UNIVERSITY OF THE PUNJAB

Fourth Prof. A/2015

Examination: Doctor of Pharmacy (Pharm.D.)

Roll No. .....

Subject: Pharmaceutics-VIII (Pharmaceutical Quality Control) **TIME ALLOWED: 3 hrs.**

PAPER: 5 **MAX. MARKS: 100**

Note: Attempt any five questions. Support your answer with appropriate diagram/sketch.

Question 1.

A. What is meant by disintegration? Why disintegration test is important for quality control of solid dosage form? Describe apparatus and method used for disintegration testing of compressed tablets. (10)
B. Name four commonly reported methods for testing flow properties of powders. Define compressibility index and Hausner ratio. (10)

Question 2.

A. Write down the names of various types of USP dissolution apparatus and give detail description of different parts of any one (10)
B. Describe the assay of ibuprofen tablets (5)
C. How will you assure the content uniformity in the given sample of hard gelatin capsules? (5)

Question 3.

A. Describe tests used in quality control of pharmaceutical syrup (8)
B. Enlist various official books used for Quality Control of Pharmaceuticals in Pakistan. What is the role of quality assurance department of a pharmaceutical industry (4+8)

Question 4.

A. Define Liquefaction time and melting range in respect to quality control of suppositories. Write a note on different methods/apparatus used for determination of Liquefaction time of suppositories. (8)
B. Write note on .(4+4+4)
   i. Role of extraction during alkaloidal assay
   ii. Friability Test in tablets
   iii. Hardness test for tablets

Question 5.

A. Define Statistical Quality Control and describes various control charts for variables. (10)

B. Explain the limits of alkalinity in different types of glass used in pharmaceuticals, and methods for determination of alkalinity of glass (06)
C. Write a note on filtration assembly and membrane filter used in sterility testing (04)

Question 6.

A. Why toxicity testing of pharmaceuticals is important? Describe the toxicity testing of plastic containers. (06)
B. Describe the testing of media to be used for sterility testing, why this testing is important. (06)
C. How you will perform sterility test solid dosage form, also describe the interpretation of results. (08)

Question 7.

A. What are biological assays? Discuss the official methods used for the quality control of Vitamin D? (10)
B. Discuss the determination of Alkaloidal drug contents in Pharmaceuticals with reference to Quality control?(10)

UNIVERSITY OF THE PUNJAB

Fourth Prof. A/2016
Examination: Doctor of Pharmacy (Pharm.D.)

Roll No. .....

Subject: Pharmaceutics-VIII (Pharmaceutical Quality Control) **TIME ALLOWED: 3 hrs.**
PAPER: 5 **MAX. MARKS: 100**

NOTE: Attempt any FIVE questions. All Questions carry equal marks.

Question 1.

A. Enlist the quality control tests performed for suppositories. Also explain the disintegration test for suppositories. (10)
B. Describe the procedure for weight variation test of compressed tablets. (05)
C. Name four commonly used methods for testing flow properties of powders and also define compressibility index and Hausner ratio. (05)

Question 2.

A. Define dissolution and disintegration? Why these tests are performed for solid dosage forms and also describe apparatus and method used for the disintegration testing of compressed tablets. (10)
B. Tabulate the acceptance criterion for dissolution testing of uncoated tablets? (03)
C. Describe various official apparatuses used for the dissolution testing of tablets. (07)

Question 3.

A. What is importance of toxicity testing in pharmaceuticals? Why we perform toxicity testing of plastic containers. (10)
B. Describe biological assays? Provide the official methods used for the quality control of Vitamin D? (10).

Question 4.

A. Write down the quality control tests applied to different types of glass and explain quality control test for Type II glass. (10)
B. Define initial, maximum temperature and response in pyrogen testing. Provide interpretation of results for *in-vivo* pyrogen test. (10)

Question 5.

A. What antimicrobial precautions have to be taken into consideration during sterility testing. (06)
B. Name two major methods of sterility testing. How you will carry out sterility testing on injectables. (14)

Question 6.

A. Define Statistical Quality Control and give different control charts for variables. (10)
B. Write a note on any two of the followings: (5 each)
   A. Leakers test
   B. Method of alcohol determination in gelanicals
   C. Alkaloidal drug assay
   D. Determination of total solids

Question 7.

A. What quality control tests are performed for syrups? (12)
B. What is role of Long Term Stability and Accelerated Stability Studies during drug development? (8)

UNIVERSITY OF THE PUNJAB

Fourth Prof. 2nd A/2016
Examination: Doctor of Pharmacy (Pharm.D.)

Roll No. .....

