



HV-M2011268

Seat No. _____

M. Pharm. (Sem. II) (CBCS) Examination

June / July - 2017

Pharmaceutical Drug Regulatory Affairs : Paper - VI

(Core - VI) (Intellectual Property Rights) (Theory)

Time : 3 Hours]

[Total Marks : 80

- Instructions :**
- (1) Answer and tie up both the sections separately.
 - (2) Figures to the **right** indicates marks.
 - (3) Answer the **three** (03) questions from each section.
 - (4) Question **one** (01) and question **five** (05) are **compulsory**.
 - (5) Draw neat and clean diagrams as required.

SECTION - I

- 1** Answer any **seven** of the following questions : **14**
- (a) Explain IP and Patent.
 - (b) What is the difference between trademark and copyright ?
 - (c) What is the role of patent agent ?
 - (d) Explain the term patent infringement.
 - (e) Enlist most commonly used URL used for patent search.
 - (f) Give full form of TRIPS, WIPO, WTO and GATT ?
 - (g) What do you mean by product patent ?
 - (h) How drug price competition is regulated ?
 - (i) What is the role of IPR ?
 - (j) What do you mean by patent commercialization ?
- 2** Answer the following questions :
- (a) How IP and conventional property are different ? **8**
Discuss the following term with respect to IPR :
 - i) Industrial design, ii) Integrated circuit,
 - iii) layout design, iv) trade secret.
 - (b) How patents are useful for research and development in pharma field ? **5**

- 3** Answer the following questions :
- (a) What is the objectives and scope of patent law in India ? Discuss current scenario of patent legislations in India. **8**
- (b) What do you mean by novelty and innovation of patent ? Discuss with one case study. **5**
- 4** Answer the following questions :
- (a) Discuss about patent claim and specification with example. Discuss at least two different examples reported recently on issue of patent infringement. **8**
- (b) Give detailed account for patent form, fees, application and procedure to file a patent in India. **5**

SECTION - II

- 5** Answer any **two** of the following questions : **14**
- (a) Enlist different international agencies for patenting. Discuss any of two such agencies.
- (b) Write a brief note on DOHA declaration and PARIS convention.
- (c) Discuss: How Hatch-Waxman Act and patent are interrelated ?
- 6** Answer the following questions :
- (a) What do you mean by patent licensing ? Discuss in detail with example. **8**
- (b) Differentiate: American and Indian Patent System. **5**
- 7** Answer the following questions :
- (a) What are the post-TRIPS consequences observed in Indian pharma industry ? **8**
- (b) Discuss: IPRs *vs.* Regulatory affairs- similarities and differences. **5**
- 8** Answer the following questions :
- (a) Discuss the role of APCTT, NRDC, TIFAC, BCIL in patent and IPR in India. **8**
- (b) Write a short note on: Working and Non-working of patents. **5**