 2204 - PHARMACEUTICAL JURISPRUDENCE AND ETHICS

Date: 08.07.2015. Time: 03 Hours

ANSWER ALL EIGHT QUESTIONS.

1.			
	1.1	Briefly describe the criteria established by WHO in medical	(50) (1)
	1.2	drug promotion for medical representatives. List the information that need to be included in a drug	(50 Marks)
	1.2	information sheet as recommended by WHO.	(50 Marks)
2.	2.1	Define the following terms according to CDDA.	-
		2.1.1 Label.	(10 Marks)
		2.1.2 Adulteration.	(10 Marks)
		2.1.3 Advertisement.	(10 Marks)
	2.2	What are the powers of authorized officers of Drug Regulatory	
	2.0	Authority?	(40 Marks)
	2.3	What are the functions of Drug Regulatory Authority?	(30 Marks)
3.			
	3.1	List the information required for the registration of new drugs.	(30 Marks)
	3.2	Briefly explain the procedure to be followed for registration of	(50 Montre)
	3.3	new drugs. List the changes that should be informed to CDDA after	(50 Marks)
		registration of drugs.	(20 Marks)
4			
4.	4.1	Define the following with five examples for each.	
		4.1.1 Poisons.	(15 Marks)
		4.1.2 Poisonous substances.	(15 Marks)
	4.2	What are the functions of opium board?	(30 Marks)
	4.3	Give the procedure followed by pharmacist while dispensing prescription with controlled drug.	(40 Marks)
			(101111111)
5.	C 1		(10036.1)
	5.1	Write an account on ethical principles for pharmacists.	(100 Marks)
6.			
	6.1	List the duties of cosmetics, Devices and Drugs Technical	
	6.2	Advisory committee	(40 Marks)
	0.2	Write an account on scheduled drugs.	(60 Marks)

7.			
	7.1	List the qualifications that are eligible for the registration as a	(20) (1)
		pharmacist in Sri Lanka.	(30 Marks)
	7.2	What are the conditions for the license to import the drugs?	(70 Marks)
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8.			
	8.1	What are provisions of the consumer protection act?	(20 Marks)
		Describe the following with reference to consumer protection	
		act	
		8.2.1 Scheme of distributions of articles.	(50 Marks)
		8.2.2 Manufacture or sale of articles below the specified	
		standard.	(30 Marks)