PHB Education

Government Exam and D. Pharm Exit Exam Preparation Questions Bank

Subject: Pharmaceutics

Chapter 18 : Quality Control and Quality Assurance

Section A: Definition and Concepts of Quality Assurance (QA) (25 MCQs

1. Quality Assurance ensures that —
   a) The final product is tested only
   b) Quality is built into the product
   c) Only defective products are removed
   d) None of these
   Answer: b
2. QA is a part of —
   a) Manufacturing only
   b) Total Quality Management
   c) Accounting process
   d) Distribution system
   Answer: b
3. The main aim of QA is —
   a) To find defects
   b) To prevent defects
   c) To sell products
   d) To advertise
   Answer: b
4. QA is —
   a) Product oriented
   b) Process oriented
   c) Marketing oriented
   d) None
   Answer: b
5. The motto of QA is —
   a) Quality by chance
   b) Quality by design
   c) Quality by testing
   d) Quality by marketing
   Answer: b
6. The head of QA is responsible for —
   a) Product release

b) Market survey

c) Machine maintenance

d) Packaging only

Answer: a

7. Documentation in QA is —

a) Not required

b) Optional

c) Mandatory

d) Dependent on QC

Answer: c

8. QA ensures compliance with —

a) GMP

b) GDP

c) ISO 9001

d) All of these

Answer: d

9. Quality assurance starts from —

a) Product testing

b) Product design

c) Product sale

d) Product marketing

Answer: b

10. “Right first time” concept belongs to —

a) QC

b) QA

c) Validation

d) Calibration

Answer: b

11. QA covers —

a) Production

b) Testing

c) Documentation

d) All of these

Answer: d

12. Quality assurance is concerned with —

a) Management of quality

b) Detection of defects

c) Financial audits

d) Procurement

Answer: a

13. SOP in QA stands for —

a) Standard Operation Plan

b) Standard Operating Procedure

c) Standard Observing Procedure

d) Simple Operating Plan

Answer: b

14. Deviation control is part of —

a) QC

b) QA

c) R&D

d) Production

Answer: b

15. Change control is implemented under —

a) QA

b) QC

c) Production

d) Finance

Answer: a

16. Internal audits are performed by —

a) Production

b) QA department

c) HR

d) Marketing

Answer: b

17. QA ensures compliance to —

a) Product quality

b) Process validation

c) Regulatory requirements

d) All of the above

Answer: d

18. The concept of “Quality by Design (QbD)” was introduced by —

a) FDA

b) ICH

c) WHO

d) USP

Answer: b

19. The objective of QA is to produce —

a) Economical products

b) Consistent and safe products

c) Attractive packaging

d) Costly drugs

Answer: b

20. QA includes —

a) Calibration

b) Validation

c) Documentation

d) All of these

Answer: d

21. The ultimate responsibility of product quality lies with —

a) Production manager

b) QA manager

c) QC analyst

d) Marketing manager

Answer: b

22. Revalidation is done —

a) After product launch

b) Periodically or after changes

c) Only during production

d) Never

Answer: b

23. Product recall is a part of —

a) QA system

b) QC test

c) Packaging

d) Labeling

Answer: a

24. The batch manufacturing record (BMR) is maintained under —

a) QA

b) Production

c) QC

d) HR

Answer: a

25. The quality policy is established by —

a) QA

b) Top management

c) QC

d) Production

Answer: b

Section B: Quality Control (QC) (25 MCQs)

