Question Bank with Answer key
Subject: Pharmaceutical Quality Assurance (BP 606T)
Year and Sem: T. Y. B. Pharm. (Sem VI)

Multiple choice-based questions

1 ICH Q 7 represents _____ guidelines.

a. Quality Risk Management
b. Good Manufacturing Practices
c. Lifecycle management
d. Pharmaceutical Development

2 Testing of raw materials and finished products is the responsibility of _____.

a. Stores department
b. Quality Assurance department
c. Production department
d. **Quality Control department**

3 _____ is a managerial tool.

a. Quality Control
b. Quality Assurance
c. Production
d. Accreditation

4 Following are tools of QbD except _____.

a. **Critical Quality Attributes**
b. Process Analytical Technology
c. Risk assessment
d. Design of Experiments

5 ICH Q 8 represents _____ guidelines.

a. Quality Risk Management
b. Good Manufacturing Practices
c. Lifecycle management
d. **Pharmaceutical Development**

6 Maintaining reference standard and retained samples is the responsibility of _____ department.

a. Stores
b. Quality Assurance
c. Production
d. **Quality Control**

7 The validity of NABL accreditation is for _____.

a. Six months
b. One year
c. **Two years**
d. Three years

8 PDCA cycle consists of _____.

a. **Plan Do Check Act**
b. Plan Develop Create Act
c. Plan Develop Correct Act
d. Plan Do Correct Act

9 Bracketing design for stability testing includes _____.

a. Testing samples of all design factors at all time points
b. **Testing samples of extreme design factors at all time points**
c. Testing samples of all design factors at half time points
d. Testing samples of extreme design factors at half time points

10 Investigation deviations in the manufacturing process is the responsibility of _____ department.

a. Stores
b. **Quality Assurance**
c. Production
d. Quality Control

11 NABL is an autonomous body established under the aegis of _____.

a. Department of Health & allied sciences
b. **Department of Science & Technology**
c. Department of Food & Drug testing
d. Department of Pharmaceutical Sciences

12 _____ is a subset of Quality Assurance.

a. **Quality Control**
b. Quality Management System
c. Quality Policy
d. Quality Framework

13 ISO 14000 relates to _____.

a. Quality Assurance System
b. Environmental management systems
c. Quality Management System
d. Product Management System

14 According to Juran, Quality is _____.

a. Customer satisfaction
b. Management's objective
c. Fitness for Use
d. Meeting standards

15 Critical quality attributes and critical process parameters are crucial part of _____ .

a. ISO
b. GMP
c. NABL
d. Quality by Design

16 Which department holds responsibility of quality audits?

a. Quality Assurance
b. Quality Control
c. Production
d. Human Resource

17 Regulatory audit is also known as _____.

a. First party audit
b. Second party audit
c. Third party audit
d. Fourth party audit

18 The buildings used for the manufacture of drugs should conform to all the conditions laid down in _____.

a. Pharmacy Act
b. **Factories Act**
c. Drug and Cosmetic Act
d. Companies Act

19 Room classification tests in the "at-rest" condition should be carried out _____.

a. **With the equipment installed, HVAC operational, but without any operators.**
b. In the empty room, in the absence of any equipment or personnel.
c. During the normal production process with equipment operating under normal conditions.
d. With the normal number of personnel present in the room.

20 A job description is an organized factual statement of the _____ of a specific job.

a. Report
b. Policy
c. Schedule
d. **Responsibilities**

21 _____ help the managers to make salary revisions, allowances and other benefits related to salaries.

a. Audit records
b. Deviation records
c. **Personal records**
d. Master records

22 The highest air pressure is maintained in _____.

a. **Clean Room**
b. Gowning room
c. Factory Hallway
d. Store room

23 Air pressure differentials in a clean room should be checked _____.

a. **Daily**
b. Yearly
c. Biannually
d. Weekly

24 The efficiency of HEPA filters should be _____at 0.22micron particle size.

a. 95.55%
b. **99.99%**
c. 93.22%
d. 90.99%

25 The recommended size of area to be swabbed for environmental monitoring of equipment and apparatus is _____.

a. 10 – 15 cm^2
b. 100 – 200 cm^2
c. **24 – 30 cm^2**
d. 2 – 3 cm^2

26 Key positions in a pharmaceutical company should be occupied by _____.

a. Consultants
b. **Full time personnel**
c. Part time personnel
d. External auditors

