AIKTC/KRRC/SoP/ACKN/QUES/2022-23/ **Date:** 25/01/23

School: SoP-PCI **Branch:** SoP **SEM:** VI

To,
Exam Controller,
AIKTC, New Panvel.

Dear Sir/Madam,

Received with thanks the following **Semester/Periodic** question papers from your exam cell:

Sr. No.	Subject Name	Subject Code	Format		No. of Copies
			SC	HC	
1	Medicinal Chemistry III	BP601T		✓	
2	Pharmacology III	BP602T		✓	
3	Herbal Drug Technology	BP603T		—	
4	Biopharmaceutics and Pharmacokinetics	BP604T		✓	
5	Pharmaceutical Biotechnology	BP605T		—	
6	Quality Assurance	BP606T		✓	

Note: SC – Softcopy, HC - Hardcopy

(Shaheen Ansari)
Librarian, AIKTC

22/11/2022

Paper / Subject Code: 87611 / Medicinal Chemistry- III

SEM - II CBCS R-2019

Duration: (3 hours) **Total Marks: 75**

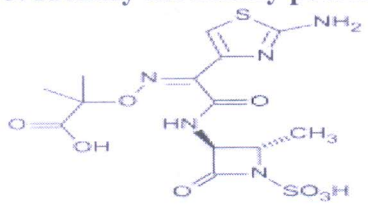
N.B: 1. All questions are Compulsory.
2. Figures to right indicate full marks.

Q I Answer the following Multiple Choice Questions. Select the most appropriate option for each statement. **(20 M)**

1. Which of the following is a pair of β- lactam antibiotics.
a) Penicillin & cephalosporin
b) Streptomycin & gentamycin
c) Minocycline & doxycycline
d) Chloramphenicol & aminoglycosides

2. Chemically tetracycline is a derivative of
a) A large macrocyclic lactone ring
b) 6-Amino penicillanic acid (6-APA)
c) Octahydronapthacene
d) 7-Amino cephalosporinic acid (6-APA)

3. Identify the moiety present in the given drug structure.



a) Azetidine & 2-aminothiazole
b) Methoxyimino & 2-aminothiazole
c) Pyridinium & 2-aminothiazole
d) Triazine & 2-aminothiazole

4. Identify prodrug of tetracycline antibiotic
a) Doxycycline
b) Oxytetracycline
c) Rolitetracycline
d) Methacycline

5. Which of the following is the azalide antibiotic?
a) Clarithromycin
b) Azithromycin
c) Roxithromycin
d) Erythromycin

6. Prodrug with two pharmacologically active compounds are called as
a) Mutual prodrug
b) Bioprecursor
c) Polymeric prodrug
d) Biotransformation

7. Identify an active metabolite of proguanil from the following
a) Chloroquine
b) Cycloguanil
c) Mefloquine
d) Pyrimethamine

8. Endoperoxide 1, 2, 4-trioxane ring is responsible for the antimalarial action of
a) Artemether
b) Primaquine
c) Pyrimethamine
d) Quinacrine
9. Identify the bioisostere of nicotinamide?
a) Ethionamide
b) Pyrazinamide
c) Cycloserine
d) Ethambutol
10. Clavulanic acid is inhibitor of
a) DNA gyrase
b) DNA dependent RNA polymerase
c) β-lactamase
d) Topoisomerase
11. Select the naphthyridine containing compound?
a) Norfloxacin
b) Ciprofloxacin
c) Nalidixic acid
d) Lomefloxacin
12. Which of the following is synthetic analogue of deoxyguanosine having acyclic carbohydrate moiety.
a) Amantadine
b) Rimantadine
c) Acyclovir
d) Zidovudine
13. Idoxuridine consists of
a) deoxyuridine halogenated pyrimidine
b) halogenated cytidine
c) halogenated adenine
d) halogenated thymidine
14. Identify antifungal antibiotic with heterocyclic benzofuran moiety?
a) Amphotericin-B
b) Nystatin
c) Natamycin
d) Griseofulvin.
15. Identify the prodrug with imidazole nucleus used for the treatment of amoebiasis?
a) Metronidazole
b) Iodoquinol
c) Ornidazole
d) Diloxanide furoate
16. Prontosil on metabolic activation leads to formation of
a) Sulfacetamide
b) Sulfanilamide
c) Sulfadiazine
d) Sulfapyridine
17. Identify a carrier linked prodrug of sulphonamide used for ulcerative colitis?
a) Sulfasalazine
b) Sulfapyridine
c) Sulfamethoxazole
d) Sulfacetamide