Subject: Pharmaceutics-VIII (Pharmaceutical Quality Control)
PAPER: 5

TIME ALLOWED: 3 hrs.
MAX. MARKS: 100

NOTE: Attempt any FIVE questions. All Questions carry equal marks.

Question 1.

A. Describe the apparatus and method used for the disintegration testing of suppositories. (15)
B. Define Liquefaction time and melting range with regard to the quality control of suppositories.(5)

Question 2.

A. Provide detail about various parts of official apparatus used for the disintegration testing of tablets. Also describe how the disintegration of enteric coated tablets is performed? (15)
B. Name various official apparatuses used for the dissolution testing of solid dosage forms and also provide their Pharmaceutical applications. (5)

Question 3.

A. Define dissolution. Describe methods for the dissolution testing of compressed tablets. (10)
B. Provide names of various compendial and non compendial quality control tests for capsules and tablets. Explain friability test in detail. (10)

Question 4.

A. Why quality testing of glass is important in Pharmaceuticals? Write down procedure for testing of Type I glass. (10)
B. What is importance of pyrogen testing in Pharmaceuticals? Name two types of pyrogens tests and shortly describe the principal involved in these two methods. (10)

Question 5.

A. How media is tested before sterility testing and why it is important to do. (6)
B. Describe in detail the rocedure of sterility testing on semi-solid dosage forms in accordance with interpretation of results.(14)

Question 6.

Write a note on the followings: (5 each)

A. Loss on drying
B. Ash test
C. Precautions in distillation method of alcohol determination
D. Particle size determination in ointments

Question 7.

A. Enlist different quality control tests for Elixers. Explain in detail various apparatuses used for viscosity determination of syrups. (12)
B. How the *in-vitro* evaluation of sustained release dosage forms is performed? (8)

UNIVERSITY OF THE PUNJAB

Fourth Prof: A/2017
Examination: Doctor of Pharmacy (Pharm.D.)

Roll No. .....

Subject: Pharmaceutics-VIII (Pharmaceutical Quality Control)
PAPER: 5

TIME ALLOWED: 3 hrs.
MAX. MARKS: 100

NOTE: Attempt any FIVE questions. All Questions carry equal marks.

Question 1

A. Give names of various compendial and non compendial quality control tests for tablets and capsules. Describe in detail method and apparatus of disintegration test for compressed tablets. (12)

B. Differentiate between biological and chemical assay. Explain with examples. (5)

C. Tabulate the acceptance criterion for dissolution test of uncoated tablets? (03)

Question 2.

A. Name different quality control tests performed for syrups. Describe different apparatuses used for the determination of viscosity of non newtonion liquids. (10)

B. What are IPQC testes for tablets? Describe principle, apparatus and procedure and for the friability of compressed tablets. (10)

Question 3.

A. Define quality, why quality in needed in pharmaceutical products? Describe the concept of pharmaceutical quality management. (10)

B. Define analysis and assay. Write down procedure for content uniformity of tablets (10)

Question 4.

A. Name the quality control tests applied to different types of glass, Write quality control test for Type II glass. (10)

B. What are pyrogens? Why their testing is important in pharmaceuticals? Describe in-vivo testing of pyrogens. (10)

Question 5.

A. Write a note on any two of the followings (5 each)

i. Leakers test
ii. Determination of total solids
iii. Method of alcohol determination in gelanicals
iv. Alkalodal drug Assay

B. Describe method for the assay of insulin. (10)

Question 6

A. Define Quality Control Charts. Give the classification of Quality Control Charts. (8)

B. Describe process compatibility index. (12)

Question 7

A. Name different test for the quality control of suppositories. Explain in detail disintegration test of suppositories. (12)

B. What is pharmacopoeia? What type of information is given in appendices and monographs? (8)

UNIVERSITY OF THE PUNJAB

Fourth Prof: 2nd Annual - 2017
Examination: Doctor of Pharmacy (Pharm.D.)

Roll No. .....

Subject: Pharmaceutics-VIII (Pharmaceutical Quality Control)
PAPER: 5

TIME ALLOWED: 3 hrs.
MAX. MARKS: 100

NOTE: Attempt any FIVE questions. All Questions carry equal marks.

Question 1.

A. Differentiate with example between official and non official quality control tests for tablets and capsules. Describe in detail method and apparatus for dissolution test of compressed tablets. (12)

B. What is Assay? Name different techniques for the assay of pharmaceutical materials. Differentiate between percentage purity and content uniformity test. (8)

Question 2.

A. Name different quality control tests performed for suppositories. Describe in detail disintegration test of suppositories. (10)

B. What is IPQC stands for give its importance in the quality control of tablets? Describe principle, apparatus and procedure and for the disintegration test of uncoated tablets. (10)

Question 3.

