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SUBJECT : BP-606, PHARMACEUTICAL QUALITY ASSURANCE

B.PHARM. SIXTH SEMESTER

UNIT III **QUESTION BANK**

MCQ's

Q.1 one of following is not Primary packaging

a) Carton

b) Bottle

c) Strip packaging

d) Ampoule

Q.2. Edge protector is

a) Primary package

b) Secondary package

c) Tertiary package

Q.3. Yellow color glass can be obtained by treatment with

a) Copper oxide

b) Ferric oxide

c) Cadmium & sulphur

d) Cobalt

Q.4. Treated soda lime glass is

a) Type 1

b) Type 2

c) Type 3

d) Type 4

Q.5. In water attack test which is determined

a) Acid

b) Alkali

c) Carbon

d) Metal

Q.6. Light emission test for glass is measured at _____ spectral region

a) 290-450nm

b) more than 500 nm

c) 500nm – 900 nm

d) 1500-2000nm

Q.7. Annealing is a process of

a) Cooling

b) Heating

c) Melting

d) Titrating

Q. 8. Puncture resistance test is

a) Energy required to make initial puncture

b) Pressure required to make initial puncture

c) Force required to make initial puncture

d) Hardness required to make initial puncture

Q.9. Packaging of a product is done for

a) Protection

b) Identification

c) Information

d) All of the above

Q.10. Material for closures are

a) Rubber

b) Metal

c) Plastic

d) All of the above

Q.11. Barrel is an example of

a) Primary packaging

b) Secondary packaging

c) Tertiary packaging

d) Quaternary packaging

Q.12. Aerosol spray can is an example of

a) Primary packaging

b) Secondary packaging

c) Tertiary packaging

d) Quaternary packaging

Q.13. For bulk handling and shipping following is used

a) Primary packaging

b) Secondary packaging

c) Tertiary packaging

d) Quaternary packaging

Q.14. Labels and leaflets are categorized under

a) Primary packaging

b) Secondary packaging

c) Tertiary packaging

d) Quaternary packaging

Q.15. Choice of packaging material depends on

a) degree of protection needed

b) compatibility with dosage form

c) Size and weight of dosage form

d) All of the above

Q.16. Example of Non parental glass is

a) Type I

b) Type II

c) Type III

d) Type IV

Q.17. Which Glass is best suitable for filling non aqueous & powders

a) Type I

b) Type II

c) Type III

d) Type IV

Q.18. Which of the following Glass has high Hydrolytic resistance

a) Type I

b) Type II

c) Type III

d) Both a & b

Q.19. Borosilicate glass is categorized under

a) Type I

b) Type II

c) Type III

d) Both a & b

Q.20. De- alkalization by Sulphur is done for

a) Type I

b) Type II

c) Type III

d) Type IV

Q.21. Following is an example of Thermosetting plastics

a) Urea Formaldehyde

b) Polyurethanes

c) Nylon

d) Both a & b

Q.22. Following is an example of Thermoplastics

a) Urea Formaldehyde

b) Polyurethanes

c) Epoxy resin

d) Polystyrene

Q.23. To test the isolated packaging material, which test is under environmental test:

a) Folding

b) Creasing

c) pH of material

d) Absorption of water

Q.24. Test limit of consumption of 0.02N H_2SO_4 for Powdered glass test for Type III glass is

a) 1 ml for all size containers

b) 15ml for all size containers

c) 8.5 ml for all size containers

d) 0.2 ml for all size containers

Q.25. Fixed and hydraulic platform are used for which test for Glass containers

a) Annealing Test

b) Thermal shock test

c) Burst Pressure Test

d) Vertical load test

Q.26. In metal container test for eye ointment if the metal particle score is > 150 it implies

a) Lot fails

b) Lot Passes

c) Repeat the test

d) a & c

Q.27. Which test is performed for plastic container for non injectable preparations

a) Clarity test

b) Transparency test

c) Leakage test

d) a & C

Q.28. Standard suspension in transparency test for plastic container for injectables is prepared by

a) Hydrazine sulphate and Hexamine

b) Dichloro Hexamine

c) Hexamine alone

d) Hydrazine sulphate alone

Q.29. Which dye is officially used for testing self sealability of multi dose rubber closures

