Bachelor of Pharmacy (B.Pharm) Sixth Semester

BP606 - Quality Assurance

P. Pages : 1 **GUG/W/18/1181**

Time : Three Hours * 0 8 9 4 * Max. Marks : 80

Notes : 1. All questions carry equal marks.
2. Diagrams and Chemical equation should be given wherever necessary.
3. Illustrate your answers wherever necessary with the help of neat sketches.
4. Que. **1** is compulsory, solve **any four** from remaining.

1. Solve **any four.** **16**

a) Explain the effect of WTO with regards to pharmaceuticals.

b) Give the standard operating procedure for coating.

c) Define validation. Describe equipment validation.

d) Write a note on trademark.

e) Write a note on clinical research protocol.

f) Explain total quality management.

2. a) Give a detail account on GMP. **8**

b) What is validation? Describe in detail about process and personnel validation. **8**

3. a) Explain Responsibilities and sampling test procedure of quality control department. **8**

b) Write a note on quality control documentation and audits of QC facilities. **8**

4. Explain preclinical and clinical trials in detail. Describe procedure and application of Investigational new drug. **16**

5. a) Give a detail account on GLP. **8**

b) Explain in detail patent procedure. Add a note on patent licensing. **8**

6. a) Write a note on ICH guidelines. **8**

b) Describe the broacher preparation for IND. **8**

7. Solve **any four.** **16**

a) Copyright. b) Intellectual property rights.

c) ISO. d) Clinical research protocol.

e) Validation of air handling system.

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