جامعة طنطا
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Tanta University
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Examination For Fourth Year Pharmacy Students

Course Title: Industrial Pharmacy (GMP)

Date: 4/6/2014 Model answer	**Term : Second**	**Total Marks: 100** **Total pages: 8**	**Time allowed: 1.5 hours**

You are provided with **80 MCQs** (100 marks), together with answers for each question. You need to select the best answer for each question and blacken the corresponding square in the provided answer sheet.

Answer sheet

No	A	B	C	D	No	A	B	C	D	No	A	B	C	D
1		X			35			X		69		X		
2		X			36			X		70	X			
3	X				37				X	71		X		
4			X		38		X			72			X	
5				X	39				X	73	X			
6	X				40		X			74				X
7			X		41	X				75			X	
8				X	42		X			76		X		
9		X			43				X	77		X		
10	X				44	X				78		X		
11	X				45		X			79				X
12				X	46	X				80			X	
13		X			47				X					
14			X		48	X								
15		X			49		X							
16	X				50	X								
17		X			51		X							
18				X	52	X								
19			X		53	X								
20				X	54		X							
21	X				55		X							
22	X				56		X							
23				X	57			X						
24			X		58		X							
25				X	59		X							
26	X				60	X								
27		X			61	X								
28	X				62	X								
29				X	63	X								
30			X		64		X							
31			X		65		X							
32		X			66	X								
33		X			67	X								
34	X				68	X								

Questions 1-14 can be answered after reading the following case:

A drug company decided to produce a batch of carbamazepine 200mg tablets. The production department received a document from the QA department. This document contains all the necessary information for production of this **product**.

1- The document in the above case is called …..
   a- Batch processing record. b- master production document
   c- master formula

2- The document in the above case is specific for this batch only.
   a- true b- false

3- After recording the batch number and production date in the above document, it will be considered as …..
   a- Batch processing record. b- master production document
   c- master formula

4- The first step in production of the above batch is ……
   a- dispensing of raw materials b- weighing of the materials
   c- area clearance check d- non of them and the answer is …….

5- If the above product was not produced during the last 3 months, the step in the above question should be conducted by ……
   a- the production staff b- by the research and development staff
   c- head of production department d- QC staff

6- If the batch in the above case was the second consecutive batch in campaign production of carbamazepin, the step in the above question should be conducted by:
   a- the production staff b- by the research and development staff
   c- head of production department d- QC staff

7- If the document in the above case indicates that 15 minutes of mixing are enough to produce homogenous mixture with a homogeneity in the range of 98-102 % of the labeled amount. The mixing operation was conducted as required and the mixture was sampled and sent to QC department for analysis. The **initial** results indicated deviation from the homogeneity range. In this case the head of QC should ……
   a- ask the production to continue mixing for longer time
   b- ask the production staff to continue the production operation anyway
   c- ask another QC staff to repeat the test d- non of them

8- The sampling operation in question 7 should be conducted by ……. staff
   a- QC b- QA c- production d- both a and b are correct

9- The process conducted in question 7 is termed QC.
   a- true b- false

10- The document in the above case should be revised and re-issued every 2 years.
   a- true b- false

11- After completing the production and packaging operation of the batch in the above case it should be sampled and sent to the QC. This process is termed ……
   a- QC b- IPC c- QA d- all of them is correct

12- While being evaluated by the QC staff, this batch should be stored in …….
   a- Packaging area b- Production department c- regular storage area
   d- Quarantine

13- If you were responsible for storing this batch and received an order from the head of the production department to release the above batch from its temporary storage to the shipping department, you would ……..
   a- accept this order b- reject the order

14- The reason for your answer in the above question is .....
a- the head of production department is responsible for releasing the batch
b- the director of the company is responsible for releasing the batch
c- the QC manager is responsible for releasing the batch

15- QA is that part of GMP that ensure that a product will meet the specification intended for its purpose
a- True b- False

16- GMP are the part of quality assurance that ensures that drugs are consistently produced and controlled in such a way to meet the quality standards appropriate to their intended use
a- True b- False

17- Quality control is confined to laboratory operations
a- True b- False

18- The procedures for product release include a review and evaluation of .....
a- QC results b- batch production records c- packaging records
d- all of them

19- ..... is the sum total of organized arrangements made with the objective of ensuring that product will be of the Quality required by their intended use
a- GMP b- QC c- QA d- both a and c

20- ..... is concerned with sampling, specifications, testing and within the organization, documentation, and release procedures which ensure that the necessary and relevant tests are carried out
a- QA b- IPC c- GMP d- non of them

21- Recirculation of air within a ventilation system without appropriate efficient filtration:
a- Is an unacceptable practice and should be stopped by all GMP inspectors.
b- Is the only economic option and may be used in all facilities.
c- Depends on the local health and safety rules. d- non of them.