27 Installation qualification of an equipment verifies that ____.

a. Equipment is operating consistently
b. User requirements are incorporated into equipment design
c. **Equipment is installed and calibrated**
d. Installed equipment gives quality product consistently for long period

28 Following products cannot be manufactured in the same manufacturing facility

a. **Penicillin products & Antidiabetic products**
b. Antiviral product & Anti-inflammatory product
c. Antiviral product & Antihypertensive product
d. Antimalarial product & Anti-inflammatory product

29 The dispensing of raw materials from Stores must follow the principle of _____.

a. First Out Then In
b. Fast Out Fast In
c. Fast In Fast Out
d. **First In First Out**

30 Approval of release of finished product is the responsibility of ____.

a. Head of Stores
b. Head of Quality Control
c. **Head of Quality Assurance**
d. Head of Production

31 The following is verified during operational qualification of an equipment.

a. Equipment is installed and calibrated
b. **Equipment operates consistently within operational limit**
c. Equipment shows satisfactory performance over long period.
d. Equipment is installed and connected to utilities

32 Service bay is maintained at _____.

a. Class 10
b. Class 20
c. Class 50
d. **Class 1000**

33 Airlock doors should be equipped with systems that_____.

a. **Prevent simultaneous opening of both the doors**
b. Allow simultaneous opening of both the doors
c. Prevent simultaneous opening of doors by unauthorized persons
d. Allow simultaneous opening of both the doors by authorized persons

34 Personal records are records of _____ in an organization.

a. Employer
b. **Employees**
c. Visitors
d. Auditors

35 In sterile area (Grade A), the limit on microbial contamination in air sample is ____.

a. < 1 CFU/mm3

b. < 200 CFU/mm3

c. < 100 CFU/mm3

d. < 10 CFU/mm3

36 Cleaning of the equipment is a part of _____.

a. Periodic maintenance

b. Predictive maintenance

c. Corrective maintenance

d. Curative maintenance

37 Calibration of an equipment should be performed using _____.

a. Test sample

b. Certified Standards

c. Inhouse standards

d. Reference sample

38 Minimum number of glass containers of 3 ml nominal capacity used for hydrolytic resistance test are _____.

a. 20

b. 10

c. 5

d. 2

39 Subpart G of GLP for non- clinical laboratory study is _____.

a. General Provision

b. Equipment

c. Facilities

d. **Protocol for and Conduct of a nonclinical laboratory study**

40 Grammage is used to determine the physical dimensions of the _____ material.

a. **Paper and paperboard**

b. Thermosetting plastic

c. Glass

d. Metal

41 The person who approves the protocol for conduct of nonclinical laboratory study is _____.

a. **Sponsor**
b. Scientist
c. Study director
d. Quality Assurance Head

42 As per USP, the limit of fragments visible to the naked eye in fragmentation test for rubber closures is

a. Not more than 500
b. Not more than 100
c. Not more than 50
d. **Not more than 5**

43 The OECD stands for

e. Organization for Environmental Coordination and Discussion
f. **Organization for Economic Cooperation and Development**
g. Organization for Environmental Cooperation and Development
h. Organization for Economic Cooperation and Discussion

44 For evaluation of metal container, sample complies with specification limit if

a. Total score is <1000
b. Total score is 100-150
c. Total score is > 150
d. **Total score is < 100**

45 As per USFDA GLP guidelines, Subpart C is _____.

a. Equipment
b. **Facilities**
c. Records and Reports
d. Organization and personnel

46 Cobb test measures the ____ of paper and board

a. Ink absorbency
b. **Water absorbency**
c. Acid absorbency
d. Alkali absorbency

47 The _____ is responsible for the conduct of a nonclinical laboratory study.

a. **Study Director**
b. Scientist
c. Quality Assurance Unit
d. Laboratory Technician

