Roll No. | | | | | | | | | | | | |

Total No. of Pages : 01

Total No. of Questions : 06

M. Pharmacy (Sem.–2)

DRUG REGULATORY AFFAIRS & IPR

Subject Code : PHCEU-434

Paper ID : [A2489]

Time : 3 Hrs. Max. Marks : 80

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries SIXTEEN marks.

1. What is an NDA? Discuss the requirements of data while filing a NDA. Give examples where a NDA can be filed. (16)

2. a) What are the cGMP guidelines for finished products? (8)

   b) Comment on the environment conditions requirement while testing stability of products in Zone III and IV. (8)

3. a) Comment on cGMP requirements for personnel. (8)

   b) Comment on the bioequivalence requirements according to ICH guidelines. (8)

4. a) Explain the "bracketing" method for conducting stability test on dosage forms. Mention the advantages of this method. (8)

   b) Discuss the Intellectual Property protection laws in India in brief. (8)

5. a) What is PCT? Discuss the content of PCT and its applications. (8)

   b) Comment on WIPO and its functions. (8)

6. Write short notes on : (4×4)

   a) Patent infringement.

   b) Patent abuse.

   c) IPAB.

   d) ICH guidelines for control of labeling.