22- A lot may be equal to or smaller than a batch
a- True b- False

23- The following should be excluded from all production areas:
a- Food and drink b- Chewing gum. c- Plants and animals.
d- All of the above.

24- Prospective validation is carried out:
a- Periodically and/or after major changes.
b- For a production process that has been operating for 6 months.
c- During the research and development phase.
d- While a new product is being commissioned on the plant.

25- Concurrent validation is carried out:
a- Periodically and/or after major changes.
b- For a production process that has been operating for 6 months.
c- During the research and development phase.
d- While a new product is being commissioned on the plant.

26- Revalidation is carried out:
a- Periodically and/or after major changes.
b- For a production process that has been operating for 6 months.
c- During the research and development phase.
d- While a new product is being commissioned on the plant.

Questions 27-30 can be answered using the following answers:

a- Has it been built correctly? b- Has it been designed correctly?
c- Does it produce product correctly? d- Does it work correctly?

27- The purpose of design qualification is to check:
28- The purpose of installation qualification is to check:
29- The purpose of operational qualification is to check:
30- The purpose of performance qualification is to check:
31- The GMP requirements for sterile production are:
a- exactly the same as for all other types of production.
b- completely different from all other types of production.
c- combination of normal GMP requirements plus some additions.
32- Terminally sterilized products are:
a- those that are sensitive to heat and gamma irradiation.
b- those that can be sterilized after filling and sealing.
c- those products that can be sterilized by filtration.
33- The personnel working in a sterile production area should be:
a- fully trained in procedures.
b- fully trained in procedures, GMP and basic microbiology.
c- identical to the rest of the staff in other departments.
34- The WHO classification system for sterile areas includes limits for:
a- particles and microorganisms. b- particles only.
c- microorganisms only. d- particles, microorganisms and pyrogens.
35- The filling of an SVP that has been sterile filtered will take place in:
a- grade A room with a grade A background.
b- grade B room with a grade D background.
c- grade A room with a grade B background.
36- Bulk process intermediates include all of the following except .....
a- tablet granules. b- compressed tablets c- Tablet batch in quarantine
37- On approaching the retest date of a raw material the company should.....
a- destroy the material b- contact the manufacture c- use it as usual
d- test the material taking its initial certificate of analysis as reference
38- Separate manufacturing buildings are required for:
a- Every different product.
b- Materials that present a high risk of cross-contamination.
c- Products of different dosage forms.
d- Sterile and non-sterile production areas.
39- Access to a manufacturing area should be restricted to:
a- Production operatives and supervisors.
b- Production personnel and QC staff.
c- People who are authorized and have a legitimate reason for being there.
d- all of the above
40- Drains should be adequate in the sterile area.
a- True b- false
41- For a pharmaceutical manufacturing company to all production lines operating at the same time they should use a ventilation system which supplies 100% fresh air.
a- True b- false
42- For the company in the above question, it is acceptable for the same production staff to move from one line to another during operation
a- True b- false

43- In the weighing room the air flow direction should be ……..
a- from top to bottom for the inlet b- near the floor for outlet
c- from bottom to top d- both a and b

44- It is permissible to carry out secondary packaging activities for different products within a packing hall.
a- True b- false

45- Planned maintenance and repair should be conducted ……..
a- during the working hours b- outside the working hours
c- both a and b are ok

46- The quality of the product:
a- Relies upon people.
b- Needs good systems with just a few good people in charge.
c- Just needs one or two good people at the top.
d- Can be achieved by one good person.

47- Key personnel include:
a- Head of production. b- Head of quality control.
c- Head of sales and distribution. d- All of the above.

48- Heads of production and quality control:
a- May share some responsibilities depending on national regulations.
b- Can never share responsibilities.
c- May report to one another depending on who is the most senior person.
d- Have no role in managing contract manufacture or analysis.

49- The head of production has the responsibility to approve or reject packaging materials.
a- true b- false

50- The head of production ensures that products are produced and stored according to the appropriate documentation.
a- true b- false

51- The head of QC department has the responsibility for the maintenance of all equipment in all departments including quality control.
a- true b- false

52- To conduct the sterility testing after steam sterilization samples should be taken from the coldest point of the autoclave.
a- true b- false

53- If radiation sterilization is to be performed away from the drug company, this company is responsible to ensure that the method is validated.
a- true b- false

54- In validation of the operation in the above question, thermosensiytive indicator can be used.
a- true b- false

55- Radiation sterilization is suitable for aqueous suspension but solutions.
a- true b- false