48 In the test for volatile sulphides in rubber closure, _____ paper is used.

a. Litmus paper
b. Starch paper
c. **Lead acetate paper**
d. Mercuric chloride

49 Records of a nonclinical study should be retained for _____ after termination / discontinuation of the study.

a. One year
b. **Two years**
c. Three years
d. Five years

50 Neutral glass is also called as _____.

a. **Type I glass**
b. Type II glass
c. Type III glass
d. NP glass

51 As per USFDA GLP guidelines, Subpart F is _____.

a. Facilities
b. Equipment
c. Records and Reports
d. **Test and Control Articles**

52 Tear strength measures the _____.

a. Energy required to make puncture in the paper
b. Force that a paper withstands before breaking
c. Degree of resistance offered by paper when it is folded
d. **Force required to tear an initial cut in the paper**

53 Changes in an approved protocol for conduct of nonclinical laboratory study are signed by _____.

a. Sponsor
b. Scientist
c. Quality Assurance Personnel
d. **Study Director**

54 Self sealability test is intended for _____.

a. Rubber closures of single dose container
b. **Rubber closures of multi dose containers**
c. Plastic closures of single dose containers
d. Plastic closures of multidose containers

55 The principles of GLP applies to _____.

a. Conduct of clinical studies

b. **Conduct of nonclinical studies**

c. Conduct of analytical studies

d. Conduct of microbiological studies

56 GLP regulations were implemented by FDA in _____.

a. 1978

b. 1971

c. 1968

d. 1981

57 Type III glass is also known as _____.

a. Soda lime glass

b. Borosilicate glass

c. Treated Soda lime glass

d. Treated borosilicate glass

58 Limit of 0.02 N sulphuric acid for Type III glass in powdered glass test is _____.

a. 8 ml

b. 1 ml

c. 7.5 ml

d. 8.5 ml

59 _____ is the test in which test piece is folded back and forth until rupture occurs

a. Folding endurance

b. Tensile strength

c. Burst Resistance

d. Tear Strength

60 Water attack test is performed on _____ glass

a. Type I

b. Type II

c. Type III

d. Type IV

61 ____ test is specifically used for testing glass containers used for aqueous parenterals.

a. Light transmission test

b. Arsenic test

c. Thermal Shock test

d. Internal bursting pressure test

62 Corrections to the final report by study director are in the form of _____.

a. Revised edition

b. Oral communication

c. Amendment

d. Revised Version

63 The primary documentation to be reviewed during technical investigation of complaints is _____.

a. Name, address, phone number and email of a customer.

b. Distribution records

c. Deviation records

d. Complaint files and batch records

64 The final Tier in the Quality documentation system is _____.

a. **Records**

b. Work instructions

c. Quality Procedures

d. Quality Policies

65 _____ is at the apex of Quality Management System.

a. Quality Records

b. **Quality Manual**

c. Working instructions

d. Quality procedures

66 Which is the second step in Handling of complaints?

a. Monthly trend analysis

b. Corrective action

c. **Technical investigation**

d. Receiving of complaints

67 Microbial contamination of non-injectable product results in _____.

a. Class I recall

b. **Class II recall**

c. Class III recall

d. No recall

68 The SOP's are reviewed after _____.

a. One year

b. **Two years**

c. Three years

d. Five years

69 The disposal of printed packaging material of pharmaceuticals is done using _____.

a. Incineration

b. Autoclaving

c. Recycling

d. Landfill

70 Complaint investigation is the responsibility of _____.

a. Marketing department

b. Quality Assurance department

c. Production department

d. Quality Control department

71 Documents should be retained for atleast _____ years after the expiry of the product.

a. One

b. Two

c. Three

d. Five

72 The good material management system ensures the following except _____.

a. Right quality of the product.

b. **Stocking large amounts of materials**

c. Minimize inventory costs

d. Right delivery time

73 Retrospective validation is performed using data from minimum _____ consecutive batches

a. One

b. Three

c. Five

d. **Ten**

74 During the qualification of UV-visible spectrophotometer, resolution is measured using ____.

a. Holmium perchlorate

b. Potassium chloride

c. Potassium dichromate

d. **Toluene in hexane**

75 The signal to noise ratio in the determination of LOD is _____.

a. **3:1**

b. 5:1

c. 10:1

d. 15:1

76 ____ is the closeness of agreement between a series of measurement obtained from multiple sampling of same homogenous sample.