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18. Identify the QSAR parameter, which is a measure of electron withdrawing or electron donating ability of a substituent.

a) Hammett constant
b) Taft constant
c) Molar refractivity
d) Partition coefficient

19. Structure Based Drug Design (SBDD) approach used in drug design is

a) 2D-QSAR
b) Molecular Docking
c) Pharmacophore modeling
d) 3D-QSAR

20. Solid phase synthesis is frequently used in combinatorial chemistry. Which means?

a) Reactions are carried out without solvent
b) Reagents and reactants are attached to a solid phase support
c) Reagents are used in the solid phase
d) Molecules are constructed on a solid phase support

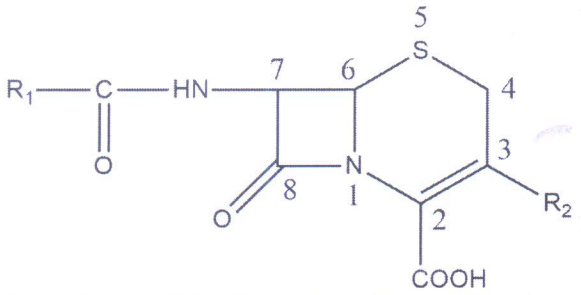
Q II Answer Any 2 of the following questions: (20 M)

Q.1.

A. With respect to penicillin, state whether the following statements are True/False. Correct if False **(4M)**

a) Introduction of electron releasing group at α-carbon increases the acid stability.
b) Increasing stearic hindrance at α-carbon decreases the β-lactamase stability.
c) Introduction of polar group at α-carbon broadens the spectrum of activity.
d) Pivampicillin is a prodrug.

B. Answer the questions with reference to following structure. **(4M)**



a) Name the scaffold & mention class of the same
b) Explain the effect of addition of alkoximino group in acyl side chain.
c) Write effect of 7α-methoxy in the scaffold.
d) Write structure of an oral drug consisting of the above scaffold.

C. Discuss the structural features of aminoglycosides with suitable example. **(2M)**

Q.2.

A. Classify following cephalosporins based on generations, write structure and also suggest suitable route of administration: Cephalexin, Cefuroxime,Cefotaxime & Cefepime.. **(4M)**

B. Write structural features of monobactam antibiotics. Why β-lactamase inhibitors are given in combination with antibiotics. **(4M)**

C. Give one example of carrier-based prodrug and the enzyme activating it. **(2M)**

Q3.A. Comment on the effect of the following changes on the core nucleus drawn. **(4M)**

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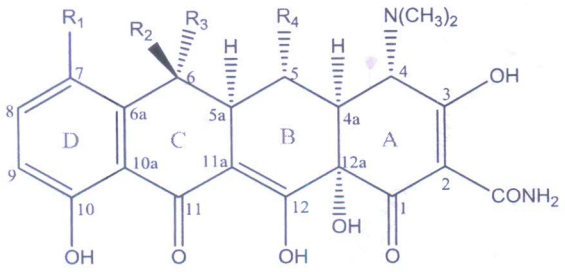


a) Substitution with –OH group at C-5.
b) Epimerization at C-4.
c) Introduction of $=CH_2$ at C-6.
d) Modification in aromatic ring D.

B. Answer the following. **(4M)**

a) The presence of a good stable leaving group on 3-position of cephalosporin is important for high acid stability. Explain. **(2M)**

b) What structural modifications are made in macrolides to increase the acid stability? **(2M)**

C. How prodrug approach can be used for improving absorption and distribution of a drug molecule? Explain with suitable example. **(2M)**

Q III Answer <u>Any 7</u> of the following questions: **(35 M)**

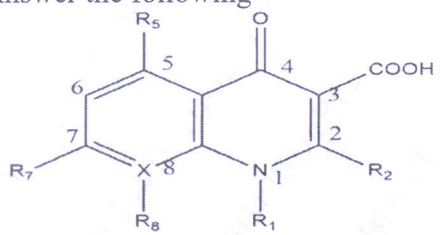
Q1.

