PALGAD - I (CBCS) :WINTER – 2015

SUBJECT – ADVANCED DRUG REGULATORY AFFAIRS-I

Day : Friday
Date : 08-01-2016

Time : 10.00 A.M. To 1.00 P.M.
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 differences between EU-GMP Guidelines and Schedule M. **[10]**

Q.2 Discuss Quality Risk Management in Detail. **[10]**

Q.3 Discuss Process Management under ISO 9001: 2008. **[10]**

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

a) Personnel Requirement in GMP
b) Injectables Area Requirements
c) Documentation Control

SECTION – II

Q.5 Discuss provisions of stability studies under ICH **[10]**

Q.6 Discuss Matrixing and Bracketing in Detail. **[10]**

Q.7 How will you manage a Clinical Trial? **[10]**

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

a) Quality Risk Management
b) Publication of Clinical Trial
c) Analytical Method Validation

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