**Printed Pages : 2**

**PHARM485(7)**

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**PAPER ID : 150864**

**Roll No.**

# 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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