SINHAGAD/ AMAZON/ PARANA/ KARNAFULI/ SURAMA/ SIYANA – II
(CBCS): SUMMER - 2015
SUBJECT: DRUG REGULATORY AFFAIRS (E – II)

Day: Tuesday
Date: 07-07-2015

Time: 10:00 AM 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) Figures to the right indicate **FULL** marks.
3) Answers to both the section should be written in **SEPARATE** answer book.

SECTION-I

Q.1 Discuss USFDA 505(b) (2) regulatory approval pathway in detail. **(10)**

Q.2 Discuss requirements of premises and equipment according to schedule M. **(10)**

Q.3 Discuss GLP with special emphasis on Laboratory equipment and maintenance. **(10)**

Q.4 Write short notes on (Any **TWO**): **(10)**

a) Biowaivers

b) Para I, II, III, IV filing

c) cGMP requirements for homeopathic medicine

SECTION-II

Q.5 What is the composition of MCC? Discuss salient features of product filing in South Africa. **(10)**

Q.6 What is an invention as per Us Patent Act? What are the essential components of US patent document **(10)**

Q.7 Discuss composition of ANVISA. Also discuss salient features of product filing in Brazil. **(10)**

Q.8 Write short notes on Any **TWO**: **(10)**

a) Amendments and provision in Indian patent Act, 1970

b) Indian patent Act – Patents trademarks, Copyrights and GI

c) Patent term extension

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