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SUBJECT: BP-606, PHARMACEUTICAL QUALITY ASSURANCE

B.PHARM. SIXTH SEMESTER

UNIT IV **QUESTION BANK**

MCQ

1. Type A complaints does not include:
   a) Purity and safety
   b) Potency
   c) Product stability
   d) Extraneous contamination, mix ups etc.
2. Responsibility of a complaint lies with
   a) production head
   b) Quality assurance head
   c) Unit head
   d) All of above
3. Primary document to be reviewed in technical investigation stage of complaint handling is
   a) Complaint files, batch records
   b) Name, address, phone number and email of customer
   c) Complaint samples
   d) Reserve samples
4. Complaints arising because of not keeping products under appropriate conditions of temperature, humidity and light so that the identity, strength, quality and purity of the drug product are affected are called as
   a) Non confirmed complain
   b) Tamper suspicion
   c) Confirmed complaint
   d) None
5. Issues related to labeling or coding of batch details, secondary packaging material problems comes under the complaint
   a) Type A
   b) Type C
   c) Type B
   d) Type D
6. Issues related to primary packaging, foreign matter in a product is
   a) Type A
   b) Type C
   c) Type B
   d) Type D
7. Receiving of wet Products is complaint associated with
   a) Product complaint
   b) Delivery complaint
   c) Packaging Complaint

d) None

8. If a complaint is received from Production, Quality Control, Warehouse, Sales Department, the source is said to be
   a) External
   b) Internal
   c) Verbal
   d) Written
9. If a is received from customers, doctors, paramedics, clinics, hospitals, drugstores etc. the source of complaint is said to be

a) External
b) Internal
c) Verbal
d) Written

10. The correct sequence for handling complaint is

a) Receiving complaint, Investigation, corrective actions, feedback to customer, Trend analysis by QC
b) Investigation, Receiving complaint, corrective actions, Trend analysis by QC, feedback to customer
c) Receiving complaint, Trend analysis by QC, Investigation, feedback to customer, corrective actions
d) Receiving complaint, feedback to customer, Trend analysis by QC, corrective actions, Investigation

11. OOS is abbreviation used for

a) Out of stock
b) Out of specification
c) Out of storage
d) Out of sterility

12. When complaint & retained sample are in compliance with specification Complaint sample is OOS due to misuse/ mishandling it is

a) Confirmed complaint
b) Non confirmed complaint
c) Tampered complaint
d) Counterfeit complaint

13. When only complaint sample is OOS, with no definite reason, like packaging material is different etc. it is referred as

a) Counterfeit complaint
b) Non confirmed complaint
c) Tampered complaint
d) Both a & c

14. Which analysis is a good statistical tool to identify main confirmed complaints that has to be treated first

a) Chareto analysis
b) Pareto analysis
c) Woodberck analysis
d) Fisher analysis

15. Bulk/ finished product when sent back to Manufacturer, distributor, importer is known as a) Returned goods
b) Recalled goods
c) Expired goods
d) Salvaged goods
16. Returned goods which had been subjected to improper storage conditions like extreme temp., humidity, smoke, fumes, pressure, radiation are known as
a) Returned goods
b) Recalled goods
c) Expired goods
d) Salvaged goods
17. Withdrawing or removing the product from distribution network as of quality issues/ adverse drug reactions is known as
a) Returning of goods
b) Restoring of goods
c) Recalling of goods
d) Reporting of goods
18. When there is probability by a product to cause serious health issues, it is
a) Class II recall
b) Class I recall
c) Class III recall
d) All of the above
19. When there is probability that Product may cause temporary or remote Adverse health issues it is
a) Class III recall
b) Class II recall
c) Class I recall
d) Class IV recall
20. When the Product may not cause any adverse health consequences, it is
a) Class III recall
b) Class I recall
c) Class II recall
d) Class IV recall
21. Serious adverse reactions of class I & II after receipt of complaint must be reported to Health authorities with in
a) 30 hr
b) 24 hr
c) 72 hr
d) None
22. Less serious adverse reactions of class III must be reported to the Health authorities with in
a) 30 hr
b) 72 hr
c) 24 hr
d) 48 hr
23. If the product is recalled from healthcare practitioners, nursing homes, it is termed as
a) Wholesale level recall

b) Retail level recall
c) Consumer level recall
d) All of the above
24. Consumer level recall includes:
a) Medical shops
b) Wholesaler
c) Retailer
d) Patient
25. Public alert is issued for which class of hazards
a) Class I
b) Class III
c) Class II
d) Both a & c
26. Placing of waste material directly into land disposal site without prior treatment is called as
a) Inertisation
b) Landfill
c) Encapsulation
d) Sewer
27. Which of the methods is also known as **immobilization**
a) Landfill
b) Incineration
c) Sewer
d) Encapsulation
28. Product recall arises under how many numerical designation heads assigned by Health Protection Branch
a) Four
b) Three
c) Five
d) Two
29. Following are the categories of complaints
a) Quality complaints
b) Adverse reaction complaints
c) Other medically related complaints
d) All of the above
30. The term Waste is defined by Environmental Protection Act in
a) 1950
b) 1964
c) 1977
d) 1990
31. Waste is broadly classified into
a) Biodegradable waste
b) Non biodegradable waste
c) Both of the above
d) None