a) Phenolphtahleine

b) Xylenol

c) Florescene

d) methylene Blue

Q.30. Cobb test for secondary packaging is done for testing

a) Water absorbency

b) Moisture content

c) Tensile strength

Q.31. Which ink is used to test ink absorbency test of paper and boards

a) N & M ink

b) M & K ink

c) K & N ink

d) O & P ink

Q.32. Which test is used to determine weight of the material/unit area of sample

a) Cobbs test

b) Gammage test

c) Ash Test

d) Pick Test

Q.33. In “crease test” done for cartons, carton is folded at an angle of

a) 60°

b) 90°

c) 180°

d) 30°

Q.34. Country of Origin for Good Laboratory Practices is

a). United Kingdom

b) United State

c) UAE

d) USSR

Q.35. Full form of OECD is

a) Organization for economic co-operation & development

b) Organization for electronic co-operation & development

c) Organization for environmental co-operation & development

d) Organization for Equipment co-operation & development

Q.36. Which of the following study is regulated?

a) Drug discovery

b) Basic research

c) Disease discovery

d) Clinical trials

Q.37. GLP focuses on

a) Resources

b) Characterization

c) Rules, Results, & quality assurance unit

d) All of above

Q.38. Which of the following related to the GLP guideline under D & C act 1945?

a) Sch. L

b) Sch. M

c) Sch. M1

b) Sch L1

Q.39. Which of the following shall be followed w.r.t. TO Protocols?

a) Each protocol should bear a unique Identification number

b) Title of the study should be short

c) Both expected start and finish dates of the study shall be mentioned in protocol

d) All of the above

Q.40. An entity which commissions, supports or submits a non clinical testing study is

a) Study director

b) Principal investigator

c) Sponsor

d) Study personnel

Q.41. Test facility mgt. is responsible for following:

a) To formulate quality Assurance programme

b) To provide appropriate facilities, equipment, materials for the study

c) To appoint the study director

d) All of the above

Q.42. Following is the main responsibility of Study director

a) To identify the individual with in test facility who fulfill the responsibilities of Mgt.

b) To provide appropriate facilities, equipments, materials for study

c) Approve the study plan

d) All of the above

Q.43. Classes of study that are included in GLP are

a) Single dose toxicity

b) repeated dose toxicity

c) Both a & b

d) None

Q.44. Under GLP, which of the following act are regulated

a) Planned, performed

b) Monitored, recorded

c) None of above

d) All of above

Q.45. Which of the following studies is not included under GLP

a) Reproductive toxicity

b) Mutagenic Potential

c) Toxicokinetics

d) None of the above

Q.46. In order to ensure Good operational management GLP principle require institutions to

a) provide adequate physical facilities & qualified staff

b) Assign roles & responsibilities to staff

c) Provide facilities of suitable size, contruction, loacation

d) all of the above

Q.47. Who has the overall responsibility for the scientific conduct of a study and can confirm the compliance of the study with the principles of Good Laboratory practice

a) Analyst

b) Principal investigator

c) Study director

d) None of above

Q48. Which of the following is included in study plant

a) Identification of study, test item, reference item

b) Information concerning sponsor & test facility

c) Date of approval of study plan by signature of study director

d) All of above

Q.49. Each test and reference item should be identified by

a) Biological parameters

b) Chemical abstracts service registry number (CAS number)

c) Both a & b

d) None of the above

Q.50. For test and control items following is not mentioned on label

a) Container number & tare weight

b) Expiry date & storage conditions

c) Distribution records

d) Initial gross weight

DESCRIPTIVE/ SUBJECTIVE:

Q.1. Discuss different types of packaging material used in pharma industry with their advantages and disadvantages

Q.2. Write a note on quality control of secondary components

Q.3. What is closure? Enlist different type of closures. Discuss their QC tests.

Q.4. Discuss in detail the QC tests of primary components.

Q.5. Discuss different type of plastics.

Q.6. What are principles of GLP.

Q.7. Describe responsibilities of study director

Q.8. What is protocol for conduct of a non clinical laboratory study?

Q.9. define the terms: IND, NDA, Non clinical study, quality assurance unit, test article

Q.10. Write a note on QA unit in GLP.

Q.11. write a note on organization & personnel requirements in GLP.

Q.12. Discuss buildings & equipment requirements for GLP.

Q.13. Discuss testing facility operation in GLP.

Q.14. What is certificate of analysis in GLP?

Q.15. What are the content of final report in GLP? Discuss.

Q.16. Explain disqualification of a facility.

Q.17. Write a note on GLASS.

Q.18. Discuss the chemical testing of glass.

Q.19.Draw a relationship between GL and GMP.

Q.20.What is tamper resistant packaging. Discuss.