A. Write a note on breaking and liquefaction test of suppositories (12)

B. Differentiate between cGMP, quality control and quality assurance. (8)

Question 4.

A. How you will perform sterility test on semi-solid dosage form, also describe the interpretation of results of sterility testing. (10)

B. What are pyrogens? Why their testing is important in pharmaceuticals? Describe in-vitro testing of pyrogens. (10)

Question 5.

A. Write a note on any two of the followings (5 each)

I. Toxicity testing
II. Particle size determination in ointments
III. Microbiological assay with example
IV. Assay of insulin

B. Why quality testing of glass is important in pharmaceuticals? How it is tested for Type I glass. (10)

Question 6

A. Define Statistical Process Quality Control (SPQC) Charts. What are different types of Quality Control Charts? (10)

B. Describe applications of Shewarts charts. (10)

Question 7

A. Write a note on Alkaloidal drug assay. (10)

B. Name different test performed for liquid dosage form. Describe in detail density determination of syrup and elixirs. (10)

UNIVERSITY OF THE PUNJAB

Fourth Prof: Annual – 2018
Examination: Doctor of Pharmacy (Pharm.D.)

Roll No. .....

Subject: Pharmaceutics-VI (Pharmaceutical Quality Management) (New Course)
PAPER: 5 (Part – II)

TIME ALLOWED: 2 Hrs. & 30 min.
MAX. MARKS: 80

Attempt this Paper on Separate Answer Sheet provided.

Attempt any 4 questions. Each question carry equal marks.

Question No 2

A. Define dissolution. Enlist various official apparatus for dissolution testing. Give a general procedure for the dissolution test of compressed tablets and how the results are interpreted. (12)

B. Name official and non-official quality control tests for tablet dosage form. Describe the weight variation test of tablet in detail. (8)

Question No 3

A. Define "Good Manufacturing Practice" Give its Objectives. Explain necessary facilities for GMP. (10)

B. Differentiate between quality control and quality assurance. Enlist various official books used for Quality Control of Pharmaceuticals. (10)

Question No 4

A. What are the different types of control charts? Discuss control charts for variables (10)

B. Explain in detail how to test the in-vivo potency of a vaccine? (10)

Question No 5

A. Name various tests for parenteral preparations. Give method (all stages) and specifications pyrogen test by rabbit. (10)

B. Give precautions to be taken for sterility testing of parenteral preparations. (10)

Question No 6

A. Define Disintegration. Discuss construction and working of Basket Rack Assembly with diagram (10)

B. Discuss construction, procedure and interpretation of USP Tablet Friability Test. (10)

Question No 7

Write a note on following test (5x4=20)

A. Test for glass containers
B. Alcoholic content determination
C. Chemical and biological assay
D. Requirements and specification for clarity testing of large and small volume parenteral

66

UNIVERSITY OF THE PUNJAB

Roll No. .....

Fourth Prof: Annual – 2018

Examination: Doctor of Pharmacy (Pharm.D.)

Subject: Pharmaceutics-VI (Pharmaceutical Quality Management) (New Course)

TIME ALLOWED: 30 min.
MAX. MARKS: 20

PAPER: 5 Part – I (Compulsory)

Attempt this Paper on this Question Sheet only.

Please encircle the correct statement. Each MCQ carries 1 Mark. This Paper will be collected back after expiry of time limit mentioned above.

Question 1

1. Specifications and method of content uniformity test of a dosage form is given in_____ of official compendia
   - A. Monograph
   - B. Appendix
   - C. General note
   - D. Miscellaneous test
2. Information about the apparatus of dissolution test is given in _____ of official compendia
   - A. Monograph
   - B. Appendix
   - C. General note
   - D. Miscellaneous test
3. Closeness of test results to obtained by an analytical procedure is:
   - A. Accuracy
   - B. Precision
   - C. Specificity
   - D. Sensitivity
4. Limit of detection and limit of quantification refer to which of the following validation term
   - A. Accuracy
   - B. Precision
   - C. Specificity
   - D. Sensitivity
5. Which of following is most selective analytical technique
   - A. Titrimetric analysis
   - B. HPLC
   - C. UV Spectroscopy
   - D. IR Spectroscopy
6. Which of the following is not an official test for tablets
   - A. Content uniformity
   - B. Disintegration
   - C. Dissolution
   - D. Weight variation
7. which of the following is an official in process quality control (IPQC) test
   - A. Content Uniformity
   - B. Disintegration
   - C. Dissolution
   - D. Percentage purity
8. According to British Pharmacopoeia, the percentage difference acceptable for tablets weighing 80 mg or less is _____
   - A. ± 10.0 %
   - B. ± 7.5 %
   - C. ± 5.0 %
   - D. ± 3.0 %
9. _____ number of tablets are used in basket rack assembly of disintegration test apparatus
   - A. 5
   - B. 6
   - C. 8
   - D. 10

