SINGHAGAD/ AMAZON/ PARANA/ KARNAFUL/ SURAMA/ SIYANA/ PALGAD-II
(CBCS 2012 COURSE): SUMMER -2016
SUBJECT: Elective- II: A) DRUG REGULATORY AFFAIRS

Day: Thursday
Date: 07-07-2016

Time: 10:00AM TO 1:00 P.M
Max Marks: 60

N.B:

1) Attempt any **THREE** questions from each section.
2) All questions carry **EQUAL** marks.
3) Write each section on different answer sheets.

SECTION-I

Q.1 What is GLP? Discuss GLP with special emphasis on Laboratory equipment and maintenance. **(10)**

Q.2 Discuss Hatch Waxmann Act. What are the provisions made for different types of product filings under this act? **(10)**

Q.3 Discuss various requirements for Solid Oral Dosage Forms under Schedule M in detail. **(10)**

Q.4 Write short notes on any (**TWO**) of the following: **(10)**

a) 505 (j)
b) 21 CFR Part 310 & 312
c) Administrative structure of USFDA

SECTION-II

Q.5 Discuss structure & functions of MCC. Add a note on stability studies guidance of MCC. **(10)**

Q.6 Discuss section 3 & 4 exclusions as per Indian patent Act, 1970. **(10)**

Q.7 Discuss salient features of drug approval process of Japan. **(10)**

Q.8 Write short notes on any (**TWO**) of the following: **(10)**

a) ANVISA
b) Patent term extension
c) US Patent- Novelty Requirements

* * * * *