Questions from 1-5 can be answered using the following answers. The same answer can be used for more than one question.

a- Marketing authorization **b- Master production document**
c- Certificate of analysis **d-Batch record** **e-Master formula**

b 1- A document specifying all the materials and detailed description of the procedures and precautions required to produce batch of a finished product.

e 2- Document produced by R &D department.

a 3- A legal document issued by ministry of health permitting the sale of a drug product.

c 4- A document containing information of analytical tests including the lab at which the tests were performed, the tests types and name and specifications of the materials, numerical results and signature of approver.

d 5- Document reviewed by ministry of health as a procedure for batch release to the market.

6- Batch certificate is issued by the fabricator for a batch of a drug that is exported and contained detailed description of the drug.

(a-) True b-False

Questions from 7-12 can be answered using the following answers. The same answer can be used for more than one question.

a - GMP **b- QC** **c- QA** **d- IPC** **e- SOP**

c 7- The total of the organized arrangements made with the objective of ensuring that drugs are of the quality required for their intended use.

d 8- The examination or testing of any material or mixture of materials during the manufacturing process.

e 9- A written procedure giving instructions for performing operations.

b 10- Ensures that the necessary and relevant tests are carried out and that products are released only if their quality is satisfactory.

a 11- It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.

b 12- Operational laboratory techniques and activities used to fulfill the requirement of quality.

Questions from 13-14 Regarding campaign production select (a) for true statement and (b) for false one:

13- It is sequential processing of more than one product in a multi-product facility over a defined period of time. a

14- Area clearance check is performed by production personnel. a

Questions from 15-18 Regarding a lot of a drug product select (a) for true statement and (b) for false one:

15- Characterized by intended homogeneity a
16- Produced by multiple production orders b
17- Identified by a distinctive number on the label of the finished product a
18- Constituting all or part of a single batch a

19- The initial results of purity testing for a raw material X received by pharmaceutical company revealed that it is OOS, the action that will be taken is:

a- Return this raw material to supplier
(b-) Repeat the quality control test by another staff
c- Performs purification process

20- Pharmaceutical company produced the first production batch of new drug product and the product passed the performed QC tests after that:
a- The ministry of health is contacted, reviewing the documents and take samples for investigating product quality before release
b- The ministry of health is contacted, and they review the documents and release the product
c- Ministry of health performed mass balance
d- Both a and c e- Both b and c

21- The product should be kept in .....till its release.
a- Production area b- Quarantine c- Packaging area

22- The last step after finishing the production of a batch of a drug product is:
a- Filling b- Packaging
c- Area clearance d- Area clearance check

23- The first step in producing the second batch of the same drug product immediately after the first one is:
a- Weighing of raw materials b- Cleaning
c- Area clearance d- Area clearance check

24- This step (in the previous question) can be performed by:
a- Production staff b- QC staff c- R&D staff d- none of them

25- Regarding the cleaning program in pharmaceutical company:
a- There must be a written SOP covering the program
b- Its validation should be based on worst case situations
c- The frequency of its application depends activity in the area
d- All of the above

Questions from 26-29 Regarding the design of the premises select (a) for true statement and (b) for false one:

26- There should be no ledges and sealing of joints in ceilings a

27- Drains with a design that prevent the possibility of back-flow are suitable in sterile areas b

28- Entrance of air from openings near to the ceilings and gets out from others near the floor a

29- It should be designed in a way that provides unidirectional flow of work a

30- GMP guidelines regarding sanitation and hygiene includes:
a- Segregated areas should be available for processing biological materials
b- Personnel are not allowed to move between areas producing different products
c- Garments should be used for protecting the product and personnel
d- All of the above

31- Emergency repair of equipment is:
a- Conducted outside the working hours
b- Conducted during the working hours
c- Followed by deep cleaning procedures
d- Both a and c e- Both b and c

Questions from 32-35 Regarding the process validation select (a) for true statement and (b) for false one:

32- It is documented act of proving that any procedure, process, equipment, material, activity or system actually leads to the expected results. a

33- The priority is for validation of processing potent drug over the non-potent one a
34- It requires the identification of critical elements of the production process a
35- All compendial methods need to be validated b

Questions 36-40 can be answered using the following answers:

a- Revalidation **b-Retrospective validation**
c- Concurrent validation **d- Prospective validation** **e- None of them**

36- It is not the preferred method of validation. b
37- It is performed periodically and after changes. a
38- It involves performing trials in which critical steps and points are simulated and their effect on the process is assessed. d
39- Involves analysis of 10 to 25 batches manufactured over a period of 12 months. b
40- It involves intensified monitoring in at least the first three production batches c
41- Its aim to ensure that the components meet the approved specification and are connected correctly, and to see how that information is recorded.
(a-) IQ b- DQ c- OQ d- PQ

Questions 42-46 are true/false type questions. Select (a) for true and (b) for false statements.

