MANIPAL COLLEGE
OF PHARMACEUTICAL SCIENCES
MANIPAL
A constituent institution of Manipal University

M. Pharm. End Semester Examination (Make Up) June 2021

Department of Pharmaceutical quality assurance

Specialization- Pharmaceutical regulatory affairs

PQA -MRA 101T: GOOD REGULATORY PRACTICES

Date: 28.06.2021 **Duration:** - 02:30 pm to 04:30 pm **Max. Marks:** 50

Long Essays: 2 X 10 Marks.

1. Following observations were recorded in form 483 of a tablet-manufacturing unit. State the cGMP part and section violated and suggest corrective actions for the same.
    a. A white powder was found on the exterior surface of the manufacturing equipment.
    b. One batch of the product failed in assay.
2. A start-up company has developed a new software for submitting ANDA. Prepare a checklist for validating the same.

Short Essays: 6 X 5 Marks.

3. You have been assigned with auditing records and logbooks in an analytical laboratory for ISO/IEC 17025 compliance. List the documents, which you will audit.
4. Explain the major differences between WHO and EU GDP guidelines.
5. Explain major differences between the following as per WHO GDP guidelines.
    a. Batch and Consignment
    b. Contamination and Cross contamination
6. Discuss types of validation.
7. Design a change control form for a pharmaceutical facility as per the regulatory requirement.
8. Discuss out of specification (OOS) with the help of a case study.