

Printing Pages: 2

Paper Code: BP-601T

B

(SVSU:2025-26/R)

Enrollment No.

Programme Name: B. PHARM

III Year Semester: VI Examination

Subject Code: BP601T

Subject Name: MEDICINAL CHEMISTRY-III

Time: 180 Minutes

Max. Marks: 75

Before answering the question, candidate should ensure that they have been supplied the correct and complete question paper. No complaint in this regard. will be entertained after the examination.

Instructions: All Sections are compulsory.

SECTION-A			
In section A attempt all questions		(20*1=20)	
S.No.	Questions	Marks	COs
1	Which parameter is used in QSAR? (a) Partition coefficient (b) Melting point (c) Odor (d) Density	1	CO6/1
2	Which of the following is not an Aminoglycoside? (a) Neomycin (b) Azithromycin (c) Chloramphenicol (d) Streptomycin	1	CO1
3	Which antibiotic belongs to Macrolide class? (a) Erythromycin (b) Penicillin (c) Streptomycin (d) Tetracycline	1	CO1
4	SAR stands for: (a) Structure Activity Relationship (b) Specific Activity Ratio (c) Standard Activity Relation (d) Substance Activity Ratio	1	CO3
5	Which drug is used as β -lactamase inhibitor? (a) Clavulanic acid (b) Streptomycin (c) Chloramphenicol (d) Rifampicin	1	CO1
6	Isoniazid is used in treatment of: (a) Tuberculosis (b) Malaria (c) Fungal infection (d) Viral infection	1	CO2
7	Identify an antifungal antibiotic: (a) Amphotericin-B (b) Ciprofloxacin (c) Isoniazid (d) Rifampicin	1	CO1
8	Which of the following is an antimalarial drug? (a) Chloroquine (b) Penicillin (c) Erythromycin (d) Tetracycline	1	CO1
9	Mechanism of action of Aminoglycosides is inhibition of: (a) Protein synthesis (b) DNA synthesis (c) Cell wall synthesis (d) RNA synthesis	1	CO2
10	Which is a quinolone derivative? (a) Ciprofloxacin (b) Rifampicin (c) Amphotericin (d) Griseofulvin	1	CO1
11	Which of the following is a prodrug? (a) Proguanil (b) Streptomycin (c) Penicillin (d) Isoniazid	1	CO2

12	Which of the following drugs is antiviral? (a) Acyclovir (b) Amphotericin-B (c) Ciprofloxacin (d) Chloroquine	1	CO1
13	Which antifungal agent acts by inhibiting ergosterol synthesis? (a) Ketoconazole (b) Rifampicin (c) Streptomycin (d) Penicillin	1	CO2
14	Rifampicin acts by inhibiting: a) RNA polymerase (b) DNA polymerase (c) Ribosome (d) Cell wall	1	CO2
15	Which of the following is a sulfonamide? (a) Sulfamethoxazole (b) Isoniazid (c) Amphotericin (d) Acyclovir	1	CO1
16	Trimethoprim acts by inhibiting: (a) Dihydrofolate reductase (b) DNA polymerase (c) RNA polymerase (d) Ribosome	1	CO2
17	Which is an antifungal imidazole derivative? (a) Clotrimazole (b) Isoniazid (c) Streptomycin (d) Rifampicin	1	CO1
18	The basic concept of QSAR includes: (a) Quantitative relation of structure and activity (b) Synthesis of drugs (c) Docking of drugs (d) Absorption only	1	CO6
19	Which antibiotic belongs to Macrolide class? (a) Erythromycin (b) Penicillin (c) Streptomycin (d) Tetracycline	1	CO1
20	Which of the following is a β -Lactam antibiotic? (a) Penicillin (b) Streptomycin (c) Tetracycline (d) Erythromycin	1	CO6
SECTION-B			
In Section-B attempt any seven questions. (7*5=35)			
Q.2(1)	What is the role of β -lactamase inhibitors?	05	CO2
Q.2(2)	Outline the mechanism of streptomycin.	05	CO1
Q.2(3)	Compare doxycycline with minocycline.	05	CO3
Q.2(4)	Write a short note on artesunate.	05	CO1
Q.2(5)	Describe the SAR of quinolones with examples.	05	CO5
Q.2(6)	Discuss the antiviral action of acyclovir.	05	CO3
Q.2(7)	Explain the application of rifabutin in TB treatment.	05	CO2
Q.2(8)	Write the therapeutic uses of nitrofurantoin.	05	CO5
Q.2(9)	Highlight differences between azoles and polyenes.	05	CO2
SECTION-C			
In Section-C attempt any two questions. (2*10=20)			
Q.3(1)	Explain the mechanism of action and classification of antiprotozoal agents.	10	CO2
Q.3(2)	Apply the knowledge of structure and SAR to differentiate β -Lactam antibiotic.	10	CO3
Q.3(3)	Analyze the SAR and Nomenclature of antibiotics.	10	CO3

11/12/2025

Printing Pages: 2
Paper Code: BP602T

A (SVSU:2025-26/C)

Enrollment No.																			
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Programme Name: B. Pharm
Semester: VI
Course/ Subject Code: BP 602T
Course/ Subject Name: Pharmacology III

Time: 180 Minutes

Max. Marks: 75

Before answering the question, candidate should ensure that they have been supplied the correct and complete question paper. No complaint in this regard, will be entertained after the examination.

