M. PHARM. (Regulatory Affairs) SEM – I (CBCS - 2019 COURSE): WINTER – 2021
SUBJECT: DOCUMENTATION AND REGULATORY WRITING

Day: Tuesday
Date: 16.11.2021 W-2021-20722

Time: 10:00 AM TO 1:00 PM
Max. Marks: 75

N.B.:

1) Attempt any **FIVE** questions from the following.
2) Figures to the right indicate **FULL** marks.

Q.1 **a)** Write in detail about the contents of a DMF. **(10)**

b) Add a note on advantages of eCTD. **(05)**

Q.2 **a)** Discuss internal and external audits in detail. **(10)**

b) Add a note on audit report. **(05)**

Q.3 **a)** Describe SUPAC documentation required for changes to manufacturing process and equipment for immediate release solid oral dosage forms. **(07)**

b) Discuss Product Development Report. **(08)**

Q.4 **a)** Describe SUPAC documentation required for changes to non sterile semi-solid dosage forms. **(07)**

b) Write a note on Product Life Cycle Management. **(08)**

Q.5 **a)** Discuss Inspection of pharmaceutical manufacturing facility. **(07)**

b) Discuss Corrective and Preventive Action. **(08)**

Q.6 Write short notes on the following: **(15)**

a) ICH CTD format

b) Site Master File

c) CBE- 30

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