BIOINFORMATICS INSTITUTE OF INDIA

Industry Program
In
Pharma Good Manufacturing Practices

EXAMINATION ASSIGNMENT

November, 2014

BIOINFORMATICS INSTITUTE OF INDIA

H-109, Ground Floor, Sector-63, Noida-201307, (UP) INDIA

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INSTRUCTIONS

- **Maximum Marks per Module- 100 (75+25)**
- **Compulsory Assignment and Research Study (Internal Examination) Maximum Marks- 25**
- **Assignment for main examination Maximum Marks- 75**
  - Electronic (E-Mail, Fax) submission of Assignments is not acceptable.
  - The Assignments have to be submitted by the students on standard A-4 size paper in hand written format only**.**
  - Do not copy the answers from internet or other participants. If it is noticed the assignments of such candidates will cancelled.
  - The Assignment of each paper should be written separately. Do not write the assignments for all the papers in continuity. However, all the assignments are to be submitted together in single envelope either by POST or COURIER or by HAND to the institute addresses.
  - No two or more students should submit the assignment in same/one envelope.
  - Last date of submission of Assignment at BII is **30th November '2014**. No assignment will be accepted after due date.
  - Mention your **Name & Enrollment Number** on the cover page of each module.
  - Mention your **Name, Enrollment Number** & **"EXAM ASSIGNMENT November 2014"** on the top or back of the envelope in capital letters.
  - Participants are advised to keep the photocopy of assignment for their own record.

The Assignments have to be submitted to:

The Director
Bioinformatics Institute of India
H-109, Ground Floor, Sector 63
Noida-201307 (UP) INDIA

QUALITY ASSURANCE OF PHARMACEUTICALS

Paper Code: PGMP- 001

Total Marks: 100

Instructions:

- SECTION-A: All questions are compulsory.
- SECTION-B: Attempt any five questions.
- SECTION-C: Attempt any two questions.
- SECTION D: Compulsory Question.

SECTION - A

Objective type questions: **2 × 5 = 10 Marks**

1. The duties of head of quality control includes
   a) Rejection & approval of products
   b) Approval of quality control procedures
   c) Both
   d) None
2. Master formula should include for
   a) Name of product
   b) Dosage form description
   c) Processing location
   d) All above
3. Rest and refreshment rooms would come under
   a) Ancillary areas
   b) Storage areas
   c) Production area
   d) Weighing area
4. The finished product should be held in _____ until its final release.
   a) Quarantine unit
   b) Recovery unit
   c) Store house
   d) All of the above
5. Which is correct for ISO
   a) International Standardization Organization
   b) International Organization for Standardization
   c) Integrated Organization for Standardization
   d) None

SECTION - B

Short answer type questions: **5 × 5 = 25 Marks**

1. What are the principles of HACCP?
2. Differentiate between contamination and cross-contamination.
3. Write short note on monitors.
4. What is herbal medicinal product?
5. What is the difference between quality assurance and quality control?
6. What are the specifications for starting & packaging material?
7. What do you mean by dry heat sterilization?

SECTION - C

Long Answer type questions: **3 × 15 = 45 Marks**

1. What is self – inspection & what are the Items required for self-inspection
2. Explain the attributes of a drug inspector.
3. Differentiate between sterilization by moist heat and sterilization by dry heat.
4. What are the guidelines for control of microbial contamination in pharmaceutical procedures?

SECTION - D

Compulsory Question: **20 Marks**

1. How far will you justify the use of animals in the pharmaceutical industry?

SCHEDULE M

Paper Code: PGMP – 002

Total Marks: 100

Instructions:

- SECTION-A: All questions are compulsory.
- SECTION-B: Attempt any five questions.
- SECTION-C: Attempt any two questions.
- SECTION D: Compulsory Question.

SECTION - A

Objective type questions: **2 × 5 = 10 Marks**

1. The equipment must for the production of alcoholic fragrance solution is
   a) Mixing tank with stirrer
   b) Filtering aid
   c) Filling and sealing equipment
   d) All of the above
2. Ointment, emulsion and lotions are considered as
   a) External liquid preparation
   b) Internal liquid preparation
   c) Oral liquid preparation
   d) All of the above
3. Crimping machine is used mainly in
   a) Toothpaste manufacturing
   b) Hair dye manufacturing
   c) Aerosol production
   d) None
4. Grade C category for aseptic preparation
   a) Aseptic preparation & filling
   b) Preparation of solution to be filtered
   c) Background room conditions for activities requiring grade A
   d) All of the above
5. Site master file must include:
   a) Information of premises
   b) Information of equipments
   c) Information of quality control
   d) All

SECTION - B

Short answer type questions: **5 × 5 = 25 Marks**

1. What do you mean by parental preparation?
2. Write short note on capsules.
3. Why the sanitation of personnel is so stressed upon in a pharmaceutical?
4. What is the significance of building and civil works in Schedule M?
5. What according to schedule M is the requirement for purified water?
6. What care should be taken during coating of tablets?
7. What are the rules for disposal of waste?