32. Making the solution in water or any suitable solvent, pouring this into effluent treatment system is a method of waste disposal for which type of dosage forms:
a) Tablets
b) Capsules
c) Granules
d) All of the above
33. Which color code is used for puncture proof containers in destroying bio medical waste/ scrap materials?
a) Red
b) Yellow
c) Black
d) Blue
34. Medium temperature of furnaces and incinerators can be used to treat an expired solid dosage form that operates at the minimum temperature of
a) 850°C
b) 1110°C
c) 750°C
d) 550°C
35. The most common waste in Pharmaceutical Industry is of which physical forms?
a) Solid
b) Gases
c) Liquid
d) All of the above
36. The Environment Protection Act and Rules in India came into existence in
a) 1970
b) 1977
c) 1972
d) 1990
37. Bio Medical Waste Management & Handling Rules, in India came into existence in
a) 1998
b) 1990
c) 1977
d) 2000
38. Aerosol containers can be disposed by
a) Crushing and flushing
b) Landfill
c) Recycle
d) Incinerator
39. Which of the following waste needs disposal within 48 hours
a) Tablets
b) Liquid oral
c) Biomedical waste
d) All of above
40. Discarded medicines, cytotoxic drugs are segregated as per which color code:

a) Blue
b) Yellow
c) Red
d) Black
41. Human and animal anatomical waste are segregated as per which color code:
a) Blue
b) Yellow
c) Red
d) Black
42. Which of the following methd is used for Pharmaceutical waste treatment and disposal
a) Secure land filling
b) Deep burial
c) Encapsulation
d) All of above
43. Elements of SOP are
a) Title page
b) Quality assurance
c) Procedures
d) All of the above
44. An audit performed by an organization on itself is called as
a) Internal audit
b) External audit
c) Self inspection
d) both a & c
45. In an audit following the quality review meeting there should be
a) a follow up period
b) Another review meeting
c) Adequacy audit
d) None of the above
46. In the Hierarchy of Quality documentation system the top most element is
a) Quality manual
b) Quality policy
c) Quality procedures
d) Work instructions
47. A complete record of all raw data generated during each test, in addition to graphs, charts, and spectra from laboratory instrumentation, all properly identified to show th specific material and the batch tested is
a) Laboratory control records
b) Validation protocols and reports
c) Manufacturing and packaging instructions
d) Certificate of Analysis
48. All deviation, investigation and OOS reports should be reviewed as part of
a) Batch master review
b) Certificate of analysis

c) Batch record review
d) Laboratory control records
49. A written data related to distribution of drug products from the manufacturer to the distributor os
a) Distribution record
b) Validation Protocols & reports
c) Technical transfer reports
d) Audit Plans
50. The final tier in Quality Documentation system is
a) Records
b) Work instructions
c) Quality Procedures
d) Quality Policy
51. This is an audit which seeks to establish the extent to which the documented system is implemented and observed by the workforce
a) Offsite audit
b) On site audit
c) Process audit
d) None
52. Principles of audit are
a) Fair Presentation
b) Evidence based approach
c) Due professional care
d) All of the above
53. Reference standard for preparing batch manufacturing record by Manufacturing units
a) Quality audit
b) Master Formula records
c) SOP
d) All of the above
54. Written data of distribution of drug products from Mfg. to distributors is
a) Good Documentation Practice
b) Good distribution practices
c) Good development Practices
d) All of above
55. Which is key element of ISO quality system i.e. ISO 9001
a) Quality policy
b) Quality documentation
c) Quality audit
d) Quality review

SUBJECTIVE :

Q.1. What are the primary reasons for Product recall?
Q.2. Define recall, market withdrawl, Batch Manufacturing Record, Master formula record, Quality audit

Q.3. Explain complaint handling systems
Q.4. Describe different types of Pharmaceutical wastes.
Q.5. Write a note on Pharmaceutical Waste management & disposal.
Q.6. Write a note on Batch Manufacturing Record
Q.7. Write the requirement of Master Formula record
Q.8. Write a detailed description on quality review
Q.9. Explain different types of quality audit
Q.10. Describe different types of Technical SOP.
Q.11. Describe different types of market complaint in the Pharmaceutical Industry.
Q.12. Explain different types of recall.
Q13. What is SOP? Write its two benefits.
Q.14. Explain methods & steps of waste & scrap disposal.
Q15. Explain the role of quality audits in Pharmaceutical Industry.
Q.16. Explain about necessary documents as per Good manufacturing practice for pharmaceuticals.
Q.17. What are essential manufacturing documents? Explain how they should be maintained?
Q.18. What are the requirements and characteristics of SOP's?
Q.19. What are the sources of complaints. Explain.
Q.20. What are the evaluation steps of a complaint received?
Q.21. Write a note on Handling of returned goods.
Q.22. What are methods to dispose off Pharmaceutical waste?
Q.23. What are methods to dispose off Biomedical waste?
Q.24. Enlist different legislations in India for waste.
Q.25. How waste is generated in a Pharmaceutical Industry?