TANTA UNIVERSITY
FACULTY OF PHARMACY
DEPARTMENT OFPHARMACEUTICAL ANALYTICALCHEMISTRY

EXAMINATION FOR CLINICAL PHARMACY STUDENTS

	COURSE TITLE:	Pharmaceutical analysis and Quality control		COURSE CODE: PC808
DATE:	24/6/2021	TERM: SECOND	TOTAL ASSESSMENT MARKS: 50	TIME ALLOWED: 120 MIN

The Exam consists of 11 pages:

You MUST select The Letter Of ONE Best Answer and mark it in the provided bubble sheet :

1-The quality control laboratory practice is necessary for

a) the process of drug manufacturing
b) promoting international harmonization of lab. practices
c) facilitating cooperation among laboratories
d) a&b
e) b&c

2- The guidelines of quality control laboratory are applicable to

a) non-governmental pharmaceutical quality control laboratories
b) national pharmaceutical quality control laboratories
c) commercial pharmaceutical quality control laboratories
d) all of them
e) a&b

3-All are true for quality control laboratory practice EXCEPT

a) they are necessary to ensure reliable results for pharmaceutical analysis
b) they are applicable for laboratories performing biological testing
c) they are adopted by WHO experts
d) they are applicable for analysis of active pharmaceutical ingredients (APIs) and excipients.

4-Compliance testing of active pharmaceutical ingredients APIs employs

a) pharmacopoeial methods
b) validated analytical methods
c) any reported analytical methods in literature
d) a & b
e)all of them

5-..... is required to detect suspicious, counterfeit or illegal substances in pharmaceuticals.

a) compliance testing b) investigative testing c) uniformity testing
d) disintegration test

6- What are the main activities performed by national quality control laboratories?

a) compliance testing b) investigative testing c) uniformity testing
d) a&b e) a&c

7-All the following sentences are true EXCEPT

a) the quantity of retained sample for further analysis should allow performance of at least one re-analyses.

b) all incoming sample are divided into three equal portions for submission to quality control laboratories.

c) all incoming samples should be visually inspected

d) none of them

8-Reagents used in laboratory should be

a) purchased from reputable and approved suppliers

b) accompanied by material safety data sheet

c) accompanied by certificate of analysis

d) all of them

9-To ensure quality control laboratory practice, it is necessary that

a) all the amount of incoming sample for analysis should be used up

b) metrological traceability should be applied

c) the environmental conditions should be monitored regularly

d) b&c

10- The quantity for incoming samples should be enough for

a) immediate testing,

b) performing confirmation test

c) for retention for further analysis in case of dispute

d) a&b

e) all of them

11- All the following sentences are true EXCEPT

a) the environmental conditions in laboratory cannot affect the quality of measurements

b) the results of analysis should be traceable

c) reference materials are used for calibration of instruments

d) The laboratory should have adequate safety equipment

12-All the following sentences are true for national quality control laboratories EXCEPT

a) they perform analysis for active pharmaceutical ingredients only

b) they perform all quality control activities

c) Their role is to enforce the law and legal action in case of detection of illegal substances in pharmaceuticals

d) a&c

13- Composting is indicated when

a) homogeneity is not a significant problem
b) homogeneity is a significant problem
c) the variability between or among units is of no great importance
d) a&c
e) b&c

14- Multiple-unit sampling is indicated

a) when the range of values in individual units is small
b) when the range of values in individual units is large
c) to establish the variability in the lot under consideration
d) a&c
e) b&c

15- Sampling is the process of.....from a large quantity of material a small portion which is truly representative of the composition of the original material

a) mixing
b) diluting
c) extracting
d) combining

16- Which of the following sentences are true for sampling

a) it presents minor problems when the sample is homogeneous liquid
b) it presents minor problems when the sample is solid mixture
c) it is one of the most common sources of analytical error
d) b&c
e) a&c

17- Casual sampling on an ad hoc basis is

a) the most reliable method of sampling
b) totally unscientific
c) can lead to decisions being taken on inadequate information
d)b&c
e) all of them

18- Single dose analysis

a) leads to reduced analytical sample size
b) requires greater number of assay
c) provides information about tablet variation
d) all of them
e) b&c

19- Which sampling method is the most reliable?

a) Sampling based on statistical approach
b) Examination of all material under investigation
c) Casual sampling on an ad hoc basis
d) b&c

20-Which of the following sentences is true about compositing?

