P48/HSC271/EE/20160525

Time : 3 Hours **Marks : 80**

Instruction :

1. All Questions are Compulsory.
2. Each Sub-question carry 5 marks.
3. Each Sub-question should be answered between 75 to 100 words. Write every questions answer on separate page.
4. Question paper of 80 Marks, it will be converted in to your programme structure marks.

1. Solve any **four** sub-questions.

   a) What is GMP? 5

   b) Define the importance of the GMP. 5

   c) Why GMP is necessary in the pharmaceutical industry? 5

   d) GMP helps to boost the pharmaceutical Business. 5

   e) What GMP Covers? Explain in the Brief. 5

2. Solve any **four** sub-questions.

   a) Explain in brief QA. QC and GMP interrelationship. 5

   b) Define the validation program. 5

   c) GMP History in brief as per the ICH Guidelines. 5

   d) What is Validation? And explain in brief. 5

   e) What is Types of water in the Pharmaceutical Industry? 5

3. Solve any **four** sub-questions.

   a) Write down the ten principle of the GMP. 5

   b) Describe the ten principles of the Documentations. 5

   c) Describe the ten personal hygiene practices. 5

   d) Explain the flow of the GMP from receiving of raw material to packing. 5

   e) Explain the type of guidelines with respect to the GMP. 5

4. Solve any **four** sub-questions.

a) Building and facilities with respect to the GMP. 5

b) Write down in brief the type of process equipment. 5

c) Write down the type of the document handling in the pharmaceutical industry. 5

d) What is equipment/instrument usage log books records? 5

e) What is rejected, reworked and recovered material? 5