



HV-M2011122 Seat No. _____

**M. Pharm. (Sem. II) (CBCS) (Quality Assurance)
Examination**

June/July - 2017

Regulatory Affairs & New Drug Application (Theory)

(Core Subject - VI)

(Specialization Paper - IV)

Time : **3** Hours]

[Total Marks : **80**

- Instructions :**
1. Answer and tie up both the sections separately.
 2. Figure 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** Write any seven out of eight : **14**
- a) Write down the selection criteria for contract Manufacturer.
 - b) Draw Flow chart of ANDA review process.
 - c) What is Structure of ANVISA?
 - d) How eCTD is different to Paper (Document) CTD?
 - e) Define : Spurious Drug.
 - f) Define Emergency Use of IND.
 - g) Enlist the permitted preservatives in food according to Prevention of Food Adulteration Act 1954.
 - h) What is advantages associated with 505(b)(2) application ?

- 2** Answer the Following :
- a) What is importance of Harmonization? Enumerate the type of Harmonization process according to ICH. Explain in detail Formal ICH procedure. **7**
 - b) What is DTAB, DCC, CDL? Describe its function according to Cosmetic Act 1940 & Rules 1945. **6**
- 3** Answer the Following :
- a) What is Certification and Licensing Procedures? Give type of certification and explain in detail. **7**
 - b) What is ICH? Give the mission or vision of ICH. Discuss in detail organization structure of ICH. **6**
- 4** Answer the Following :
- a) Describe the need of Pharmacopoeias? Explain the various parts of compendia. **7**
 - b) Write an informative note on industrial policy for safety purpose. **6**

SECTION - II

- 5** Write any Two out of three : **14**
- a) Describe in detail modules of CTD.
 - b) What is importance of IND? Explain Format and Content of IND.
 - c) What is TGA? Give the role and organization structure of TGA.

- 6** Answer the Following :
- a) Short note Supplemental New Drug Application. **7**
 - b) Discuss the Format and Content of NDA. **6**
- 7** Answer the Following :
- a) Explain in detail "Material Safety Data Sheet (MSDS)" preparation **7**
 - b) Short note on Drug Master File. **6**
- 8** Answer the Following :
- a) What is ANVISA? Write functions of ANVISA. **7**
 - b) Write a short note on Contract manufacturing. **6**
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