PALGAD - I (CBCS) : WINTER - 2016

SUBJECT – ADVANCED DRUG REGULATORY AFFAIRS-I

Day : Friday
Date : 06-01-2017

Time : 10:00 AM TO 1:00 PM
Max. Marks : **60**

N.B.:

1) Attempt **ANY THREE** questions from Section - I and **ANY THREE** questions from Section - II
2) Answers to both sections should be written in the **SEPARATE** answer books.
3) Figures to the **RIGHT** indicate full marks

SECTION-I

Q.1 Discuss important provisions of a GMP guidance generally accepted World Wide. **[10]**

Q.2 Discuss various Quality System Elements. **[10]**

Q.3 Discuss important provisions of GMP by MCC, South Africa **[10]**

Q.4 Write short note on (**ANY TWO**) **[10]**

a) Quality Plan
b) Market Complaints Handing
c) Quality Risk Management

SECTION – II

Q.5 Discuss Analytical Method Validation. **[10]**

Q.6 What are the Roles and Responsibilities of Stakeholders in Clinical Trials. **[10]**

Q.7 Discuss Stability Testing Conditions and Climate Zones. **[10]**

Q.8 Write short note on (**ANY TWO**) **[10]**

a) QSEM
b) Drug Adverse Reaction Reporting
c) Product Development Report

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