a. Accuracy

b. **Precision**

c. LOD

d. Linearity

77 In the qualification of UV-visible spectrophotometer, photometric accuracy is determined using _____.

a. Potassium dichromate

b. Holmium perchlorate

c. Sodium iodide

d. Potassium chloride

78 Prospective validation is performed on atleast _____ successive batches.

a. Ten

b. Five

c. Three

d. Seven

79 _____ is carried out in connection with the introduction of new drug products.

a. Retrospective validation

b. Prospective validation

c. Concurrent validation

d. Revalidation

80 _____ is a process that demonstrates a particular instrument produces results within specified limits, as compared to those produced by a traceable standard.

a. Validation

b. Qualification

c. Calibration

d. Verification

Descriptive Questions:

Please note important points to be covered fin the answer are mentioned below the question.

1 Enlist the ICH Q series guideline titles. Write in brief about Stability testing of new drug substances.

(Ref: ICH guidelines Q1)

ICH Q series guidelines: Enlist no. and title of the guideline

Stability Testing of New Drug Substance:

No. of batches, Types of tests to be conducted, Frequency of Testing with conditions: (For long term studies, accelerated storage, Intermediate storage condition), Evaluation of Stability Data

2 Enlist the participants of ICH. Write in brief about photostability testing of drug products.

Participants of ICH: Representatives from six parties, Additional members (non-voting members)

Photostability testing of drug products (Ref: ICH guidelines Q1B):

Types of studies: exposed drug product, product in the immediate pack, drug product in the marketing pack.

Light Source:

Procedure

Sample presentation

Evaluation

3 Define QbD. What are key elements of QbD? Differentiate between ISO 9000 & ISO 14000.

Definition

Key Elements: Quality target product profile (QTPP), Critical quality attributes (CQAs), Critical Process parameters, Design space

Differentiate between ISO 9000 & ISO 14000: Any 2 -3 points

4 Define TQM & write a note on elements and principles of TQM. Give the process for NABL accreditation.

TQM: Definition as per any one of the philosophies

Elements & Principles: Focus on the Customer, Employee Total Involvement, Continuous improvement

Briefly describe the philosophies by Deming, Juran, Feigenbaum, Philip Crosby

NABL accreditation: Process from application to issuance of certificate & renewal

5 Define QbD. Write a note on tools of QbD. Explain the benefits and process of ISO 9000 registration.

Define QbD

Tools of QbD: Design of Experiments, Risk Assessment, Process Analytical Technology

Benefits of ISO

Process of ISO 9000 registration: All the steps

6 Define TQM & write a note on philosophies of TQM. Differentiate between Quality Control & Quality Assurance.

Definition

Philosophies: Feigenbaum, Juran, Deming, Philip Crosby

Difference between QA & QC (any 4 points)

7 State the purpose of ICH. Write in brief about bracketing and matrixing design for stability testing of new products.

Purpose of ICH

Bracketing and Matrixing (Ref: ICH guidelines Q1D): Reduced design, Definition of bracketing, Application, Example – table, Definition of matrixing, Application, Example – table

8 Define Quality Assurance. Give the importance of NABL accreditation and explain the process of accreditation.

Definition

NABL: Advantages (any 4 points), Process from application to issuance of certificate

Renewal

9 What is Quality management System? Give the role of Quality Control and Quality Assurance departments in a Pharmaceutical Industry

Quality management System – Definition, Elements of QMS

Functions of QC department & Functions of QA department

10 Discuss the key elements of QbD. What is ISO? Discuss its benefits and the process of ISO registration.

Key Elements: Quality target product profile (QTPP), Critical quality attributes (CQAs), Critical Process parameters, Design space

Explain ISO 9000, 14000, Benefits of ISO

Process of ISO 9000 registration – All steps

11 What is NABL accreditation and its benefits? State the role of TQM in pharmaceutical industry and discuss its philosophy.