PTO

10. According to BP, compressed tablets should disintegrate within
    A. 10 minutes
    B. 15 minutes
    C. 30 minutes
    D. 60 minutes
11. _____ test apparatus is normally used for dissolution testing of capsules
    A. Type I (Basket apparatus)
    B. Type II (Paddle apparatus)
    C. Type IV (Flow through cell)
    D. Type V (Paddle over disc)
12. Determination of content uniformity is official test for
    A. Raw material of active pharmaceutical agent
    B. Dosage form of active pharmaceutical agent
    C. Both A & B
    D. It is not an official test for either raw material or dosage form
13. Which of the following is not an Assay procedure
    A. Identification test
    B. Content uniformity test
    C. Percentage purity
    D. Dissolution testing
14. Type of viscosities, EXCEPT _____ are dependent on the surrounding conditions
    A. Dynamic viscosity
    B. Kinematic viscosity
    C. Absolute viscosity
    D. Relative viscosity
15. _____ viscometer is used for Newtonian fluids
    A. Ostwald viscometer
    B. Falling ball
    C. Rotational viscometer
    D. All of the above
16. LAL test for pyrogen testing is a _____
    A. Qualitative test
    B. Quantitative test
    C. Semi quantitative test
    D. Not either quantitative or qualitative
17. _____ is primarily intended for the culture of anaerobic bacteria; however, it will also detect aerobic bacteria.
    A. Fluid thioglycollate medium
    B. Agar broth medium
    C. Agar casein medium
    D. Soya-bean casein digest medium
18. In clarity test of large volume parenteral. The preparation complies with the test if the average number of particles present in the units tested does not exceed 6000 per container equal to or greater than 10 µm and does not exceed _____ per container equal to or greater than 25 µm.
    A. 300
    B. 600
    C. 900
    D. 1000
19. Following Quality Control test is not performed for parenteral preparations
    A. Dissolution
    B. Weight variation
    C. Content uniformity
    D. Assay of active ingredient
20. All the following statements regarding 3 sigma are true EXCEPT
    A. Probability that a random value of measurement falls between 3 sigma limits is 0.9973
    B. Probability that a random value of measurement falls outside 3 sigma limit is 0.0027
    C. Probability that a random value of measurement falls between 3 sigma is very low
    D. Probability that a random value of measurement falls outside 3 sigma is very low

UNIVERSITY OF THE PUNJAB

Fourth Prof: 2nd Annual – 2018

Examination: Doctor of Pharmacy (Pharm.D.)

Roll No. .....

Subject: Pharmaceutics-VI (Pharmaceutical Quality Management) (New Course)

MAX. TIME: 2 Hrs. 30 Min.

MAX. MARKS: 80

PAPER: 5 Part – II

ATTEMPT THIS (SUBJECTIVE) ON THE SEPARATE ANSWER SHEET PROVIDED

Note: Attempt any four Questions from this part

Question No 2

A. Define "Good Manufacturing Practice". Explain the difference between Quality Control and Quality. (10)

B. Define pharmacopoeia. Differentiate between appendices and monograph given in pharmacopoeia. (10)

Question No 3

A. What is pyrogen. Give principle, method and specifications of LAL test. (8)

B. Write a note on the sterility testing of parenteral preparations. (12)

Question No 4

A. Q2. How Shewhart charts differ from process acceptance charts. Discuss the control charts for attributes. (10)

B. What is monocyte activation test (MAT). How it is better than LAL and animal pyrogen testing? (10)

Question No 5

A. Classify physical and chemical testing of Suppositories, Explain importance and determination of liquefaction and Melting range (melting point, melting zone) in detail (10)

B. What are common procedures used in the pharmacopoeias for assay of active ingredient? Differentiate between chemical and biological assay. (10)

Question No 6

A. What is dissolution? Give name of official dissolution test apparatus. Explain construction and working of Dissolution Test (Apparatus I) (12)

B. Explain interpretation criteria for the dissolution of the following dosage forms (8)

- Immediate release dosage form
- Delayed release dosage form

Question No 7

A. Write names of compendial and non-compendial QC tests for tablet. Write a note on weight variation test for tablets. (10)

B. Discuss procedure and apparatus for disintegration test of enteric coated tablets. (10)

UNIVERSITY OF THE PUNJAB

Fourth Prof: 2nd Annual – 2018

Examination: Doctor of Pharmacy (Pharm.D.)

