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SUBJECT : BP-606, PHARMACEUTICAL QUALITY ASSURANCE

B.PHARM. SIXTH SEMESTER

UNIT- I

MCQ:

1. Quality assurance is aimed to prevent which of the following defects
 - a) In the finished product
 - b) In the process used to make the product
 - c) In the formula of making produce
 - d) None
2. Process control is carried out
 - a) During production
 - b) After production
 - c) Before product
 - d) All of the above
3. Objective of ISO 9000 family of Quality management is
 - a) Environmental issues
 - b) Employee issues
 - c) Skill enhancement
 - d) Customer satisfaction
4. Which of the following is for environmental management?
 - a) ISO 14000
 - b) ISO 9000
 - c) ISO 26000
 - d) ISO 31000
5. TQM & ISO focuses on
 - a) Supplier
 - b) Employee
 - c) Customer
 - d) All of the above
6. Who is responsible for quality objective?
 - a) Frontline management
 - b) Top level management
 - c) Middle level management
 - d) All
7. EMS stands for
 - a) Employees management system
 - b) Environmental management system
 - c) Engineering management system
 - d) Equipment management system
8. ISO 14001 stresses on

- a) Environmental protection
 - b) Plan-Do-Check-Act
 - c) Prevention instead of detection
 - d) All of the above
9. Which one is key element of TQM is
- a) Continuous improvement
 - b) Focus on customer
 - c) Employee involvement
 - d) All of the above
10. In PDSA, Plan, Do, Act, S stands for _____
- a) Secure
 - b) Study
 - c) Short
 - d) Steady
11. Charts that show the frequency distribution of observed values of a variable are called as
- a) Control charts
 - b) Flow charts
 - c) Scatter diagrams
 - d) Histograms
12. Which one of the following does not belong to Deming's 14 points?
- a) Institute Leadership
 - b) Quality Circles
 - c) Top management commitment
 - d) On job training
13. Which one is a dominant form of communication?
- a) Downward
 - b) Upward
 - c) None
 - d) a & b both
14. The TQM philosophy of Do it right the first time was Given by
- a) Philip B Crosby
 - b) Kaoru Ishikawa
 - c) Genichi Taguchi
 - d) Armand V Feigenbaum
15. Who is considered to be the father of Quality circles?
- a) Philip B Crosby
 - b) Armand V Feigenbaum
 - c) Kaoru Ishikawa
 - d) Genichi Taguchi
16. Design of experiments (DOE) to product design concept was given by
- a) Kaoru Ishikawa
 - b) Genichi Taguchi
 - c) Armand V Feigenbaum
 - d) Philip B Crosby
17. NABL is in compliance with ISO
- a) 17025

- b) 16025
 - c) 14001
 - d) 12025
18. As per Q series climate zone IV, has temp and humidity
- a) 21°C, 45%
 - b) 25°C, 60%
 - c) 30°C, 70%
 - d) 30°C, 35%
19. Design of a stability schedule in which selected possible samples are tested at a specified time point for all the factors is
- a) Bracketing
 - b) Matrixing
 - c) Full study design
 - d) All
20. Stability studies of a New Drug substances and Products is attributed to which of the following series:
- a) M series
 - b) Q series
 - c) E series
 - d) F series
21. GMP is under which part of Sch M
- a) 1
 - b) 2
 - c) Both
 - d) 3

SHORT QUESTIONS

- 22. What are Critical quality attributes and Material attributes in QbD?
- 23. Differentiate between QA and QC.
- 24. Define: API, Contamination, Pharmaceutical Product, Quarantine, TQM
- 25. Write the components of GMP.
- 26. Write in brief about 4 types of ICH guidelines.
- 27. Enlist the Q series guidelines with purpose for stability testing of new drug substances and products.
- 28. What is plant layout? Write importance, factors and types of Plant Layout.
- 29. What are the benefits and elements of ISO 9000?
- 30. Write the steps required to get ISO 14000 certification.
- 31. Differentiate between certification and accreditation.

LONG QUESTIONS:

- 32 Write briefly various TQM Philosophies.
- 33. What is QbD? Discuss the various elements and tools of QbD.
- 34. What are the benefits of NABL accreditation. What are the various steps for obtaining NABL accreditation?