

Printed Pages : 2



PHARM485(7)

(Following Paper ID and Roll No. to be filled in your Answer Book)

**PAPER ID : 150864**

Roll No.

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**B.Pharm.**

(SEM VIII) THEORY EXAMINATION, 2014-15  
**GMP, QUALITY ASSURANCE & VALIDATION**

Time : 3 Hours]

[Total Marks : 80

**Note :** Answer all questions.

1 Answer **any two** of the following- **8×2=16**

- (a) Differentiate between GMP and cGMP.
- (b) Write a detailed note on GLP.
- (c) Discuss about ISO 9000 series of quality management system.

2 Answer **any two** of the following : **8×2=16**

- (a) Describe content and format of NDA filing.
- (b) Explain the various parts of export registration for marketing.
- (c) Give the importance of maintenance of records in pharmaceutical industry.

**3** Answer **any two** of the following : **8×2=16**

- (a) Discuss in detail control of quality variation.
- (b) Write detailed note on master formula record.
- (c) Give the basic concept of quality assurance system.

**4** Answer **any two** of the following : **8×2=16**

- (a) Describe the types of process validation. Give their importance in manufacturing industry.
- (b) What is the process validation? Explain their benefits.
- (c) Discuss the validation of analytical methods.

**5** Answer **any two** of the following : **8×2=16**

- (a) Give the importance of IPQC test.
  - (b) Write short note on sampling plan.
  - (c) Describe sampling characteristics curve.
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