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Roll No. in Words. .....

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Signature of Supdt.:

Subject: Pharmaceutics-VI (Pharmaceutical Quality Management) (New Course)

MAX. TIME: 30 Min.

MAX. MARKS: 20

PAPER: 5 Part – I (Compulsory)

Attempt this Paper on this Question Sheet only.
Please encircle the correct option. Division of marks is given in front of each question.
This Paper will be collected back after expiry of time limit mentioned above.

Q.1. Encircle the right answer cutting and overwriting is not allowed. (1x20=20)

1. Specifications and method of Assay of a dosage form is given in _____ of official compendia
   A. Monograph
   B. Appendix
   C. General note
   D. Miscellaneous test

2. Closeness of test results obtained by an analytical procedure to that of true value is:
   A. Accuracy
   B. Precision
   C. Specificity
   D. Selectivity

3. _____ refers to the sensitivity of an analytical procedure.
   A. Limit of detection
   B. Limit of quantification
   C. Content uniformity
   D. % content

4. Which of the following is not an official test for tablets
   A. Content uniformity
   B. Disintegration
   C. Dissolution
   D. Weight variation

5. Which of the following is an official in process quality control (IPQC) test
   A. Content Uniformity
   B. Disintegration
   C. Dissolution
   D. Percentage purity

6. Acceptable hardness range for compressed tablet is
   A. 2-5 Kg/cm^2
   B. 5-10 Kg/cm^2
   C. 10-15Kg/cm^2
   D. 1-20 Kg/cm^2

7. According to British Pharmacopoeia, the percentage difference acceptable for tablets weighing 250 mg or more is _____
   A. ± 10.0 %
   B. ± 7.5 %
   C. ± 5.0 %
   D. ± 3.0 %

8. _____ number mesh is used in basket rack assembly of disintegration test apparatus
    A. 10
    B. 20
    C. 30
    D. 40
9. Dissolution test represents in vivo drug _____ however far from being understood properly.
    A. Absorption
    B. Elimination
    C. Disintegration
    D. Stability
10. _____ test apparatus is normally used for dissolution testing of transdermal patches
    A. Type I (Basket apparatus)
    B. Type II (Paddle apparatus)
    C. Type IV (Flow through cell)
    D. Type V (Paddle over disc)
11. Determination of percentage purity is official test for
    A. Raw material of active pharmaceutical agent
    B. Dosage form of active pharmaceutical agent
    C. Both A & B
    D. It is not an official test for either raw material or dosage form
12. Which of the following is not an Assay procedure
    A. Identification test
    B. Content uniformity test
    C. Percentage purity
    D. Dissolution testing
13. Which of the following statements is False?
    A. Common variations are those, where causes of variation cannot be assigned
    B. Special variables are those where cause can be assigned
    C. Random variables are build-into-process
    D. Special variable are also called as common variables
14. Following method is NOT used to determine flow properties of powder
    A. Angle of repose
    B. Flow through cell
    C. Compressibility index
    D. Shear cell methods
15. Following type of viscosity is independent of the surrounding conditions
    A. Dynamic viscosity
    B. Kinematic viscosity
    C. Absolute viscosity
    D. Relative viscosity

16. _____ viscometer is not used for the determination of viscosity of Non-Newtonian fluids
    A. Ostwald viscometer
    B. Spindle viscometer
    C. Cone and plate viscometer
    D. Rotational viscometer

17. At the first stage of pyrogen testing, _____ healthy rabbits are selected
    A. 3
    B. 6
    C. 9
    D. 12

18. Quality control test EXCEPT _____ test is not performed for parenteral preparations
    A. Dissolution
    B. Weight variation
    C. Content uniformity
    D. Assay of active ingredient

19. Membrane filters having a nominal pore size not greater than _____ are used in sterility testing by membrane filtration procedure.
    A. 0.25 µm
    B. 0.45 µm
    C. 0.35 µm
    D. 0.50 µm

20. In clarity testing of small volume parenteral, if the number of particles of 10 µm or greater size exceeds _____ for the combined 25 ml, the precautions taken for the test are not sufficient.
    A. 10
    B. 25
    C. 30
    D. 50

UNIVERSITY OF THE PUNJAB

Fourth Prof: 2nd Annual – 2018

Examination: Doctor of Pharmacy (Pharm.D.)

Roll No. .....