NABL accreditation: Accreditation body, Purpose & advantages of accreditation

TQM – Advantages, Philosophies -Feigenbaum, Juran, Deming, Philip Crosby

12 What is Quality management system? Give the difference between QA & QC.

Definition, Relationship between QMS, QA, QC, GMP, Benefits of QMS

Difference (four points)

13 Discuss the training, hygiene and personal records with reference to GMP in a pharmaceutical industry.

Ref: GMP schedule M

Types or training

Job responsibility

Health checks, Clothing, Personal hygiene

Disease reporting

Personal record and their purpose

14 Explain the process of equipment selection and maintenance in the pharmaceutical manufacturing unit.

Criteria for equipment selection

Purchase specification

DQ, IQ, OQ, PQ

Periodic maintenance

Predictive maintenance

15 Write a note on utilities and maintenance of sterile areas. Illustrate a layout of injection manufacturing unit.

Explain utilities (compressed air, gas, steam, heating, ventilation and air conditioning)

Control of utilities/periodic checks

Clean room classification

Control of clean room/Maintenance of sterile area (particle count, microbial contamination, air pressure differentials)

Draw a layout mentioning class, air pressure / air flow, material entry, gowning area, personal entry etc.

16 Explain in detail the equipment selection and maintenance of stores for raw materials

Criteria for equipment selection: Purchase specification, DQ, IQ, OQ, PQ, Periodic maintenance, Predictive maintenance

Maintenance of store for raw material: Layout & Storage, Receiving, Sampling, Dispensing, Cleaning & sanitation

18 Explain the design and construction of building for a pharmaceutical manufacturing unit.

(Ref: GMP schedule M)

Material of construction, Design & Layout, Measures to avoid cross contaminations

Sanitation & Cleaning, Drains & waste disposal, Environmental control measures

19 Discuss the process of equipment selection and its maintenance.

Criteria for equipment selection, Purchase specification, DQ, IQ, OQ, PQ

Periodic maintenance, Predictive maintenance

20 Write a note on maintenance of sterile area. Illustrate a layout for manufacturing of injectables.

Clean room criteria, Maintenance/control measures & testing frequency, Design/layout with reference to air flow and air pressure.

21. Write in brief about personal training. Discuss the responsibilities of key personnel.

Types of training

Responsibilities of Head of Production, QA & QC

22 What is the role of Quality Assurance Unit in a testing facility? Write in brief about animal care for conduct of nonclinical study.

Role of Quality Assurance Unit: Responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations in this part.

Animal care: (Ref: 21 CFR GLP Subpart C & subpart E): Animal housing, Health

Cleaning, Sanitization, Pest Control, Labelling & Identification of animals, Documentation – Diagnosis, treatment, date, health record, Feed, water, bedding

23 Define GLP. Write in brief about disqualification of testing facility.

Definition: As per OECD

Disqualification of testing facility (Ref: 21 CFR GLP subpart K): Grounds for disqualification, Notice and Opportunity for Hearing on Proposed Disqualification, Final Order, Actions upon disqualification

24 Enlist the quality control tests for glass containers. Write in brief about powdered glass test.

Quality control tests for glass containers: Hydrolytic Resistance Test, Surface Test Water Attack Test, Powdered Glass Test, Light Transmission Test, Arsenic Test etc.
Powdered glass test: Purpose, Procedure, Limits

25 Enlist the quality control tests for glass containers. Discuss in brief the hydrolytic resistance test.

Enlist the Quality control tests for glass containers
Hydrolytic resistance test: Purpose, Process, Limits & Surface test

26 Explain in brief quality control test for metal containers used for eye ointment.

(Refer IP): Enlist the tests, Procedure, Limits

27 Write a note on quality control tests for secondary packaging.

Enlist, brief tests for paper & paperboard

28 Define GLP. Discuss in brief the protocol for conduct of nonclinical study.

Definition as per OECD
Protocol for conduct of nonclinical laboratory tests (Ref 21 CFR GLP subpart G)
Every study – approved protocol
Contents of protocol
All changes in or revisions of an approved protocol and the reasons therefore shall be documented, signed by the study director, dated, and maintained with the protocol

