

**M.PHARM. (PHARMACEUTICAL QUALITY ASSURANCE) SEM.-I**  
**(CBCS – 2019 COURSE) : WINTER - 2021**  
**SUBJECT : QUALITY CONTROL AND QUALITY ASSURANCE**

**Day** : Wednesday  
**Date** : 17-11-2021

**Time** : 10:00 AM-01:00 PM  
**Max. marks** : 75

**W-20732-2021**

**N.B.**

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

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- Q.1** a) Discuss audit planning in pharma industry in detail. (10)  
b) Add a note on internal audit. (05)
- Q.2** a) Discuss Good Laboratory Practices. (10)  
b) Add a note on IPQC for tablets. (05)
- Q.3** a) Write about cGMP requirements. (07)  
b) Discuss raw material analysis. (08)
- Q.4** a) Write a note on finished product testing for parenterals. (07)  
b) Write a note on finished product testing for semi solids. (08)
- Q.5** a) Write about QC of containers and closures. (07)  
b) Write about Documentation in pharma industry. (08)
- Q.6** Write notes on the following. (15)  
a) Requirements of GMP related to organization and personnel  
b) QC of secondary packaging material  
c) ICH QSEM guidelines

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