Subject: Pharmaceutics-VIII (Pharmaceutical Quality Control) (Old Course)
PAPER: 5

MAX. TIME: 3 Hrs.
MAX. MARKS: 100

NOTE: Attempt any FIVE questions. All questions carry equal marks.

Question No 1

A. Define Disintegration. Discuss construction and working of Basket Rack Assembly with diagram (10)

B. Discuss construction, procedure and interpretation of USP Tablet Friability Test. (10)

Question No 2

A. Define "Good Manufacturing Practice" Give its Objectives. Explain necessary facilities for GMP. (10)

B. Differentiate between quality control and quality assurance. Enlist various official books used for Quality Control of Pharmaceuticals. (10)

Question No 3

A. Define dissolution. Enlist various official apparatus for dissolution testing. Give a general procedure for the dissolution test of compressed tablets and how the results are interpreted. (12)

B. Name official and non-official quality control tests for tablet dosage form. Describe the weight variation test of tablet in detail. (8)

Question No 4

A. Name various tests for parenteral preparations. Give method (all stages) and specifications pyrogen test by rabbit. (10)

B. Give precautions to be taken for sterility testing of parenteral preparations. (10)

Question No 5

A. What are the different types of control charts? Discuss control charts for variables (10)

B. How the in-vivo potency of a vaccine is tested? (10)

Question No 6

A. Write a note on different apparatuses used for viscosity testing (10)

B. Give name of different test for Quality Control of suppositories. Write in detail about apparatus of disintegration test for suppositories. (10)

Question No 7

Write a note on following test

A. Test for glass containers
B. Alcoholic content determination
C. Chemical and biological assay
D. Requirements and specification for clarity testing of large and small volume parenteral

UNIVERSITY OF THE PUNJAB

Doctor of Pharmacy (Pharm.D.) Fourth Prof: Annual–2019

Subject: Pharmaceutics-VI (Pharmaceutical Quality Management)
Paper: 5 Part – I (Compulsory) (New Course) Time: 30 Min. Marks: 20

Roll No. in Fig. .....
Roll No. in Words. .....
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Signature of Supdt.:

ATTEMPT THIS PAPER ON THIS QUESTION SHEET ONLY.
Division of marks is given in front of each question.
This Paper will be collected back after expiry of time limit mentioned above.

Q.1. Encircle the correct option. **(20x1=20)**

1. QC means the part of GMP concerned with all except: a) Sampling b) Specifications c) Marketing d) Documentation	2. Dissolution apparatus II is: a) Paddle apparatus b) Flow through cell apparatus c) Basket apparatus d) Paddle over disc
3.The only validation parameter required by identification tests is: a) Accuracy b) Precision c) Specificity d) Selectivity	4. Antibiotics can be tested: a) Chemically b) Biologically c) Microbiologically d) All of above
5.All are chemical tests except: a) Disintegration b) Dissolution c) Content uniformity d) Assay	6. Mesh size of the basket in dissolution apparatus is a) 10 b) 20 c) 30 d) 40
7. All statements are true about vaccines except: a) They are biosimilar b) They are homogeneous c)They require extensive clinical testing d) They need stability studies	8. Which of the following is an official in process quality control (IPQC) test a) Content Uniformity b) Disintegration c) Dissolution d) Percentage purity
9. A refractometer normally determines: a) Angle of repose b) Critical angle c) Contact angle d) All of the above	10. The rabbit pyrogen test is: a) Quantitative b) Semi-quantitative c) Qualitative d) Semi-qualitative
11. In the rabbit pyrogen test. any temperature decrease is regarded as: a) Positive rise b) Negative rise c) Zero rise d) Linear rise	12. General instructions about the apparatus and method of Quality control procedure is given in _____of official compendia a) Monograph b) Appendix c) General note d) Miscellaneous test

P.T.O.

13. Dissolution test represents in vivo drug - _____ however far from being understood properly. a) Absorption b) Elimination c) Disintegration d) Stability	14. Determination of percentage purity is official test for a) Raw material of active pharmaceutical agent b) Dosage form of active pharmaceutical agent c) Both A & B d) It is not an official test for either raw material or dosage form
15. ----- glass containers are recommended for parenteral preparations:: a) Type I b) Type II c) Type III d) Type IV	16. --------- screens out the less significant factors in an analysis a) Scatter diagram b) Control chart c) Flow chart d) Pareto chart
17. For fat based suppositories disintegration should occur in not more than : a) 10 min b) 20 min c) 30 min d) 60 min	18. To determine the abnormal toxicity of immunosera and vaccines, injection is usually given to mice: a) Intraperitonealy b) Intravenously c) Intramuscularly d) Intracardiacally
19. % recovery is a determinant of : a) Linearity b) Accuracy c) precision d) Specificity	20. The viscosity of semi solid is usually determined by employing: a) Spindle viscometer b) Cone and plate viscometer c) Falling ball viscometer d) Capillary viscometer

UNIVERSITY OF THE PUNJAB

Roll No. .....