A.Match the following. **(4M)**

Generic name	**Chemical class**	**Mechanism of action**
Isoniazid	an aminoglycoside antibiotic	blocking the ability of 30S ribosomal subunits to make proteins
PAS	Pyrazine derivative	Folic acid synthesis inhibitor
Pyrazinamide	Salicylic acid derivative	FASI (Fatty acid synthesis inhibitor)
Streptomycin	Carboxylic acid hydrazide derivative	Mycolic acid synthesis inhibitor

B. Write structure of antitubercular prodrug. **(1M)**

Q2.A. Answer the following **(4M)**



a) Name any one drug containing the above basic structure & enzyme inhibited by it.
b) Annelation of R_1 & R_8 leads to which active drug.
c) Indicate any one substitution at R_7 that give potent compound.
d) Comment on the substitution that influences phototoxicity.

B. Draw the structure of fluoroquinolone with N-cyclopropyl substituent. **(1M)**

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Q3.A. Write the synthetic scheme for **acyclovir** mentioning reagents & reaction conditions. **(3M)**

B. Write structure & MOA of Amantadine. **(2M)**

Q4. Classify antifungal agents based on chemistry, explain MOA in brief with one structure from each class. **(5M)**

Q5.A. Write the synthetic scheme for **Sulfamethoxaole** mentioning reagents & reaction conditions. **(3M)**

B. Explain mechanism of action of sulphonamides. **(2M)**

Q6. A. Give the synthetic scheme for **Metronidazole** mentioning reagents & reaction conditions. **(3M)**

B. Write two degradation products of penicillin antibiotic along with reactions. **(2M)**

Q7. A. Indicate to which therapeutic class the following drugs belong. **(3M)**
(Structures to be written)

a) Chloramphenicol b) Mebendazole

B. Write structure and Discuss mechanism of diethylcarbamazine citrate. **(2M)**

Q8. Write a note on application of following parameters used in QSAR? **(5M)**

a) Tafts steric parameter
b) Hansch analysis

Q9. Enlist various approaches used in drug design. Explain any one approach. **(5M)**

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24/11/22

Paper / Subject Code: 87612 / Pharmacology- III

Sem - VI CBCS R-19

(3 Hours) **Total Marks: 75**

N.B.: (1) All questions are **compulsory.**
(2) Figures on the right indicate full marks.

Q I. Choose the ONE best answer and write it down **20 M**

Penicillins act by:

