CBCS SCHEME

USN | | | | | | | | | |

16/17BBT/BBC422

Fourth Semester M.Tech. Degree Examination, June/July 2019
QC, QA and Validation

Time: 3 hrs. Max. Marks: 80

Note: ***Answer FIVE full questions, choosing one full question from each module.***

Module-1

1 a. Explain the basic concept of quality assurance add a note on quality components. **(08 Marks)**
b. Discuss the strategies followed to ensure quality control in biological products. **(08 Marks)**

OR

2 a. Write a note on Quality control and antibiotics. **(08 Marks)**
b. Give an account of GMP in manufacturing of biological products. **(08 Marks)**

Module-2

3 a. Enumerate the good laboratory practices. **(08 Marks)**
b. Discuss the GLP process followed in control of records and reports. **(08 Marks)**

OR

4 a. How do you implement GLP practices for facilities and equipment? **(08 Marks)**
b. Elaborate the GLP concept in non clinical testing. **(08 Marks)**

Module-3

5 a. Discuss the strategies followed in processing intermediates and bulk product. **(08 Marks)**
b. Elaborate the significance of SOP and records in drug manufacturing. **(08 Marks)**

OR

6 Write a note on :
i) IPQC ii) Master production and control record iii) SOPs iv) Drugmaster file. **(16 Marks)**

Module-4

7 a. Explain the scope significance and organizations for validation process. **(08 Marks)**
b. Discuss the general principles of analytical method validation taking HPLC as an example. **(08 Marks)**

OR

8 a. Give an account of process validation of formulation. **(08 Marks)**
b. Explain the validation process for HAVC system. **(08 Marks)**

Module-5

9 a. Discuss the ICH guidelines for regulatory affairs. **(08 Marks)**
b. Give an account of INDA and NDA regulations. **(08 Marks)**

OR

10 a. What is regulatory affair explain its significance and implications. **(08 Marks)**
b. Give an account of good clinical practices followed in Biopharmaceutical industry. **(08 Marks)**

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