a) it is the procedure of choice for sampling for all kinds of samples
b) samples taken from composite is always representative to the bulk material
c) it is one in which the individual units or representative portions of the units are mixed to form uniform mixture
d) a&c
e) b&c

21-All the following sentences are true EXCEPT

a) sampling is at least as important as, if not more important than, the analytical methods used
b) Failure to achieve homogeneity on sample preparation will affect the results of the analysis regardless of the method used
c) Sampling can contribute to the largest proportion of the analytical error in case of the analyte to be detected is present in high concentration
d) a&c

22-Which sampling method is impracticable?

a) Statistical approach of sampling
b) Examination of all materials under investigation
c) Casual sampling on an ad hoc basis
d) none of them

23- Which of the following sentences is true?

a) gross samples cannot be used for direct analysis
b) gross sample does not require subsampling
c) test or analytical samples can be prepared directly from bulk sample
d) none of them

24- All of the following sentences are true EXCEPT

a) the test or analytical sample should be of appropriate size for analysis
b) the test or analytical sample should have the same composition as the bulk material
c) sampling can contribute to the largest proportion of the analytical error in case of the analyte to be detected is homogeneously dispersed in the mixture
d) the sub-sample may require treatment, for example reduction in particle size

25-For the quality of a medicine sample to be correctly assessed:

a) the submission of a sample should be accompanied by a statement of the reason why the analysis has been requested
b) the analysis should be correctly planned
c) the results should determine whether the sample complies with the specifications
d) all of them

26-.....creates in the client the mental state of security about the properties and effects of a medicine.

a-durability of the product b-serviceability of the product.
c-perceived quality of the product d-reliability of the product

27- The degree to which a product's design and operating characteristics meet established standards is called

a-Conformance b-Reliability.
c-Durability d- Serviceability

28- <u>Serviceability</u> means

a- a measure of product life b- a product availability at pharmacies
c-a probability of not malfunctioning during a specified period.
d-all of them e-none of them

29-.....ensures a product or service is manufactured, implemented, created, or produced in the right way.

a-quality control b-quality assurance c-GLP d-none of them

30-..... is defined as product's primary operating characteristics.

a-performance b-serviceability c-conformance d- features e-durability

31- The in-process limits are ..... the final acceptance limits

a-more restrictive than b- less restrictive than
c-the same as d-concerned to

32- Most critical in-process control and testing are performed for solid products

a- true b- false

33-Quality must be built into the product during research, development and production.

a-true b-false

34- <u>Features</u> of pharmaceutical product means

a-Product's primary operating characteristics.
b-Supplements to a product's basic functioning characteristics.
c-A probability of not malfunctioning during a specified period.
d-all of them

35-The FDA has issued regulatory guidelines known as GMP which is denoted to

a- green method processing b- green management practices
c-governmental manufacturing practices d- good manufacture practices

36- Drug originality and immediate effect of a medicine are aspects of perceived quality

a-true b-false

37-PDCA is denoted to which of the following

a-Deeming cycle b- one of the tool of quality assurance

c- shewhart cycle d- all of them

38-FDA is an abbreviation to

a-Food and drug analysis b-Free drug analysis

c- Food and drug administration d- none of them

39-GLP was issued by FDA to assure the public that the marketed drug product .....

a-has been properly manufactured b-has been clinically tested.

c-has been properly packaged d- has been properly produced

40-.....is defined as performance superiority in delighting customers.

a- quality assurance b- quality control

c- TQM d-in-process control

41- .....evaluates whether or not the end result is satisfactory.

a-quality control b-quality assurance

c- GMP d- GLP

42- The Fourth step in Shewhart cycle is

a-process b-check

c- do d-act

43-.....is designed to make sure processes are sufficient to meet objectives

a-GMP b-TQM

c-quality control d-quality assurance

44- An important part of TQM is improving the quality of the materials that organization used

a-true b-false

45-..... are employees who receive the output of other employees within the organization.