---

26. Quality Control is —

a) Product-oriented

b) Process-oriented

c) Marketing-oriented

d) Cost-oriented

Answer: a

27. QC involves —

a) Raw material testing

b) In-process testing

c) Finished product testing

d) All of these

Answer: d

28. The main objective of QC is —

a) To ensure compliance of product

b) To control packaging

c) To maintain sales

d) To increase price

Answer: a

29. The instrument used for assay analysis is found in —

a) Production

b) QC laboratory

c) Warehouse

d) QA department

Answer: b

30. QC checks —

a) Appearance

b) pH

c) Content uniformity

d) All of these

Answer: d

31. Retention samples are maintained by —

a) QC

b) QA

c) Production

d) HR

Answer: a

32. In QC, sampling is done according to —

a) Random procedure

b) Standard sampling plan

c) Operator's choice

d) Production plan

Answer: b

33. Analytical balance calibration is the responsibility of —

a) QC

b) QA

c) Maintenance

d) Production

Answer: a

34. The QC laboratory must comply with —

a) GLP

b) GMP

c) GDP

d) ISO

Answer: a

35. Stability studies are monitored by —

a) QA

b) QC

c) Production

d) Marketing

Answer: b

36. Out-of-specification (OOS) results are investigated by —

a) QA

b) QC

c) Production

d) HR

Answer: b

37. QC ensures —

a) Product testing

b) Correct labeling

c) Product quality compliance

d) a and c

Answer: d

38. Reference standards are maintained by —

a) QC

b) QA

c) Production

d) Stores

Answer: a

39. Control samples are tested —

a) Monthly

b) Periodically

c) Before release

d) After marketing

Answer: c

40. Finished product release is authorized by —

a) QA

b) QC

c) Production

d) Store

Answer: a

41. QC report is reviewed by —

a) QA

b) Production

c) Marketing

d) Accounts

Answer: a

42. QC testing ensures —
    a) Compliance with pharmacopoeial standards
    b) Market appeal
    c) Cost reduction
    d) Packaging quality
    Answer: a
43. Microbiological testing is part of —
    a) QC
    b) QA
    c) R&D
    d) Maintenance
    Answer: a
44. Environmental monitoring in clean rooms is under —
    a) QC (Microbiology)
    b) QA
    c) HR
    d) Stores
    Answer: a
45. QC laboratory documentation includes —
    a) Log books
    b) Test reports
    c) Equipment records
    d) All of these
    Answer: d
46. The key document in QC is —
    a) Analytical report
    b) BMR
    c) SOP
    d) Log sheet
    Answer: a
47. QC testing is performed as per —
    a) SOP
    b) GMP
    c) GLP
    d) All of these
    Answer: d

48. The QC function begins from —
    a) Receipt of raw materials
    b) Packaging
    c) Distribution
    d) Marketing
    Answer: a
49. QC ensures —
    a) Consistent quality of batches
    b) Random testing
    c) Market survey
    d) Sales increase
    Answer: a
50. The department responsible for OOS investigation closure is —
    a) QA
    b) QC
    c) Production
    d) Stores
    Answer: a

Section C: Current Good Manufacturing Practice (cGMP) (25 MCQs)

---

51. GMP stands for —
    a) General Manufacturing Process
    b) Good Manufacturing Practice
    c) Gross Manufacturing Plan
    d) Government Manufacturing Policy
    Answer: b
52. The term “cGMP” means —
    a) Classical GMP
    b) Current GMP
    c) Certified GMP
    d) Custom GMP
    Answer: b
53. GMP ensures —
    a) Uniform production
    b) Product safety

c) Product efficacy

d) All of these

Answer: d

54. GMP was first introduced by —

a) USFDA

b) WHO

c) ICH

d) ISO

Answer: a

55. WHO-GMP guidelines are given in —

a) TRS 823

b) TRS 986

c) TRS 957

d) TRS 823 (Annex 3)

Answer: d

56. Premises and sanitation requirements are part of —

a) GMP

b) QC

c) QA

d) R&D

Answer: a

57. GMP documentation includes —

a) BMR

b) SOP

c) Validation reports

d) All of these

Answer: d

58. The fundamental principle of GMP is —

a) Product safety

b) Proper documentation

c) Employee training

d) All of these

Answer: d

59. The organization responsible for cGMP enforcement in India —

a) CDSCO

b) FDA (USA)

c) ICH

d) ISO

Answer: a

60. Personal hygiene in manufacturing is a requirement of —

a) GMP

b) QA

c) QC

d) ISO

Answer: a

61. Batch numbering ensures —

a) Traceability

b) Marketing

c) Cost control

d) Productivity

Answer: a

62. GMP compliance audit is conducted by —

a) Regulatory bodies

b) Marketing team

c) Production manager

d) Finance department

Answer: a

63. Clean room classification is part of —

a) GMP

b) QA

c) R&D

d) QC

Answer: a

64. Documentation in GMP follows the principle —

a) “If it’s not written, it didn’t happen.”

b) “Write less, do more.”

c) “Ignore minor details.”

d) “Focus on output only.”

