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School of Medical and Allied Sciences

Bachelor of Pharmacy

Semester End Examination - May 2024

Duration : 180 Minutes

Max Marks : 75

Sem VIII - BPQA8016 - Chemist-In-Process Quality Assurance Pharma Biologics and Medical DeviceGeneral Instructions*Answer to the specific question asked**Draw neat, labelled diagrams wherever necessary**Approved data hand books are allowed subject to verification by the Invigilator*

- 1) What are electronic signatures? K1 (2)
- 2) Explain about problem solving techniques for routine work related issues. K2 (2)
- 3) Define SS system. K1 (2)
- 4) Relate the term DMF. K2 (2)
- 5) Define legislative requirements. K1 (2)
- 6) Illustrate about the penalties for violation at workplace. K2 (2)
- 7) What are the industrial procedures for environment? K1 (2)
- 8) Illustrate about CQA. K2 (2)
- 9) Tell about audit. K1 (2)
- 10) Illustrate the note on types of communication methods. K2 (2)
- 11) Make use of waste samples . K3 (5)

OR

Develop a note on the evaluation in regulatory guidelines. K3 (5)

- 12) Examine the responsibilities of QA unit. K4 (5)
- 13) Identify the benefits of SOPs K3 (5)
- 14) Examine about cleanroom behaviour. K4 (5)
- 15) Develop a note on master formula record. K3 (5)
- 16) Simplify the process documentation audit by quality assurance team. K4 (5)

OR

simplify how a BMR is prepared.

K4 (5)

17) Analyze the performance qualification of instruments.

K4 (5)

18) Develop a brief review on documentation related to GMP and GDP.

K6 (10)

19) Importance of quality assurance audit.

K5 (10)

OR

Write about the evaluation of complaints.

K5 (10)