

Roll No.

--	--	--	--	--	--	--	--	--	--

Total No. of Pages : 02

Total No. of Questions : 22

B.Pharm (2017 Batch) (Sem.-6)
QUALITY ASSURANCE-THEORY
Subject Code : BP-606T
M.Code : 77991

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

1. **SECTION-A** is **COMPULSORY** consisting of **TEN** questions carrying **TWO** marks each.
2. **SECTION-B** contains **THREE** questions carrying **TEN** marks each and students have to attempt any **TWO** questions.
3. **SECTION-C** contains **NINE** questions carrying **FIVE** marks each and students have to attempt any **SEVEN** questions.

SECTION-A**Define briefly :**

1. Difference between QA and QC
2. Master Formula Record
3. Quality audit
4. Validation
5. SOP
6. Material Management
7. Control Articles
8. Difference between primary and secondary packaging material
9. Line clearance
10. Pareto analysis

SECTION-B

11. ICH guidelines are divided into which major categories, enumerate them with codes and explain guidelines for stability testing.
12. Define QBD. What are different components of QBD? Discuss in brief.
13. Discuss the general principle of calibration. Also brief about Analytical method Validation.

SECTION-C

14. Define TQM. Enumerate components of TQM. Explain in detail any one of them.
15. Enumerate different quality management tools and explain fish bone diagram.
16. Explain Matrix design.
17. Briefly discuss ISO 14000
18. What are the principals of NABL Accreditation?
19. Discuss the significance of personnel responsibilities.
20. What is the procedure of purchase of equipments?
21. What is the protocol for conduct of A Non clinical Laboratory Study?
22. What is significance of SOP? Discuss the significance of reports and documents.

NOTE : Disclosure of identity by writing mobile number or making passing request on any page of Answer sheet will lead to UMC against the Student.