A. Inhibiting cell wall synthesis of bacteria

B. Inhibiting DNA gyrase

C. Inhibiting 30S ribosomal unit

D. Inhibiting folic acid synthesis

2. What is meant by antibiotic resistance?

A. It means our body has become resistant to the antibiotic

B. It means the bacteria have developed resistance for the antibiotic

C. It means that the antibiotic concentration has to be elevated

D. It means that our body has become resistant to the antibiotic's side effects

3. The benefit of bulk forming laxatives is:

A. That they are not absorbed from the intestines into the body so are safe for long-term use

B. They are potent laxatives

C. They are quick in action

D. They may be used safely in patients with kidney failure

4. Amphetamine acts by:

A. Enhancing serotonin levels in brain

B. By antagonizing cannabinoid receptors

C. By increasing the bulk in diet

D. Stimulating norepinephrine release or blocking its reuptake

5. Montelukast inhibits which receptors?

A. Histamine

B. Leukotriene

C. PAF

D. Bradykinin

6. The drug ambroxol is prescribed as:

A. Bronchial secretion enhancer

B. Alpha-2 adrenergic antagonist

C. Mucolytic

D. Respiratory stimulant

7. Ratio of sulphamethoxazole and trimethoprim in cotrimoxazole is:

A. 5:1

B. 1:5

C. 4:1

D. 1:4

8. An adverse reaction to chloramphenicol in neonates is:

A. Ototoxicity

B. Nephrotoxicity

C. Gray Baby syndrome

D. Crystalluria

9. Triple drug therapy used as immunosuppressant consists of:

A. Cyclosporine+ Azathioprine+ Prednisolone

B. Cyclosporine+ Methotrexate+ Prednisolone

C. Tacrolimus+ Methotrexate+ Prednisolone

D. Cyclosporine+ Azathioprine+ Methotrexate

10. Which of the following is triazole class of antifungal drug?

A. Clotrimazole

B. Fluconazole

C. Ketoconazole

D. Miconazole

11. Which of the following is a characteristic of acute toxicity?

A. Slowly occurring

B. Slowly changing

C. Sudden in onset

D. Persistent over months

12. The antineoplastic agent that is classified as an alkylating agent is:

A. Vincristine

B. Tamoxifen

C. Bleomycin

D. Busulfan

13. A side effect of ethambutol is:

A. Neurotoxicity

B. Nausea, vomiting and diarrhea

C. Hypersensitivity and urticarial

D. Loss of color vision due to optic neuritis

14. Anti-IgE monoclonal antibody used in bronchial asthma is:

A. Mepolizumab

B. Omalizumab

C. Keliximab

D. Altrakincept

15. Carcinogenicity due to cigarette smoking is an example of:

A. Acute toxicity

B. Chronic toxicity

C. Sub-acute toxicity

D. Sub-chronic toxicity

16. The anthelmintic drug piperazine:

A. Inhibits tubulin polymerization

B. Inhibits glucose uptake

C. Acts as a GABA agonist to paralyze the worms

D. Uncouples oxidative phosphorylation

17. British anti lewisite is used as an antidote for:

A. Arsenic poisoning

B. Silver poisoning

C. Mercury poisoning

D. Lead poisoning

18. Melatonin plays a role in:

A. Hunger

B Digestion

C. Growth

D. Sleep cycle

19. The risk of asthmatic attacks is higher between:

A. 4.00 am-5.00 am

B. 5.00pm-6.00 pm

C. 11.00 am-12 noon

D. 11.00 pm -12.00 am

20. Which of the following is a mechanism for multidrug resistance in cancer chemotherapy?

A. Decreased activity of DNA repair pathways

B. Decreased sensitivity of dihydrofolate reductase

C. Increased synthesis of cell surface glycoprotein P-170

D. Increased receptor affinity to the drug

Q. II. Answer any TWO of the following: **20 M**

1. Classify appetite suppressant drugs with their mechanism of action and adverse effects.
2. Write a short note on the aminoglycoside class of antibiotics mentioning classification with examples, mechanism of action, adverse effects and clinical uses.
3. Discuss about the site of action of antimalarial drugs. Elaborate on the mechanism of action, adverse effects and uses of 4-aminoquinoline drugs.

Q. III. Answer any SEVEN out of the following questions: **35 M**

1. Classify drugs used in the treatment of constipation with examples. Discuss briefly the pharmacology of osmotic purgatives
2. Write a short note on corticosteroids used in the treatment of asthma.
3. Discuss various mechanisms by which bacteria acquire resistance against antibiotics.
4. Write a note on first line therapy used in tuberculosis. Add a note on the mechanism of action and unwanted effects of rifampicin.
5. Write a note on chemotherapy of amoebiasis.
6. Classify immunosuppressant drugs with examples. Add a note on Calcineurin inhibitors.
7. Classify anticancer agents. Describe the pharmacology of vinca alkaloids in detail.
8. Explain mutagenicity and genotoxicity with examples. Describe is the difference between the two.
9. Describe the symptoms and management of opioid poisoning.

30.11.22

Paper / Subject Code: 87614 / Biopharmaceutics and Pharmacokinetics

Sem-VI CBCS R-19

[Time: 3 Hours] **Total Marks: 75**

Note: All Questions are Compulsory.
Figures to the right indicate full marks.
Draw diagrams wherever required.

Use of Scientific calculator is permitted

Q. 1 **Choose the appropriate option for following multiple choice based questions.** **20**

1 The movement of drug between one compartment and other like blood or extravascular tissue is referred to as **1**
a Drug Disposition
b Drug Distribution
c Drug Binding
d Drug Elimination

2 What is the correct order of bioavailability of different dosage forms? **1**
a Solutions > Emulsion > Capsules > Tablet > SR Tablet
b Solutions > Emulsion > Tablet > Capsules > SR Tablet
c Emulsion > Solutions > Tablet > Capsules > SR Tablet
d Emulsion > Solutions > Capsules > Tablet > SR Tablet

3 Fick's law is used for study of **1**
a Dissociation Rate
b Dissolution Rate
c Disintegration rate
d Diffusion Rate

4 _____ Involves the engulfment of small molecules or fluid **1**
a Endocytosis
b Pinocytosis
c Phagocytosis
d None of the above

5 Very weak acids like barbiturates having pka value greater than 8 will remain ---------- in all pH values of GIT **1**
a Ionised
b Unionised
c Neutral
d Ion pair