42- Validation master plan describes the overall philosophy, intention and approach for establishing performance adequacy (validation policy). a
43- All instructions and procedures for producing drug product in Egyptian company are written only in English. b
44- The more critical the area, the fewer the number of persons allowed to work there. a
45- Reserve samples of finished product enough to perform the required testing at least one time should be maintained. b
46- Bulk process intermediates are products undergo further processing before being final product and characterized by a holding time and storage conditions. a

Questions from 47-50 can be answered using the following answers. The same answer can be used for more than one question.

a- Terminal sterilization **b- Aseptic preparation**
c- Sterilization by filtration **d- All of the above**

47- Used for products that are tolerant to sterilization in their final containers. a
48- A method in which the product is manufactured under clean conditions, and then sterilized and filled into sterile containers under aseptic conditions. c
49- All components, such as primary containers, must be sterilized before they are introduced into the filling area. c
50- The sterilization method of choice for thermo labile aqueous suspension. b
51- The GMP requirements for sterile products are additional to the usual requirements for pharmaceutical products, rather than a replacement for them.
(a-) True b-False
52- It is the time required to reduce the bioburden by 90%.
(a-) D value b- Z value c- Fo d- All of them
53- It is the difference in temperature required to change the D value by 90%.
a- D value (b-) Z value c- Fo d- All of them
54- Mathematical expressions that have been developed to enable prediction of the probability of non-sterility.
a- D value b- Z value c- Fo (d-) All of them

Questions from 55-63can be answered using the following answers. The same answer can be used for more than one question.

a- Dry heat sterilization **b- Steam sterilization**
c- Radiation sterilization **d- Ethylene oxide sterilization**
e- Sterilization by filtration

b 55- Its validation test involves placement of 15-20 thermocouples in free spaces within the chamber.

a 56- The USP recommends a 3-log reduction in the endotoxin challenge using Lamulus amebocyte Lysate reagent in this method.

C 57- Dosimeters are employed to validate the efficiency of this sterilization method.

a 58- Sterilization method that is able to destroy pyrogen.

d 59- Used only when no other method is practically possible

d 60- Direct contact with microbial cells is essential to achieve sterilization.

b 61- The parenteral association suggested that any deviation by more than ±2.5% °C from the chamber mean temperature is considered undesirable.

d 62- The sterilizing cycle is a combination of time, temperature, humidity and gas concentration.

e 63- In this method membrane integrity testing, time taken and pressure difference should be validated.

64- Samples for sterility testing of products prepared by aseptic processing are taken:
a- At the end of batch production b- At the beginning of batch production
c- From intermediates of the production process (d-) All of them

65- In case of sterility test failure, it is necessary to investigate:
a- Type of organism b- Batch records
c- Environmental monitoring records (d-) All of the above

Questions 66-71 can be answered using the following answers:

a- Head of production responsibilities **b- Head of quality control responsibilities**
c- Shared responsibilities of both a and b
d- Head of sales and distribution responsibilities

66- The arrangements for the storage of records relevant to batches. C

67- Maintenance of quality control department, premises and equipment b

68- Approval and implementation of production instructions and in-process QC. a

69- Performing promotions and marketing of the drug product. d

70- Monitoring of the manufacturing environment. C

71- Development of the training programme. C

72- Rules regulating the work of persons in pharmaceutical company include:
a- The presence of a clear job description
b- Sufficient number of staff must be available to carry out the work
c- People with sufficient knowledge and experience should be present to perform the work
(d-) All of the above

Questions from 73-75 Regarding pharmaceutical products complaint, select (a) for true statement and (b) for false one:

73- The complaints should be considered as important work and carefully reviewed a

74- The company can accept the complaint and respond to it after long time b

75- The complaint should be recorded with all the original product details a

Questions from 76-78 can be answered using the following answers. The same answer can be used for more than one question.

a- Major defects **b- Critical defects** **c- Minor defects**

76- Product withdrawal would normally be initiated within a few days as there is little risk on patients C

77- Those defects which may put the patient at some risk but are not life threatening and will require the product to be withdrawn within a few days. a

78- Microbiological contamination of a sterile product is an example. b

79- The reasons for product recall include:

a- Detection of GMP failure after release
b- Request by the national authorities
c- Known counterfeiting or tampering
d- All of them

80- If the complaints were not justified, which of the following is **not true**:

a- The customers should be informed with results
b- There should be punishment for the customers who complained
c- A product advertising campaign should be carried out

Best wishes