PALGAD -II:(CBCS 2012 COURSE): SUMMER- 2016
SUBJECT: ADVANCED DRUG REGULATORY AFFAIRS-III

Day: Tuesday
Date: 05-07-2016

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

N.B:

1) Attempt any **THREE** questions from each section.
2) All questions carry **EQUAL** marks.

SECTION-I

Q.1 Discuss the requirements of pharmaceutical products in India.

Q.2 Describe with respect to Cosmetics: Schedule M-II Drugs and Cosmetics Act and ISI standards.

Q.3 What are the salient features of Schedule M of the Drugs and Cosmetics ACT?

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

a) GLP as per schedule M
b) Schedule M-I
c) GMP for Ayurvedic and Siddha Products

SECTION-II

Q.5 Write in detail about US and Indian pharmacopoeal requirements for" packaging materials".

Q.6 Discuss the salient features of various "phases" of clinical trials as per Schedule Y.

Q.7 Describe the contents of BPR, MFR and packaging Records as per Schedule M of Drugs and Cosmetics Act.

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

a) Annual Product Review
b) Validation of analytical method
c) MSDS

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PALGAD-II (CBCS 2012 COURSE): SUMMER -2016
SUBJECT: ADVANCED DRUG REGULATORY AFFAIRS- II

Day: Saturday
Date: 02-07-2016

Time: 10:00AM-TO1:00P.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 Discuss salient features & specific requirements for 505 (b) (2) filing. **(10)**

Q.2 Discuss various provisions for getting biowaiver for product registration in US. **(10)**

Q.3 Discuss cGMP requirements under 21 CFR part 210 & 211. **(10)**

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

a) Europe cGMP
b) Generic filing in US
c) US regulatory Approval pathways

SECTION-II

Q.5 Discuss all provisions for *in vitro* release testing for solid orals. **(10)**

Q.6 Discuss requirements for a new drug & generic drug registration in Europe. **(10)**

Q.7 Discuss salient features of CMC on extended release oral solid dosage form. **(10)**

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

a) *In vivo* bioequivalence
b) Scale up & post approval changes
c) Drug Master File

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