

**M. PHARM. SEM-II (CHOICE BASED CREDIT & GRADE SYSTEM)  
: SUMMER - 2018**

**SUBJECT: ADVANCED DRUG REGULATORY AFFAIRS-III**

Day: **Thursday**  
Date: **05/07/2018**

**S-2018-4011**

Time: **10.00 AM to 01.00 PM**  
Max Marks: 60

---

**N.B:**

- 1) Attempt any **THREE** questions from each section.
  - 2) All questions carry **EQUAL** marks.
- 

**SECTION-I**

- Q.1** Discuss the requirements for dossier submission for India.
- Q.2** Describe Schedule L-I of Drugs and Cosmetics Act.
- Q.3** What are the salient features of Schedule M of the Drugs and Cosmetics Act?
- Q.4** Write short notes on any **TWO** of the following:
- a) ISI standards for cosmetics
  - b) Regulatory requirements for nutraceuticals in India
  - c) Schedule T of the Drugs and Cosmetics Act

**SECTION-II**

- Q.5** Write in details about Annual Product Quality Review.
- Q.6** Discuss the salient features of clinical studies to be carried out in “ Special Populations” as per Schedule Y.
- Q.7** Write about Post Marketing Surveillance PSUR in detail.
- Q.8** Write short notes on any **TWO** of the following:
- a) Y- license
  - b) COA
  - c) MSDS

\* \* \* \* \*