Maharajah's College of Pharmacy
Approved by AICTE, PCI, New Delhi
Affiliated to Andhra University,Visakhapatnam &
SBTET, Govt of A.P.
Phool Baugh Vizianagaram-535 002

NATIONAL BOARD OF ACCREDITATION

IIIyr B.Pharmacy –Quality assurance-Continuous Assessment

Answer the following questions

1. Quality assurance includes:
   a. All matters that individually or collectively influence product quality
   b. Quality management, quality control and GMP
   c. Only GMP and quality control
   d. A quality system and quality control

2. Quality assurance is the responsibility of
   a. Top management of the company only
   b. Only the staff in quality control department
   c. Staff at many different levels and in many different departments
   d. Only those people who make the product

3. Quality control is
   a. Confined to laboratory functions only
   b. Part of GMP concerned with all the sampling, specification, testing, organization documentation and release procedures to ensure quality
   c. Dependent on the production department for all its staffing and budget
   d. Not required by small manufacturers

4. Under GMP a company should investigate complaints
   a. About marketed products and take appropriate action to prevent reccurrence of justified complaints
   b. Only when we know that government may insist on a recall
   c. Only if the company believes the person making the complaint is truthful and is not just looking for free replacement
   d. Only if the production department agrees.

5. Separate manufacturing buildings are required are required for
   a. Every different product
   b. Materials that present a high risk of cross contamination
   c. Products of different dosage forms
   d. Sterile and non sterile production areas.

6. Ensuring that products are fit for their intended use is the responsibility of

a. The quality control manager
b. The production director
c. The chairman
d. All senior management and staff at all levels

7. Prospective validation is carried out
a. Periodically and/or after major changes
b. For a production process that has been operating for 6 months.
c. During the research and development phase
d. While a new product is being commissioned on the plant

8. Concurrent validation is carried out
a. Periodically and/or after major changes
b. For a production process that is routinely used.
c. During the development phase
d. During the normal production of a batch

9. Retrospective validation is carried out
a. Periodically and/or after major changes
b. For a production process that is routinely used on a routine basis, based on analysis of accumulated data
c. During the development phase
d. While a new product is being commissioned on the plant

10. The purpose of design qualification is to check
a. Has it been built correctly?
b. Has it been installed correctly?
c. Does it produce product correctly?
d. Does it work correctly?

********#*********