DII-003-010409 Seat No. _____

M.Sc. (Chemistry) (Sem. IV) (CBCS) Examination

May / June – 2015

CPA - 403 : Pharma Regulatory Affairs

Faculty Code : 003
Subject Code : 010409

Time : $2\frac{1}{2}$ Hours] [Total Marks : **70**

Instruction :

(1) All questions are compulsory.

(2) All questions carry equal marks.

1 Answer the following : (any seven)

(a) What is impurity profile ? Define enantiomeric impurity.

(b) Define : working standard and certified reference material.

(c) What is calibration ? Why it is important ?

(d) Explain self life and archives.

(e) What is source of SOP and who write SOP ?

(f) What is GLP ? Give the list of key components of it.

(g) Explain revalidation in brief.

(h) Give the full name of the following :

(i) WHO

(ii) CRM

(iii) ICH

(iv) USP

(v) DCGI

(vi) cGMP

(i) Describe the factor affecting stability of compound.

(j) Enlist primary features of well organized QA system.

2 Answer the following : (any three)

(a) Define validation and discuss in detail cleaning validation.

(b) What is certified glassware ? Write SOP for its calibration.

(c) Discuss photostability study with its importance.

(d) Explore the terms : IQ, OQ, PQ, DQ

3 Answer the following :

(a) Describe ICH guidelines.

(b) Describe schedule-M and its provisions.

OR

(b) Describe process validation in detail.

4 Answer the following : (any two)

(a) Discuss analytical method validation and its parameters.

(b) Write note on SOP for SOP.

(c) What is API ? Write temperature and humidity condition for accelerated and real time stability.

5 Answer the following : (any two)

(a) Write SOP for calibration of HPLC and pH meter.

(b) What is OVI ? Discuss residual solvents and their classification as per ICH with suitable example.

(c) Write detailed note on GMP.

(D) Write note on registration of pharmaceutical product as per DCGI.