6 Apparent volume of distribution is _____ **1**
a Plasma drug concentration X amount of drug in body
b Plasma drug concentration / amount of drug in body
c Amount of drug in the body X plasma drug concentration
d Amount of drug in the body /plasma drug concentration

7	Transfer of drug from plasma to tissue depends on	1
a	Blood perfusion rate of tissue	
b	Weight of tissue	
c	Size of tissue	
d	Gastric emptying rate	
8	Glomerular Filtration is	1
a	Non selective Multidirectional process	
b	Selective Unidirectional process	
c	Non selective Unidirectional process	
d	Selective Multidirectional process	
9	Renal Clearance is expressed as	1
a	Rate of urinary excretion/ plasma drug concentration	
b	Elimination rate/ Plasma drug concentration	
c	plasma drug concentration / Rate of urinary excretion	
d	Plasma drug concentration / Elimination rate	
10	Bioavailability of drug can be calculated by using which parameter?	1
a	Total systemic clearance	
b	Volume of distribution	
c	Area Under the Curve	
d	Absorption rate Constant	
11	The term use to denote that the drug substance in two or more identical dosage forms, reaches the systemic circulation at the same relative rate and to the same relative extent is	1
a	Pharmaceutical equivalence	
b	Chemical Equivalence	
c	Therapeutic Equivalence	
d	Bioequivalence	
12	Type IV USP Dissolution test apparatus is___	1
a	Rotating Paddle	
b	Flow through Cell	
c	Reciprocating cylinder	
d	Paddle over disc	
13	Biowaivers are applicable for	1
a	BCS class I Drugs	
b	BCS Class III Drugs	
c	Drugs with narrow therapeutic index	
d	Sublingual or buccal tablet	
14	In catenary model, compartments are joined _____	1
a	in series	
b	in parallel	
c	clustered	
d	like planetary system	

15 Non compartmental analysis model is based on 1
a Blood perfusion to the organ
b Physiological organs
c Drug diffusion to organ
d Statistical moments theory

16 Which organ can be the part of central compartment _____ 1
a Muscle
b Bones
c Lungs
d Adipose tissue

17 Extent to which drug accumulates relative to first dose is 1
a Accumulation Factor
b Accumulation Index
c Apparent volume of distribution
d Drug toxicity

18 In multi compartment model all transfer processes in and out of compartment are assumes to follow 1
a Zero order kinetics
b First order Kinetics
c Second Order Kinetics
d Mixed order kinetics

19 Capacity limited kinetics is also called as 1
a Linear Pharmacokinetics
b Non linear pharmacokinetics
c Dose dependent kinetics
d First order Kinetics

20 In Michaelis- Menton equation When value of Km=C 1
a Rate of process is zero order
b Rate of process is first order
c Rate of Process is half the maximum rate
d Rate of process is double the maximum rate

Q. 2 Answer any two questions. **20**

1 After an IV Bolus dose of 180 mg of Drug, following profile was observed **10**

$C=99.5e^{-0.264t}$

Calculate the following:

a. Plasma Concentration at the end of 4 hours. 1 Mark
b. Elimination half Life 1 Mark
c. Volume of Distribution 2 Mark
d. Clearance 2 Mark
e. Amount of drug eliminated from body after 8 Hours 2 mark
f. Time required to eliminate 75% Dose of Drug 2 Mark

2	Discuss Pharmacokinetic parameters after IV bolus administration of drug following Two compartment modelling.	10
3	State different mechanism of drug Transport through GIT. Explain Passive diffusion process.	10

Q. 2 B Answer any five questions **35**

4	Explain any two physiological barriers to distribution of drugs.	5
5	What is the significance of protein binding on the volume of distribution of drugs?	5
6	What are the causes of non-linearity in absorption of drug	5
7	Write a note on Biotransformation of drug.	5
8	Explain limitations of pH partition hypothesis.	5
9	Write a note on the type1 dissolution test apparatus as per IP.	5
10	Explain any three factors affecting Renal Excretion of Drug.	5
11	What are the methods for measurement of bioavailability? Explain any one	5
12	What do you mean by compartmental modelling in Pharmacokinetics? Give the advantages of compartmental modelling.	5

05/12/22

Paper / Subject Code: 87616 / Quality Assurance

Sem-VI CBCS R-19

(3 Hours) **(Total marks: 75)**

N.B.: 1. All questions are compulsory.
2. Figures to right indicate full marks.

