

FINAL YEAR B.PHARM. SEMESTER-VIII (2011 COURSE) :
SUMMER - 2018
SUBJECT : DRUG REGULATORY AFFAIRS

Day : **Thursday**
Date : **03/05/2018**

Time : **02.00 PM TO 05.00 PM**
Max. Marks : 80

S-2018-3986

N.B.:

- 1) **Q.No.1 and Q.No.5 are COMPULSORY.** Out of the remaining questions attempt **ANY TWO** questions from each section
- 2) Answers to both the sections should be written in **SEPARATE** answer books.
- 3) Figures to the right indicate **FULL** marks.

SECTION – I

- Q.1** Attempt **ANY FIVE** of the following: **[10]**
- a) What is composition of Joint Pharmacy Council?
 - b) Write in brief importance of Education Regulation.
 - c) What is loan license?
 - d) What is DCC?
 - e) Write functions of Central Drug Laboratory (CDL).
 - f) What is ceiling price?
 - g) Which are different requirement for drug store under D and C Act?
- Q.2** a) Discuss functions and responsibilities of Government Analyst. **[08]**
b) What are different administrative bodies under D and C Act? **[07]**
- Q.3** a) Explain qualification and duties of Drug Inspector. **[08]**
b) Write in detail about DTAB. **[07]**
- Q.4** Write short notes on **ANY THREE** of the following: **[15]**
- a) Schedule C and C₁
 - b) Schedule M
 - c) Schedule X
 - d) State Pharmacy Council

SECTION – II

- Q.5** Attempt **ANY FIVE** of the following: **[10]**
- a) Explain formula used for calculation of MRP under DPCO.
 - b) Explain pre-grant opposition of patent.
 - c) What is patentability?
 - d) Define compulsory license.
 - e) What is not patentable?
 - f) What is ASU?
- Q.6** a) Elaborate offences and penalties under NDPS. **[08]**
b) Write note on DPCO. **[07]**
- Q.7** a) Discuss salient features of Indian Patent System. **[08]**
b) Explain salient features of Medicinal and Toilet Preparation Act, 1955. **[07]**
- Q.8** Write short notes on **ANY THREE** of the following: **[15]**
- a) Pharmacist in relation to his job
 - b) WHO guidelines
 - c) Cannabis and cocoa derivative
 - d) Illicit traffic

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