Doctor of Pharmacy (Pharm.D.) Fourth Prof: Annual–2019

Subject: Pharmaceutics-VI (Pharmaceutical Quality Management)
Paper: 5 Part – II (New Course) **Time: 2 Hrs. 30 Min. Marks: 80**

ATTEMPT THIS (SUBJECTIVE) ON THE SEPARATE ANSWER SHEET PROVIDED

Note: Attempt any *FOUR* questions. Each question carries equal marks.

Question No 2

A. Define "Good Manufacturing Practice" Describe its Objectives. Discuss the requirements of GMP for a layout design of a pharmaceutical industry. (10)
B. Differentiate between quality control and quality assurance. Enlist various official books used for Quality Control of Pharmaceuticals. (10)

Question No 3

A. What are different official apparatuses for dissolution testing give names and their uses. Tabulate criteria of dissolution testing of compressed tablet. (10)
B. Name official and non-official quality control tests for tablet dosage form. Explain friability test of tablet in detail. (10)

Question No 4

A. Define Disintegration. Discuss construction and working of disintegration apparatus for suppositories. (10)
B. Discuss construction, procedure and interpretation of disintegration test/ apparatus for tablet dosage form. (10)

Question No 5

A. Write a note on sterility test of parenteral preparations. (10)
B. Write a note on in-vitro pyrogen test. (10)

Question No 6

Write a note on following test

A. Alcoholic content determination (10)
B. Chemical and biological assay with examples (10)

Question No 7

A. Give a detailed account of statistical quality control. (10)
B. Write a note on different glass tests. (10)

UNIVERSITY OF THE PUNJAB

Doctor of Pharmacy (Pharm.D.) Fourth Prof: Annual–2019

Roll No. .....

Subject: Pharmaceutics-VIII (Pharmaceutical Quality Control) (Old Course)

Paper: 5

Time: 3 Hrs. Marks: 100

Note: Attempt any *FIVE* questions. Each question carries equal marks.

Question No 1

A. Define "Good Manufacturing Practice" Give its Objectives. Explain the requirements of GMP for a layout design of a pharmaceutical industry. (10)

B. Differentiate between quality control and quality assurance. Enlist various official books used for Quality Control of Pharmaceuticals. (10)

Question No 2

A. What are different official apparatuses for dissolution testing give names and their uses. Tabulate criteria of dissolution testing of compressed tablet. (10)

B. Name official and non-official quality control tests for tablet dosage form. Describe friability test of tablet in detail. (10)

Question No 3

A. Define Disintegration. Discuss construction and working of disintegration apparatus for suppositories. (10)

B. Discuss construction, procedure and interpretation of disintegration test/ apparatus for tablet dosage form. (10)

Question No 4

A. Write a note on sterility test of parenteral preparations. (10)

B. Write a note on in-vitro pyrogen test. (10)

Question No 5

Write a note on following test

A. Alcoholic content determination (10)

B. Chemical and biological assay with examples (10)

Question No 6

A. Give a detailed account of statistical quality control. (10)

B. Write a note on different glass tests. (10)

Question No 7

Write a note on following test

A. Alkaloidal drug assay (10)

B. Requirements and specification for clarity testing of large and small volume parenteral (10)

UNIVERSITY OF THE PUNJAB

Doctor of Pharmacy (Pharm.D.) Fourth Prof: Annual–2021

Roll No. in Fig. .....

Roll No. in Words. .....

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Signature of Supdt.:

Subject: Pharmaceutics-VI (Pharmaceutical Quality Management)
Paper: 5 Part – I (Compulsory) (New Course) **Time: 30 Min. Marks: 20**

ATTEMPT THIS PAPER ON THIS QUESTION SHEET ONLY.
Division of marks is given in front of each question.
This Paper will be collected back after expiry of time limit mentioned above.

