First Year M. Pharm Degree Examination - Oct/Nov 2014 [Max. Marks: 100]

 $2 \times 20 = 40 \text{ Marks}$

5 X 10 = 50 Marks

Quality Assurance (Revised Scheme 4) **Q.P. CODE: 9361**

Your answers should be specific to the questions asked. Draw neat, labeled diagrams wherever necessary.

LONG ESSAY (Answer any TWO)

[Time: 3 Hours]

- Explain in detail quality audits of manufacturing processes and facilities. Write a note on audits 1. of quality control.
- Write a typical standard operating procedure for a 16-station rotary tablet compression 2. machine.
- 3. Write a note on "Investigator Brochure" as per ICH E6 guidelines.

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SHORT ESSAY (Answer any FIVE)

- Write a note on gualification and training of a new guality control chemist and new production 4. chemist as per schedule M.
- A batch of enteric-coated tablets failed to meet disintegration specifications. Explain the 5. investigation process and CAPA (Corrective and Preventive Actions) for the same.
- Name and explain the significance of any three "In Process Quality Control Tests" for injections 6. and capsules.
- 7. Write a standard testing protocol for the assay of Paracetamol tablets IP.
- Write a note on "Good Warehousing Practices". 8.
- 9. Write a note on new drug product registration in United States of America.

SHORT NOTES

2 X 5 = 10 Marks

- 10. What are Trademarks and Copyrights?
- www.first.a.**** What are online, inline and atline testing as per PAT guidelines of USFDA? 11.