Enrollment No:-_____ Exam Seat No:-_____

C.U.SHAH UNIVERSITY

Summer-2015

Subject Code: 4PS04PLE1 **Subject Name: Pharmaceutical Legislation & Ethics**

Course Name: B.Pharm Date: 21/5/2015

Semester: IV Marks: 70

Time: 10:30 TO 01:30

Instructions:

1) Attempt all Questions in same answer book/Supplementary.
2) Use of Programmable calculator & any other electronic instrument prohibited.
3) Instructions written on main answer book are strictly to be obeyed.
4) Draw neat diagrams & figures (if necessary) at right places.
5) Assume suitable & perfect data if needed.

SECTION – I

Q.1		Define the following terms: a) Pharmacist b) Drug c) PCI d) AICTE e) Law f) Ethics g) CDL	07
Q.2	(a)	Discuss Drugs Enquiry Committee.	05
	(b)	Explain the power and duties of Drug Inspector.	05
	(c)	Write functions of Pharmacy Council of India (PCI).	04
		OR	
Q.2	(a)	Give the objectives of Pharmacy act.	05
	(b)	Define Registered Pharmacist. Discuss the procedure for subsequent registration.	05
	(c)	Describe the constitution of Pharmacy Council of India.	04
Q.3	(a)	Describe constitution and function of DTAB.	05
	(b)	Write short note on sale of opium.	05
	(c)	State the object of Medicinal and Toilet Preparations Act. Write offences and penalties related with the Medicinal & Toilet Preparation Act.	04
		OR	
Q.3	(a)	Explain the role of insecticide Inspector.	05
	(b)	Explain the role of Animal Ethics Committee.	05
	(c)	Write short note on Bonded Laboratory.	04

SECTION – II

Q.4	Define the following terms:	
	a) Hemp	2
	b) Coca leaf 2	2
	c) CDSCO	1
	d) NIPER	1
	e) CPSCEA1	1

Q.5	(a)	State the objectives of Drug Policy 2002 and discuss any six salientfeatures of said policy.	05
	(b)	Define Bulk Drugs, Formulation. Discuss the objectives and provisions under the drugs price control order Act 1995.	05
	(c)	Write a note on poison act.	04
		OR	
Q.5	(a)	Write a note on Medical Termination of Pregnancy Act.	05
	(b)	What are the provisions for safety in the factories act? Discuss.	05
	(c)	Write a note on Prevention of Cruelty to Animals Act.	04
Q.6	(a)	Describe the conditions for the manufacture of drugs other than those specified in schedule C,C_1 and X.	05
	(b)	Write a short note on retail price of formulation as per DPCO.	05
	(c)	Write a short note on Central Insecticide Laboratory.	04
		OR	
Q.6	(a)	What are the special lablelling requirements for following category: (i) Schedule - G drugs (ii) Ophthalmic preparations	05
	(b)	Define Magic Remedy. Write a note on prohibited and exempted advertisements.	05
	(c)	Define (i) Worker (ii) Factory and (iii) Relay and Shift under the act.	04