



DM-M-2011122

Seat No. _____

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

April / May – 2015

**Regulatory Affairs & New Drug Application (Theory)
(Quality Assurance)
(Specialization Paper - IV)
(Core Subject - VI)**

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 any three (03) questions from each section.
(4) Question one (1) and question five (5) are compulsory.
(5) Draw neat and clean diagrams as required.

SECTION – I

- 1** Write any seven out of eight. **14**
- (a) Give the name of Research Tool of WHO.
 - (b) What is Structure of ANVISA?
 - (c) Give the Aim of MHRA.
 - (d) Define Emergency Use of IND.
 - (e) Draw Flow chart of NDA review process.
 - (f) What is advantage associated with 505(b)(2) application ?
 - (g) Define : Spurious Drug.
 - (h) Write down the selection criteria for contract manufacturer.
- 2** What is importance of Harmonization? Enumerate the **13**
type of Harmonization process according to ICH. Explain
in detail Formal ICH procedure.

- 3** Answer the Following :
- (a) Describe in detail "Common Technical Document". **8**
 - (b) Explain in detail "Material Safety Data Sheet (MSDS) preparation. **5**

- 4** Answer the Following :
- (a) Short note on Abbreviated New Drug Application (ANDA). **6**
 - (b) Write a short note on Contract manufacturing. **7**

SECTION – II

- 5** Write **any Two** out of three. **14**
- (a) Short note on Supplemental New Drug Application
 - (b) What is ANVISA? Write functions of ANVISA.
 - (c) What is TGA? Give the role and organization structure of TGA.

- 6** Answer the Following :
- (a) Short note on Study of Compendia. **7**
 - (b) Write an informative note on Industrial Safety & Health Guidelines for filing in countries like US & EU. **6**

- 7** Answer the Following :
- (a) Discuss the Format and content of NDA. **7**
 - (b) What is importance of IND? Explain Format and content of IND. **6**

- 8** Answer the Following :
- (a) What is Certification and Licensing Procedure? 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**