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SUBJECT : BP-606, PHARMACEUTICAL QUALITY ASSURANCE

B.PHARM. SIXTH SEMESTER

UNIT- II

MCQ:

1. Factories Act in India constituted in
   a) 1950
   b) 1948
   c) 1944
   d) 1960
2. Which one of the following material is not recommended for floor in production area
   a) Terrazzo
   b) Ceramic& vinyl sheeting
   c) Epoxy flooring
   d) Welded vinyl sheeting
3. When all equipments, machines, tolls, other items required for processing are placed as per sequence of operations, is ____ plant layout
   a) Product or line layout
   b) Process layout
   c) Location Layout
   d) All of the above
4. Between Manufacturing area and support areas difference of pressures required must be atleast
   a) 15 pascal
   b) 25 pascal
   c) 100 pascal
   d) 500 pascal
5. Water pollution control can be done by
   a) Physical Treatment
   b) Chemical Treatment
   c) Biological Treatment
   d) All of the above
6. By Removing particulate matter & gaseous pollutants from environment, your are controlling which pollution
   a) Water
   b) Air Pollution
   c) Noise Pollution
   d) All of the above
7. . Wet cooling towers and dry cooling towers are used to control which pollution in Pharmaceutical Industry
   a) Air Pollution

b) Water Pollution
c) Thermal Pollution
d) None

8. Intensity of light required to facilitate the various processes in Pharmaceutical Industry is of
   a) min. 500 lux
   b) 10 lux
   c) 5 lux
   d) 0.5 lux
9. Max. Number of permitted particles/cubic meter of the size 0.5 μ during operation for GRADE A area is
   a) 3,50,000
   b) 35,00,000
   c) Not defined
   d) 3500
10. For aseptic preparation, Handling of components after washing is carried out in which Grade area
    a) Grade B
    b) Grade C
    c) Grade D
    d) Grade A
11. HEPA filter integrity testing (smoking testing) is done
    a) Yearly
    b) At six months
    c) Weekly
    d) Everyday
12. Water for injection should have microbiological specification of
    a) not more than 1 cfu/100 ml
    b) not more than 10 cfu/100 ml
    c) not more than 1000 cfu/100 ml
    d) not more than 10000 cfu/100 ml
13. Bulk solutions of liquid parenterals & disinfectants for aseptic areas are made with
    a) Potable Water
    b) Water for Injection
    c) Distilled water
    d) DM water
14. Which technology utilizes automated machines in one continuous operation i.e. formation of containers from thermo plastic granules, filling and then sealing
    a) Form Fill and Seal (FFS)
    b) Blow Fill and Seal (BFS)
    c) Any of the above
    d) None of the above
15. General considerations for purchase of equipments are listed in
    a) Sch M

b) Sch C
c) Sch H
d) Sch Y

16. Class 100 cleanrooms is equivalent to which ISO class clean room
    a) Class 1
    b) Class 5
    c) Class 3
    d) Class 10
17. The purpose of Environmental modeling is
    a) Environmental control
    b) Microbiological control
    c) None
    d) Both
18. Clean rooms are classified according to the
    a) Airchecks/ hour
    b) Material being processed
    c) Number & size of particles permitted per volume of air
    d) All of above
19. Efficiency of HEPA filters should be ____at 0.12µ Particle Size
    a) 99.99%
    b) 95.55%
    c) 90.99%
    d) 93.22%
20. Air pressure differential should be checked
    a) 5 days
    b) Yearly
    c) 6 months
    d) Daily
21. Major type of contaminants found in Pharmaceutical industry are
    a) Chemicals
    b) Bacteria
    c) Air molecules
    d) All of the above
22. Highest air pressure is maintained in
    a) Gowning area
    b) Clean room
    c) Factory hallway
    d) None
23. Service bay is maintained at which class
    a) Class 1 or Class 10
    b) Class 50 or 10
    c) Class 1000 or class 10000
    d) Class 0.5 or 5
24. Contamination may be caused by
    a) Poor hygiene practices
    b) Residual cleaning agents

c) Inadequate cleaning
d) All of above

25. Airlock doors should be equipped with systems that
    a) Allow simultaneous opening of both doors
    b) Prevent simultaneous opening of both doors
    c) Both are necessary
    d) It is not specific

SHORT QUESTION

26. What are the factors to be considered for premises during purchasing, construction or alteration of existing facilities?
27. Write a note on various essential utilities and services for a Pharmaceutical Premise.
28. What are general considerations for purchase (Sch M)?
29. Write a note on Records on equipment cleaning and evaluation of equipment cleaning.
30. What are the factors affecting selection and purchase of equipments?
31. What are recommendations for control on raw materials and finished dosage forms?
32. Discuss advantages and disadvantages of various types of manufacturing unit Plant Layout.
33. Write notes on Clean in place (CIP) & Sterile in place (SIP).

LONG QUESTIONS:

34. What is plant layout? Write importance, factors and types of Plant Layout.
35. Explain WHO guideline for personnel involved in the manufacturing of API's and sterile products.
36. What are the requirements for manufacturing premises for sterile and parenteral preparations? Discuss in detail