Subject Code: PAQ2C

M. Tech –II Semester [R05] Regular/Supply Examinations, December, 2013

QUALITY ASSURANCE OF PHARMACEUTICALS -II

(PA&QA)

Time: 3 Hours **Max Marks: 60**

Answer any FIVE questions

All questions carry EQUAL marks

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1). Write about the regulatory requirements for the preformulation studies of injections and semisolid dosage forms as per Indian regulatory authorities. [12]

2). Write about the regulatory requirements as per European community for [6+6]
a) Manufacturing information and formula
b) Data requirement for new drug

3). Explain about the regulatory guidelines for testing and evaluation of packaging material [12]

4). Explain the following [6+6]
a) Design of stability testing regulatory requirements for testing of dosage form in their final packing as per Indian regulatory authorities
b) Pharmacokinetic and toxicokinetic validation

5). Write in detail about the different testing parameters as per regulatory requirements of United States regulatory authorities for dosage form manufacturing process [12]

6). Explain in detail about the current guidelines as per regulatory requirements of Indian regulatory authority in respect of clinical bioavailability and study design presentation [12]

7). Define clinical trials. Explain in detail about the different phases in clinical trial studies. [12]

8). Explain the following [6+6]
a) Procedure for obtaining and writing a patent
b) Intellectual Property Rights (IPR's)

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