

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

Day : Thursday
Date : 22/11/2018

W-2018-4150

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

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) Write functions of Central Drug Laboratory.
 - b) Write in brief importance of Education Regulation.
 - c) What is loan license?
 - d) What is composition of DTAB?
 - e) What is DCC?
 - f) Which are different penalties under Schedule M?
- Q.2** a) Discuss power and duties Government Analyst. **[08]**
b) Write in detail about State Pharmacy Council. **[07]**
- Q.3** a) Explain qualification and duties of Drug Inspector. **[08]**
b) What are different administrative bodies under D and C Act? **[07]**
- Q.4** Write short notes on **ANY THREE** of the following: **[15]**
- a) Schedule C and C₁
 - b) Schedule F
 - c) Labeling and packaging of cosmetics
 - d) Schedule Y

SECTION – II

- Q.5** Attempt **ANY FIVE** of the following: **[10]**
- a) What is TGA?
 - b) What is patent?
 - c) Enlist criteria for grant of patent.
 - d) What is not patentable?
 - e) Enlist the criteria for opposition to grant.
 - f) What is patentable under Indian Patent System?
- Q.6** a) Write note on DPCO. **[08]**
b) Discuss NDPS 1985 Act. **[07]**
- Q.7** a) Discuss Penalties and Offences under drug and magic remedies act. **[08]**
b) Discuss Medicinal and Toilet Preparation Act, 1955. **[07]**
- Q.8** Write short notes on **ANY THREE** of the following: **[15]**
- a) Compulsory license
 - b) USFDA
 - c) WHO guidelines
 - d) TGA

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