29 Discuss the quality control tests for plastic containers.

Enlist the tests, Procedure for each test with limit

30 Discuss the QC tests for rubber closures

Enlist, Procedure, Limit for all tests

31 What is Complaint? Discuss the steps involved in handling of complaints in a pharmaceutical company.

Definition, Types, Steps for handling of complaints – Receipt to monthly trend analysis

32 What is product quality review? Discuss "Quality audit" in pharmaceutical industry.

Product Quality Review: Definition, Purpose

Quality audit: Definition, Types, Objectives, Principles

33 Discuss Quality Review and Quality documentation in pharmaceutical industry.

Quality Review: Definition, Objective, Process/Phases

Quality Documentation: Write about each tier of documentation

34 Define SOP. Discuss the general format of SOP

Definition

General Format of SOP: Header, Footer, Validity, Contents, Signatures & Authorizations

Illustrate Sample SOP

35 Explain the process of recall. Write a note on disposal of waste in pharmaceutical industry.

Recall types, Recall process

Disposal of waste: Types of waste, Different process of disposal

36 Enlist the types of documents maintained in pharmaceutical company. Write in brief about batch formula record.

Ref: Pharmaceutical Quality Assurance by Manohar Potdar

Types of documents (enlist any 4-8)

Batch Formula record: Contents, Sample batch record

37 Define SOP. Explain the general format of SOP and its implementation.

Definition

Contents – Company name and pagination, Title, Identification, Effective Date, Review Period/Validity, Scope, Responsibility, Procedure, Review and approval

Implementation – Training & distribution

38 What is recall? Explain in detail the process for handling of complaints.

Definition of recall, Enlist types of recall, Steps – Handling of complaints

39 State the purpose of distribution records. Write a note on Master Formula Record.

Purpose

Master Formula Record – Definition, Purpose, Contents, Sample format

40 What is recall and returned product? Write in brief about handling of complaints.

Definition recall

Explain returned product

Complaint handling steps

41 Write a note on handling of returned goods. Discuss the disposal of waste in pharmaceutical industry

Explain Returned goods, handling, documentation

Disposal of waste – discuss different methods

42 Define Validation. Give the process for qualification of UV-visible spectrophotometer.

Definition

Qualification of UV-visible spectrophotometer: (Ref USP/IP)

Write in detail about the reference/standards used and acceptance criteria for following tests: Control of Wavelength, Limit of Stray light, Resolution, Control of Absorbance

43 What are good warehousing practices? Write a note on material management.

Good warehousing practices: Layout & segregation, Sanitation, Control of stock

Documentation, Maintenance of stock – system, Identification & labelling, Warehouse staff and access to warehouse

Material Management: Planning and procuring materials, Vendor selection,

Purchasing, Receipt of materials (including sampling for quality control), Inventory management, Dispensing of materials.

44 Enlist the types of process validation. Explain the process for calibration of pH meter.

Types of Process validation: Prospective validation, Retrospective validation

Concurrent validation

Process of calibration of pH meter: Three point or two-point calibration, Buffers used, Electrode care & storage

45 State the importance of inventory management. Discuss the Good warehousing practices in detail.

Inventory management: List advantages of inventory control

Good warehousing practices: Layout & segregation, Sanitation, Control of stock, Documentation, Maintenance of stock – system, Identification & labelling, Warehouse staff and access to warehouse

46 Define validation. Explain in brief the types of process validation.

Definition, Prospective validation, Retrospective validation, Concurrent validation

Revalidation

47 Explain in brief the objectives and elements of material management.

Material Management: Benefits & Purpose, Planning and procuring materials,

Vendor selection, Purchasing, Receipt of materials (including sampling for quality control), Inventory management methods, Dispensing of materials.

48 Define validation. Write a note on analytical method validation

Ref: ICH Q2 R guidelines

Definition

Analytical method validation – Accuracy, precision, LOD, LOQ, Linearity & Range, Robustness

49 Define validation. Give the difference between validation & calibration. Write a note on prospective validation.

Definition, Difference (2 points), Prospective validation – purpose, no. of batches studied, process.

50 Write the difference between Prospective, Concurrent & retrospective validation. Discuss calibration of pH meter

Difference (two points)

Calibration: three-point method