

PARUL UNIVERSITY
FACULTY OF PHARMACY
M.Pharm. Summer 2017 - 18 Examination

Semester: 2
Subject Code: MQA 202T
Subject Name: Pharmaceutical Validation

Date: 16/05/2018
Time: 10.00 am to 1.00 pm
Total Marks: 75

Instructions:

1. Figures to the right indicate maximum marks.
2. Make suitable assumptions wherever necessary.

Q.1 Essay Type Questions. (any 2 out of 3) (15 Marks Each) (30)

1. Write a note on water system validation
2. What is the significance of cleaning validation? Describe validation protocol of cleaning validation in detail.
3. Write in detail about Media fill test.

Q.2 Short Essay Type Questions. (any 5 out of 6) (5 Marks Each) (25)

1. Describe performance qualification of Autoclave.
2. Write a brief note on validation of membrane filtration.
3. Describe types of patent applications.
4. What is the importance of AMV? Describe determination of precision and robustness?
5. Explain validation with its objective, scope, importance and types?
6. Describe performance qualification of UV-Visible spectrophotometer.

Q.3 Short Answers. (2 Marks Each) (20)

1. Enlist contents of Validation Master Plan.
2. Compare Factory Acceptance Test (FAT)/Site Acceptance Test (SAT).
3. What is the importance of URS?
4. Describe Critical parameters tested for Dry Powder Mixers.
5. Describe concepts of Intellectual Property.
6. Enlist patent application forms.
7. What are the revalidation criteria for process validation?
8. Enlist types of PV.
9. What is the Economic importance of Intellectual Property?
10. Enumerate sampling techniques for cleaning validation and compare.