M.PHARM. (REGULATORY AFFAIRS) SEM.-I (CBCS-2019 COURSE) : WINTER - 2021
SUBJECT : GOOD REGULATORY PRACTICES

Day : Monday
Date : 15-11-2021 W-2021-20711

Time : 10:00AM TO 1:00P.M.
Max. Marks : 75

N.B.

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

Q.1 **a)** Discuss on US cGMP part 210 and part 211. **(10)**

b) cGMP for IVDS. **(05)**

Q.2 **a)** Elaborate on GLP regulations with special reference subpart K. **(10)**

b) Controlling the GLP inspections process. **(05)**

Q.3 **a)** Discuss on SOP for GALP requirements. **(08)**

b) Checklist for software evaluation. **(07)**

Q.4 **a)** Discuss requirements for GDP for various regulatory agencies. **(08)**

b) Self-inspection process. **(07)**

Q.5 **a)** Concept of quality and its implementation in cGMP. **(08)**

b) QBD and OOS. **(07)**

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

a) Cleaning validations
b) Principles of HAVC validation
c) Water system validation

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