SECTION - C

Long Answer type questions: **3 × 15 = 45 Marks**

1. Explain the requirements to carry out manufacturing process.
2. Explain some guidelines for proper use of equipments.
3. Explain the air handling system of the manufacturing area.
4. Explain the use of reference sample.

SECTION - D

Compulsory Question: **20 Marks**

1. What do you understand by Schedule M and its significance in pharmaceutical industry?

QUALITY ASSURANCE AND CONTROL

Paper Code: PGMP – 003

Total Marks: 100

Instructions:

- SECTION-A: All questions are compulsory.
- SECTION-B: Attempt any five questions.
- SECTION-C: Attempt any two questions.
- SECTION D: Compulsory Question.

SECTION - A

Objective type questions: **2 × 5 = 10 Marks**

1. Total number of principles of Total Quality Management are:
   a) 5
   b) 7
   c) 9
   d) 11
2. What among the following is considered as analytical parameter?
   a) Accuracy
   b) Precision
   c) Ruggedness
   d) All of the above
3. The personnel of production is not responsible for ensuring
   a) GMP regulations are followed
   b) Cross examination is avoided
   c) Appropriate basic substances are used
   d) None
4. The full name of IEC is
   a) International Electro chemical Commission
   b) International Electro technical Commission
   c) International Electro mechanical Commission
   d) All of the above
5. ICH was formed in
   a) 1980
   b) 1970
   c) 1960
   d) 1990

SECTION - B

Short answer type questions: **5 × 5 = 25 Marks**

1. What do you mean by electronic product radiation?
2. What do you mean by adolescent era?
3. What is do you mean by Quality Function Deployment?
4 Mention any three situations in which method revalidation is needed.
5. Write short note on advanced quality tools.
6. What is CAPA?
7. What is calibration. Discuss its objectives?

SECTION - C

Long Answer type questions: **3 × 15 = 45 Marks**

1. Discuss few basic principles of Total Quality Management.
2. What are the benefits of ISO Standards to society?
3. Discuss the six sigma approaches.
4. What information is submitted to FDA for Drug Approval?

SECTION - D

Compulsory Question: **20 Marks**

1. Standards like GMP, ISO, ICH & Quality assurance is a requirement of society for a safe & healthful life? Give your opinion

GOOD MANUFACTURING PRACTICES, QUALITY ASSURANCE AND REGULATION

Paper Code: PGMP – 004

Total Marks: 100

Instructions:

- SECTION-A: All questions are compulsory.
- SECTION-B: Attempt any five questions.
- SECTION-C: Attempt any two questions.
- SECTION D: Compulsory Question.

SECTION - A

Objective type questions: **2 × 5 = 10 Marks**

1. Any distinctive symbol such as combination of letters or number or both, from which the history of manufacturing, packaging, labeling and distribution of a unit of batch can be determined is called
   a) Design history file
   b) Control number
   c) Quality policy
   d) Nonconformity
2. Herbal material, in addition to herbs include
   a) Fresh juice
   b) Resins
   c) Gums
   d) All
3. Heat penetration measurement are recommended for injectable products in case of
   a) Higher viscosity
   b) Volumes larger than 5 ml
   c) Both
   d) None
4. Herbal medicines manufacturing involves which analytical techniques
   a) Mass spectrometry
   b) Capillary electrophoresis
   c) Gas chromatography
   d) All
5. Full name of APIs
   a) Addition of pharmaceutical ingredients
   b) Active pharmaceutical ingredients
   c) Allergic pharmaceutical ingredients
   d) None

SECTION - B

Short answer type questions: **5 × 5 = 25 Marks**

1. What are exotic organisms?
2. Write short note cell bank system.
3. What is bio-generator?
4. Write a note on qualifications of personnel hired for manufacturing of APIs & intermediates.
5. What measures could be taken to avoid cross-contamination in production?
6. Write short note on herbal medicines?
7. What are Device history records?

SECTION - C

Long Answer type questions: **3 × 15 = 45 Marks**

1. Discuss WHO guidelines for generic drugs.
2. Describe in detail universal tests / criteria for new drugs.
3. What are the guidelines for reprocessing & re-use of rejected APIs?
4. What are the instructions for packaging of pharmaceutical products?

SECTION - D

Compulsory Question: **20 Marks**

1. Why do you think there is a need of strengthening the central drug regulatory agency?