Q.1. Encircle the correct option. (20x1=20)

Q1. Weight of the water will be ..... By increasing the temperature

A) Decreased
C) Increased
B) Maximum
D) Constant

Q2. In Karl fisher titrimetric method water is quantitatively measured by titration under ..... conditions

A) Hydrous
C) Hydrophilic
B) Anhydrous
D) Aseptic

Q3. How many suppositories should be taken to repeat content uniformity test

A) 10
C) 25
B) 20
D) 40

Q4. Powdered glass test challenges the leaching potential of:

A) Exterior structure of glass
C) Interior structure of glass
B) Plastic containers
D) Intact surface of glass

Q5. According to USP, the volume of Sulfuric acid required to neutralize leached alkali in Type I glass should not exceed:

A) 5 ml of 0.02N H_2SO_4
C) 10 ml of 0.02N H_2SO_4
B) 2 ml of 0.02N H_2SO_4
D) 1 ml of 0.02N H_2SO_4

Q6. Which of the following is NOT the principle problem areas exists in plastic containers:

A) Leaching
C) Permeation
B) Hardness
D) Sorption

Q7. Which one of the following not belongs to the biological products?

A) Vaccines
C) Probiotics
B) Xeno-transplantation product
D) Iscoms

Q.8 In alkaloidal assay, during pulverization avoid the loss of....

A) Inorganic materials
C) Water
B) Minerals
D) Organic matter

Q.9 Loss on drying is expressed as ...

A) v/v
C) w/ml
B) w/L
D) m/m

Q10.The process to ensure the production quality meets the required standards is called:

A) Quality assurance
C) Good manufacturing practices
B) Quality control
D) Total quality management

Q.11.BCG vaccine is the example of:

A) Live attenuated vaccine
C) Conjugate vaccine
B) Killed vaccine
D) Subunit Vaccine

P.T.O.

Q.12 Methylene Blue is used for....

A) Pyrogen test

B) Leaker test

C) Light obstruction test

D) Sterility test

Q.13.According to British Pharmacopoeia, the percentage difference acceptable for tablets weighing 250 mg or more is _____

A) ± 10.0 %

B) ± 7.5 %

C) ± 5.0 %

D) ± 3.0 %

Q.14.Following type of viscosity is independent of the surrounding conditions

A) Dynamic viscosity

B) Kinematic viscosity

C) Absolute viscosity

D) Relative viscosity

Q15.One unit of dried digitalis powder is:

A) 95 mg

B) 76 mg

C) 145 mg

D) 89 mg

Q16.Quality control department focus on:

A) Procurement

B) Processes

C) Outputs

D) Trainings

Q17.Control charts for _____ are used to monitor characteristics that have discrete values and can be counted, e.g., % defective, number of flaws in a shirt, number of broken eggs in a box

A) Variables

B) Attributes

C) Characteristics

D) Procedures

Q.18. In Roche friabililator, every time tablets fall from a distance of.....inches

A) 3

B) 7

A) 3

B) 7

Q.19. Pore size of membrane used for sterilization of injection is .....

A) 0.34 µm

B) 0.50 µm

C) 0.45 µm

D) 0.25 µm

Q.20. Enteric coated tablets should disintegrate in...

A) Simulated intestinal juice

B) Simulated gastric juice

C) Distilled water

D) 0.1N HCl

UNIVERSITY OF THE PUNJAB

Roll No. .....

Doctor of Pharmacy (Pharm.D.) Fourth Prof: Annual–2021

Subject: Pharmaceutics-VI (Pharmaceutical Quality Management)
Paper: 5 Part – II (New Course)

Time: 2 Hrs. 30 Min. Marks: 80

ATTEMPT THIS (SUBJECTIVE) ON THE SEPARATE ANSWER SHEET PROVIDED

Note: Attempt any *FOUR* questions. Each question carries equal marks.

Q.2 a) How the Ash contents are determined and what is its importance. (10)

b) Write note on following parameters of in vivo Pyrogen test. (10)

1) Selection and protocol

2) Material and preparation of samples

3) Interpretation of results

Q.3 a) What are the alkaloids? Explain assay of alkaloids along with example. (10)

b) Name official and non-official QC tests for tablet. Describe the weight Variation and hardness test of tablet in detail. (10)

Q.4 a) Classify the glass materials used in pharmacy. Discuss the method to determine The alkalinity of glass and interpretation of results. (12)

b) Describe the levels of evaluation of Quality care and factors affecting The quality assurance in Industry? (08)

Q.5 a) Define Good Manufacturing Practice. Give its Objectives. Explain necessary Facilities for GMP. (10)

b) Define syrups and elixirs. Discuss QC tests of syrups and elixirs in detail. (10)

Q.6 a) What are the microbiological assays? Discuss the Principal and Microbiological assay of Antibiotics and Vitamin B_{12}? (10)

(b) Define dissolution. Enlist various official apparatus for dissolution. Give a General procedure for the dissolution of uncoated tablets and how the Results are interpreted. (10)

Q.7 Write Note on (05 each)

a) Difference between quality control and quality assurance.

b) Alcoholic contents determination.

c) Viscometer used for semisolids

d) LAL test