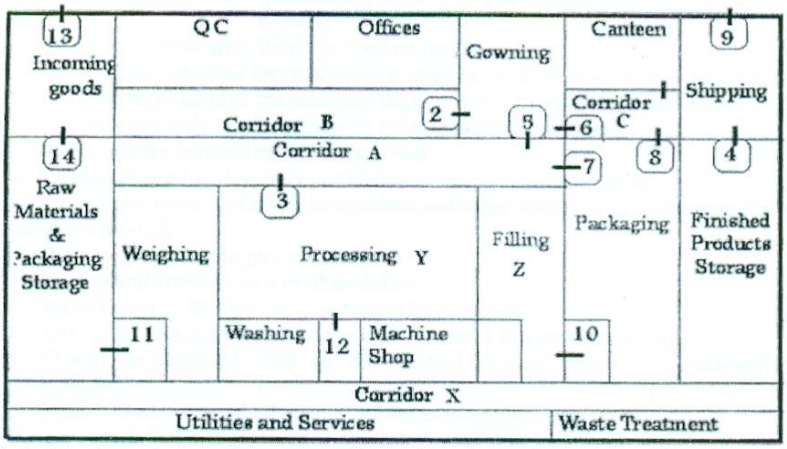
56- An inspector from the ministry of health arrives to conduct inspection and refuses to wear hair covering. What should the company do?
a- Stop production process during inspection
b- He should not be given an access to the production areas.
c- non of them and the answer is ……

57- The sterility testing should be conducted in:
a- grade A room with a grade A background.
b- grade B room with a grade D background.
c- grade A room with a grade B background.

58- Process validation is only done by large companies who can afford to do it.
a- true b- false

Questions 59-69 can be answered using the following diagram:

The horizontal — and vertical | lines indicate the door



59- In the above layout, the pressure in corridor A should be lower than that of the gowning room.
a- True b- False

60- In the above layout, the quality of air in corridor A should be better than that of the gowning room.
a- True b- False

61- In the above layout, the pressure in raw material storage should be lower than that of the weighing room.
a- True b- False

62- In the above layout, the entrance number 11 (between the storage and weighing room) should have double doors which cannot open at the same time.
a- True b- False

63- In the above layout, if the processing area Y is dealing with dusty dosage form, its pressure should be lower than that of corridor A.
a- True b- False

64- For the same operation in question 63, the glass containers to be washed should be taken from the storage area to corridor A then to processing area Y and then to the washing area.
a- True b- False

65- The secondary packaging material should be transported from the store through the entrance number 11 then to corridor A then to the packaging area.
a- True b- False

66- The production pharmacist can go to the canteen by walking through corridor A then enter through entrance 5, then entrance 6 then to the canteen.
a- True b- False

67- In the above layout, if the processing area Y is dealing with attenuated vaccine, its pressure should be lower than that of corridor A.
a- True b- False

68- For the same operation in question 67, the quality of air in corridor A should be at least similar to that of area Y.
a- True b- False

69- For the same operation in question 67, air recycling is allowed
a- True b- False

70- Distribution records are critical for product recalls because:
a- The company can find the material that must be recalled as quickly as possible.
b- The company can give the customer the choice of returning material or not.
c- The company only needs to warn its most important customers.

71- The principle for complaints handling is that:
a- Companies need review only complaints about defective products.
b- A company must review all complaints and other information about potentially defective product.
c- Only complaints from pharmacists are reviewed.

72- Any complaint concerning a product defect:
a- Doesn't need to involve the quality control department.
b- Only needs thorough investigation if it will result in a product recall.
c- Should be recorded with all the original product details, and thoroughly investigated.
d- Doesn't need to record all details as long as the results are recorded.

73- If a product defect is discovered in one batch:
a- A company must have given consideration as to whether other batches should be reviewed.
b- The company must investigate batches containing reprocessed product from that batch.
c- There is great relief that no other batches need investigating.

74- After investigating a complaint:
a- There is a need for follow-up action to maintain product confidence.
b- The company is allowed to relax because the Sales Manager will talk to the person who complained and smooth things over.
c- The company can do everything except consider a product recall.
d- non of the above.

75- All decisions and measures taken:
a- Are only recorded if there is a product recall.
b- Are recorded but do not need to be cross-referenced to original batch records.
c- Should be recorded and referenced to the corresponding batch records.

76- The principle for product recall is:
a- Is not the responsibility of the manufacturer once the product has left the factory.
b- That there should be a system to recall from the market, promptly and effectively, products known or suspected to be defective.
c- To only to recall products that have been the subject of a complaint.

77- The person inspecting the complaint should be senior staff.
a- true b- false

78- If after investigating a complaint the company discovered that the product was labelled with incorrect name or incorrect strength. The product should be recalled after the holiday.
a- true b- false

79- The clothing requirements for working in a sterile production area are:
a- Optional. b- applied only to full-time staff, not to visitors.
c- exactly the same as for other parts of the factory.
d- different for different production areas depending on the activities and product.

80- Equipment used in a sterile production area must be:
a- made of whichever material is cheapest.
b- not different from other equipment in the factory.
c- designed to be operated with the minimum amount of contact from personnel.
d- all of the them.

GOOD LUCK