Q. I Choose appropriate option for the following multiple choice-based questions. **20**

1 ICH Q 8 represents _____ guidelines. **01**
   a. Quality Risk Management
   b. Good Manufacturing Practices
   c. Lifecycle management
   d. Pharmaceutical Development

2 Airlock doors should be equipped with systems that_____. **01**
   a. Prevent simultaneous opening of both the doors
   b. Allow simultaneous opening of both the doors
   c. Prevent simultaneous opening of doors by unauthorized persons
   d. Allow simultaneous opening of both the doors by authorized persons

3 Following are tools of QbD except__. **01**
   a. Critical Quality Attributes
   b. Process Analytical Technology
   c. Risk assessment
   d. Design of Experiments

4 As per USFDA GLP guidelines, Subpart C is_____. **01**
   a. Equipment
   b. Facilities
   c. Records and Reports
   d. Organization and personnel

5 Personal records are records of_____in an organization. **01**
   a. Employer
   b. Employees
   c. Visitors
   d. Auditors

6 Retrospective validation is performed using data from minimum ____ consecutive batches **01**
   a. One
   b. Three
   c. Five
   d. Ten

7 Cleaning of the equipment is a part of_____. **01**
   a. Periodic maintenance
   b. Predictive maintenance
   c. Corrective maintenance
   d. Curative maintenance

8 The SOP's are reviewed after_. **01**
   a. One year
   b. Two years
   c. Three years
   d. Five years

9 The validity of NABL accreditation is for___. 01
   a. Six months
   b. One year
   c. Two years
   d. Three years

10 Air pressure differentials in a clean room should be checked_____. 01
   a. Daily
   b. Yearly
   c. Biannually
   d. Weekly

11 Self sealability test is intended for___. 01
   a. Rubber closures of single dose container
   b. Rubber closures of multi dose containers
   c. Plastic closures of single dose containers
   d. Plastic closures of multidose containers

12 Minimum number of glass containers of 3 ml nominal capacity used for hydrolytic resistance test are_____. 01
   a. 20
   b. 10
   c. 05
   d. 02

13 _____is carried out in connection with the introduction of new drug products. 01
   a. Retrospective validation
   b. Prospective validation
   c. Concurrent validation
   d. Revalidation

14 Grammage is used to determine the physical dimensions of the____material. 01
   a. Paper and paperboard
   b. Thermosetting plastic
   c. Glass
   d. Metal

15 The efficiency of HEPA filters should be___at 0.22micron particle size. 01
   a. 95.55%
   b. 99.99%
   c. 93.22%
   d. 90.99%

16 Cobb test measures the_____of paper and board 01
   a. Ink absorbency
   b. Water absorbency
   c. Acid absorbency
   d. Alkali absorbency

17 Neutral glass is also called as _____. 01
   a. Type I glass
   b. Type II glass
   c. Type III glass
   d. NP glass

18 Which is the second step in Handling of complaints? 01
   a. Monthly trend analysis
   b. Corrective action
   c. Technical investigation
   d. Receiving of complaints

19 The highest air pressure is maintained in_____. 01
   a. Clean Room
   b. Gowning room
   c. Factory Hallway
   d. Store room

20 _____is a managerial tool. 01
   a. Quality Control
   b. Quality Assurance
   c. Production
   d. Accreditation

Q. II Answer any two questions. (Any 2) **20**

1 Define QbD. Write a note on tools of QbD. Explain the benefits and process of ISO 9000 registration. 10

2 Define GLP. Discuss in brief the protocol for conduct of nonclinical study. 10

3 Write a note on handling of returned goods. Discuss the disposal of waste in pharmaceutical industry 10

Q. III Answer any seven questions (Any Seven) **35**

1 Enlist the ICH Q series guideline titles. Write in brief about Stability testing ofnew drug substances 5

2 Enlist the quality control tests for glass containers. Discuss in brief the hydrolytic resistance test. 5

3 Discuss Quality Review and Quality documentation in pharmaceutical industry. 5

4 What is Quality management system? Give the difference between QA & QC. 5

5 Write in brief about personal training. Discuss the responsibilities of key personnel. 5

6 Define validation. Explain in brief the types of process validation. 5

7 What is recall? Explain in detail the process for handling of complaints. 5

8 Discuss the process of equipment selection and its maintenance. 5

9 Enlist the types of process validation. Explain the process for calibration of pH meter. 5