a- external customers b- internal customers

c-front line employees d-quality gurus

46- Raw materials used in the process of manufacture are considered as a source of impurities in the final product

a-true b-false

47-Aspirin can be determined by

a- non-aqueous titration b- direct titration with NaOH

c- redox titration d- residual titration

48-Non- aqueous titration is used for

a- identification of pharmaceutical compounds b- assay of weakly acidic compounds

c-purification of pharmaceutical compounds d-all of them

49- Mercuric acetate should be added then titrate with perchloric acid for non-aqueous titration of

a- EphedrineHCl b-Aspirin

c-Methyl DOPA d-Benzylpenicillin

50-The selection in the previous point is due to

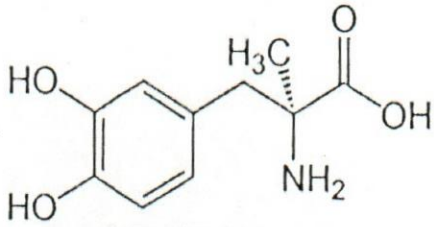
a- Methyl DOPA is very weak base

b-chloride salt is very weak base cant react quantitatively with perchloric acid

c-Mercuric acetate increases solubility of benzylpenicillin

d-Ephedrine HCl is strongly basic

51-Methyl DOPA can be determined by



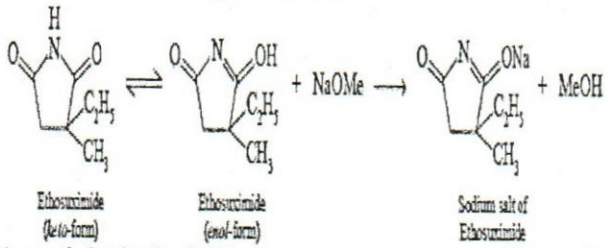
a-redox titration with ceric sulfate

b- acid–base titration with NaOH using methyl orange as indictor

c- iodometric titration

d- non-aqueous titration using crystal violet as indicator

52- In the following titration



a-Azo-violet is the indicator

b- sodium methoxide is the titrant and methyl orange indicator

c- dimethyl formamide is used as solvent

d-a&c

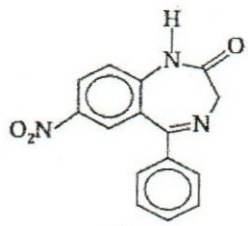
53- Iodometric titration is used for determination of

a-oxidizing agents

b-reducing agents

c- benzylpenicillin

d-none of them



Nitrazepam

54-The following drug can be determined by

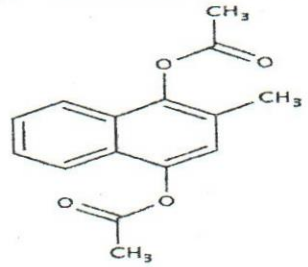
a- non- aqueous titration using crystal violet indicator

b- non- aqueous titration with end point detected potentiometrically

c-residual titration with excess NaOH

d-direct titration using phenolphthalein indicator

55-For redox titration of the following drug it should be hydrolyzed



a-in alkaline medium into corresponding acid

b- in acidic medium into dione derivative

c- in acidic medium into corresponding phenol

d- in alkaline medium into corresponding phenol

56-The titrant used in the previous point is

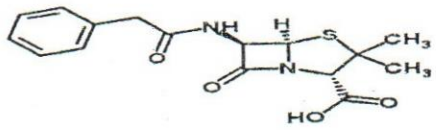
a-iodine

b-ammonium thiocyante

c- sodium thiosulfate

d- ammonium ceric sulfate

57- The following drug (benzyl penicillin) can be assayed by



a-reaction of hydrolyzed product with iodide

b-oxidation of hydrolyzed product by iodine

c- direct titration with iodide

d-non-aqueous acidimetry

58-Alkalimetry in non aqueous medium is used for determination of

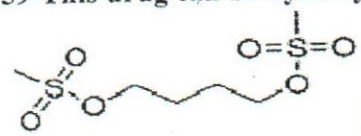
a-primary and secondary amines

b-halogen acid salts of bases

c-sulphonamides & enols

d-a&b

59-This drug can be hydrolyzed into



Busulfan

a-methane sulfonic acid

b-sulfuric acid

c-sulfate

d-none of them

60-The hydrolyzed product of Busulfan is titrated

a-iodimetrically

b- directly with NaOH

c- by residual titration with excess NaOH

d-by sodium methoxide in non aqueous medium

61- Validation of an analytical method is the process by which it is established, by laboratory studies, that the performance characteristics of the method.

a- meet the requirements for purity test

b- meet the requirements for bioequivalence studies

c- meet the requirements for the intended analytical applications

d- meet the requirements for any analytical applications

62- The minimum specified range to be considered for the assay of a drug substance or a finished (drug) product is normally from 50-100% of test concentration

a- true b- false

63-The closeness of test results obtained by the method to each others is known as

a- linearity b-precision

c-robustness d- accuracy

64-Accuracy may be expressed as

a-coefficient of variation b-correlation coefficient

c- %recovery d-none of them

65- Repeatability is a measure of within-laboratory variations (different days, different analysts, different equipment)

a-true b- false

66- provided with the following table

Method	Correlation coefficient of the calibration curve
I	0.992
II	0.980
III	0.994
IV	0.9998

