

Roll No.

Total No. of Pages : 01

Total No. of Questions : 06

M.Pharmacy(Pharmaceutical Analysis) (Sem.-2)
QUALITY CONTROL & QUALITY ASSURANCE

Subject Code : MPA-203T

M.Code : 74927

Date of Examination : 08-07-22

Time : 3 Hrs.

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. Discuss in brief :
 - a) Calculation of expiry date (5)
 - b) Calculation of yield (5)
 - c) Cross contamination (5)
2.
 - a) Briefly discuss three tier documentation. (8)
 - b) How to write a standard operating procedure? (7)
3.
 - a) What are the official quality control tests of closures? (8)
 - b) Write a note on quality audit plan and report along with few market examples of failure in audit. (7)
4.
 - a) Elaborate on finished product quality control of tablets *w.r.t.* I.P., B.P. and USP.
 - b) Discuss the similarities and differences in official QC tests. (15)
5. Discuss developing specifications of ICH guidelines. (15)
6. Discuss computational modeling of drug disposition in view of USFDA. (15)

NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.