Answer: a

65. The Indian GMP guidelines are under —

a) Schedule M

b) Schedule P

c) Schedule C

d) Schedule G

Answer: a

66. Equipment qualification is a part of —

a) Validation

b) GMP

c) QA

d) QC

Answer: a

67. Air handling system validation is done under —

a) HVAC

b) GMP

c) QC

d) R&D

Answer: a

68. Personnel training in GMP is —

a) Optional

b) Mandatory

c) Annual

d) None

Answer: b

69. GMP ensures —

a) Consistency and reproducibility

b) Marketing

c) Financial gain

d) New product discovery

Answer: a

70. The principle of GMP is mainly focused on —

a) Safety and quality

b) Design and cost

c) Color and taste

d) None

Answer: a

71. GMP for sterile products is specified in —

a) Annex 1

b) Annex 5

c) Annex 7

d) Annex 9

Answer: a

Section D: Validation and Calibration (25 MCQs)

---

76. Validation ensures —

a) A process consistently produces quality product

b) Random testing

c) New product innovation

d) Employee safety only

Answer: a

77. Calibration ensures —

a) Accuracy of instruments

b) Product safety

c) Process reproducibility

d) Data accuracy

Answer: a

78. Types of validation include —

a) Process validation

b) Cleaning validation

c) Analytical validation

d) All of these

Answer: d

79. Validation is a part of —

a) QA

b) QC

c) R&D

d) HR

Answer: a

80. Calibration is carried out —

a) Periodically

b) Daily

c) Once in lifetime

d) Randomly

Answer: a

81. Installation Qualification (IQ) confirms —

a) Equipment installed as per specification

b) Equipment performs as expected

c) Equipment cleaning

d) Operator training

Answer: a

82. Operational Qualification (OQ) confirms —

a) Performance of equipment

b) Design verification

c) Installation check

d) Material handling

Answer: a

83. Performance Qualification (PQ) confirms —

a) Consistent performance in routine use

b) Design

c) Installation

d) Calibration

Answer: a

84. Validation Master Plan (VMP) is a document for —

a) Planning all validation activities

b) Production planning

c) Marketing

d) QC testing

Answer: a

85. Analytical method validation ensures —

a) Accuracy, precision, specificity

b) Packaging

c) Labeling

d) Cleaning

Answer: a

86. Recalibration is required when —

a) Instrument is repaired

b) New product introduced

c) Cleaning is done

d) Batch is rejected

Answer: a

87. The calibration of weights is traceable to —

a) National Standards

b) WHO

c) GMP

d) ISO 45001

Answer: a

88. Validation should be re-performed when —

a) Major change occurs

b) Minor deviation

c) Routine testing

d) Annual training

Answer: a

89. Validation protocol includes —

a) Objective, scope, procedure

b) Marketing data

c) Sales plan

d) Audit report

Answer: a

90. Revalidation frequency depends on —

a) Process change

b) Product type

c) Regulatory requirements

d) All of these

Answer: d

91. Calibration of pH meter is done using —

a) Buffer solutions

b) Water

c) Alcohol

d) Oil

Answer: a

92. Thermometer calibration is done using —

a) Standard temperature baths

b) Ice cubes

c) Hot water

d) None

Answer: a

93. Analytical balance calibration involves —
    a) Standard weights
    b) Random samples
    c) Sugar
    d) Chemicals
    Answer: a
94. Cleaning validation ensures —
    a) No cross-contamination
    b) New batch identity
    c) Better yield
    d) Faster drying
    Answer: a
95. Process validation types —
    a) Prospective, Concurrent, Retrospective
    b) Internal and External
    c) Direct and Indirect
    d) Random
    Answer: a
96. Prospective validation is done —
    a) Before production
    b) During production
    c) After production
    d) After market
    Answer: a
97. Concurrent validation is done —
    a) During actual production
    b) Before production
    c) After release
    d) During audit
    Answer: a
98. Retrospective validation is done —
    a) Based on historical data
    b) New product
    c) Failed batch
    d) New equipment
    Answer: a

99. Calibration certificate must include —

a) Date, result, signature

b) Cost of product

c) Manufacturing process

d) Audit details

Answer: a

100. Validation and calibration are essential for —

a) GMP compliance

b) Product advertisement

c) Finance approval

d) Market analysis

Answer: a

Dr. Arvind Kumar Gupta
(M.Pharm, PDCR, PGDMM & Ph.D)
GATE 2003 Qualified with 97.2 percentile
Dr. S. N. Dev College of Pharmacy
Shamli (U.P.)