Which of the following methods gives the best linearity

a-method(I) b-method(II)

c-method(III) d- method(IV)

67- For the establishment of linearity, a minimum of three concentrations is recommended

a-true b-false

68- ..... is a measure of the degree of interference in the analysis of complex sample mixtures

a- ruggedness b-robustness

c-reproducibility d-specificity

69-The concentration gives a response ten times the response of the blank considered as..... for this method

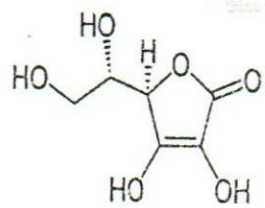
a-limit of detection b-limit of quantitation

c-mean concentration d- maximum concentration

70-Accuracy should be assessed using a minimum of 9 determinations over a minimum of .....concentration levels covering the specified range

a-five b-three

c-seven d-two

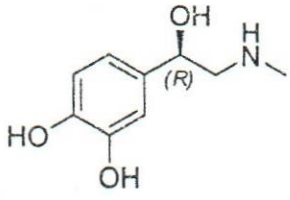


Ascorbic acid

71-.....is considered as SIAM for the following drug

a-polarographic method b- iodimetric method

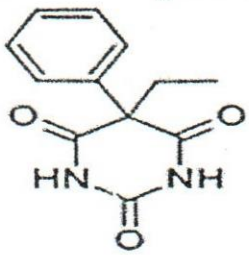
c-ferric hydroxamate method d-diazometric method



72- Adrenaline becomes inactive by

a-sulfonation
b- racemization
c-oxidation
d-all of them

73-The possible route of degradation of the following drug is

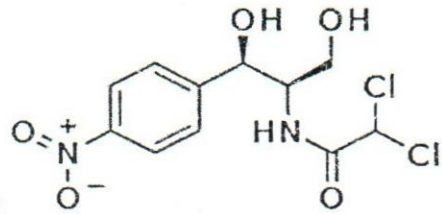


(barbiturates)

a-oxidation
b-hydrolysis
c-racemization
d-none of them

74- The UV spectrum of barbiturates is pH dependent

a-true
b-false



75-$Na_2Fe(CN)_5NO.2H_2O$ and chloramphenicol are susceptible to

a-atmospheric oxidation
b- dehydration
c- photodegradation
d-all of them

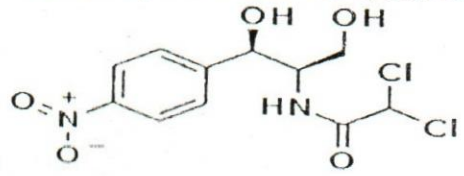
76- Bioavailability of Tetracyclines& Prostaglandin E changes due to

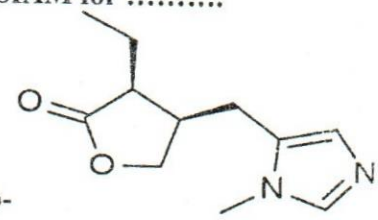
a-dehydration affect their dissolution
b-dehydration changes the crystal form
c-dehydration creates a double bond
d- dehydration causes precipitation

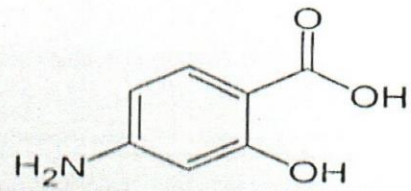
77-Oxidation is the main route of degradation of Penicillins

a- true
b-false

78- Ferric-hydroxamate test is considered SIAM for .....

a- 

b- 

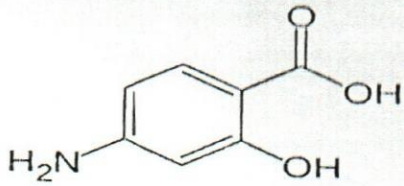
c- 

d-a&b

79- the following drug(s) show chemical incompatibility when admixed with aspirin

a-codeine
b- phenylephrine
c-both of them
d-none of them

80-The possible route of degradation of the following drug is.....



PAS

a-hydrolysis
b-oxidation
c- dehydration
d-decarboxylation

Good luck