

MASTER OF PHARMACY (M. PHARM.) (CBCS-2019 COURSE)

M.Pharm. Sem-I : SUMMER : 2022

SUBJECT: GOOD REGULATORY PRACTICES

Day : Wednesday

Time : 10:00 AM-01:00 PM

Date 04-May-2022

S-20711-2022

Max. Marks: 75

N.B.

1) Attempt ANY FIVE questions from the following.

2) Figures to the RIGHT indicate FULL marks.

3) Answers to both sections should be written in separate Answer book.

Section I

Q.1 a) Discuss on WHO cGMP guidelines. (10)

b) Global Harmonisation Taskforce. (05)

Q.2 a) Elaborate on various subparts of USFDA GLP. (10)

b) Process of recognition and de-recognition of Laboratories. (05)

Q.3 a) Discuss on Goals of Laboratory Quality Audits. (08)

b) Training Documentation in GALP. (07)

Q.4 a) Discuss requirements for returns and recall procedure under GDP. (08)

b) Stability testing principles. (07)

Section - II

Q.5 a) Concept of OOS and OOT in Quality Management. (08)

b) Importance of change control. (07)

OR.

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

a) ICH guidelines on Quality and Safety

b) Revised schedule M

c) TQM

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