Instructions: All Sections are compulsory.

SECTION-A				
In section A attempt all questions				
S.No.	Questions	Marks	(20*1=20)	
				COs
Q1 (1)	Which of the following is a bronchodilator used in asthma? (a) Salbutamol (b) Atropine (c) Diazepam (d) Propranolol	1		CO602T.1
Q1 (2)	Which of the following is a respiratory stimulant? (a) Caffeine (b) Morphine (c) Diazepam (d) Lidocaine	1		CO602T.1
Q1 (3)	Which of the following is a respiratory stimulant? (a) Caffeine (b) Morphine (c) Diazepam (d) Lidocaine	1		CO602T.1
Q1 (4)	Guaifenesin acts as a/an (a) Expectorant (b) Antitussive (c) Bronchodilator (d) Decongestant	1		CO602T.1
Q1 (5)	Omeprazole acts by (a) Blocking H ₂ receptors (b) Inhibiting proton pump (c) Neutralizing acid (d) Increasing acid	1		CO602T.1
Q1(6)	Loperamide is used for (a) Constipation (b) Diarrhoea (c) Vomiting (d) Ulcer	1		CO602T.1
Q1(7)	Cotrimoxazole is (a) Sulfamethoxazole + Trimethoprim (b) Amoxicillin + Clavulanic acid (c) Ampicillin + Sulbactam (d) Ceftriaxone + Tazobactam	1		CO602T.2
Q1(8)	Erythromycin belongs to (a) Macrolide (b) Cephalosporin (c) Quinolone (d) Aminoglycoside	1		CO602T.2
Q1(9)	Isoniazid is used in (a) Tuberculosis (b) Leprosy (c) Malaria (d) Fungal infection	1		CO602T.3
Q1(10)	Fluconazole is an (a) Antifungal (b) Antibacterial (c) Antiviral (d) Anthelmintic	1		CO602T.3
Q1(11)	Theophylline belongs to (a) Xanthines (b) β_2 -agonist (c) Steroids (d) Antihistamines	1		CO602T.1
Q1(12)	Oxymetazoline is used as (a) Nasal decongestant (b) Antitussive (c) Expectorant (d) Antiemetic	1		CO602T.1
Q1(13)	Doxapram acts as (a) Respiratory stimulant (b) CNS depressant (c) Bronchodilator (d) Sedative	1		CO602T.1
Q1(14)	Ranitidine is (a) H ₂ blocker (b) Antacid (c) PPI (d) Antiemetic	1		CO602T.1
Q1(15)	Lactulose is used for (a) Constipation (b) Ulcer (c) Asthma (d) Vomiting	1		CO602T.1
Q1(16)	Sulfonamides inhibit (a) Folic acid synthesis (b) Protein synthesis (c) DNA replication (d) Cell wall	1		CO602T.2
Q1(17)	Ciprofloxacin is a (a) Fluoroquinolone (b) Macrolide (c) Tetracycline (d) Penicillin	1		CO602T.2
Q1(18)	Amikacin belongs to (a) Aminoglycosides (b) Macrolides (c) Cephalosporins (d) Sulfonamides	1		CO602T.2
Q1(19)	Rifampicin is used for (a) Tuberculosis (b) Fungal infection (c) Malaria (d) Leprosy	1		CO602T.3
Q1(20)	Clofazimine is used for (a) Leprosy (b) Malaria (c) UTI (d) Fungal infection	1		CO602T.3

SECTION-B**In Section-B attempt any seven question.****(7*5=35)**

Q.2(1)	Classify anti-asthmatic drugs and explain mechanism of β_2 -agonists.	5	CO602T.1
Q.2(2)	Describe mechanism and uses of antiulcer agents.	5	CO602T.1
Q.2(3)	Explain the general principles of chemotherapy.	5	CO602T.2
Q.2(4)	Write short notes on penicillins and cephalosporins.	5	CO602T.2
Q.2(5)	Discuss mechanism and uses of antitubercular agents.	5	CO602T.3
Q.2(6)	Explain the pharmacology of antifungal agents.	5	CO602T.3
Q.2(7)	Write a note on chemotherapy of UTIs and STDs.	5	CO602T.4
Q.2(8)	Write notes on immunostimulants and immunosuppressants.	5	CO602T.4
Q.2(9)	Explain clinical features and management of lead poisoning.	5	CO602T.5

SECTION-C**In Section-C attempt any two question.****(2*10=20)**

Q.3(1)	Explain in detail about the pharmacology of drugs used in bronchial asthma and COPD.	10	CO602T.1
Q.3(2)	Discuss classification, mechanism, and uses of antibiotics.	10	CO602T.2
Q.3(3)	Describe types of toxicity and principles of poisoning management with examples.	10	CO602T.5

Printing Pages: 2
Paper Code: BP603T

B

(SYN/12028-26/G)

Enrollment No.

Programme Name: B. Pharm
III Year Semester: VI Examination
Course/ Subject Code: BP603T
Course/ Subject Name: Herbal Drug Technology

Max. Marks: 75

Time: 180 Minutes

Before answering the question, candidate should ensure that they have been supplied the correct and complete question paper. No complaint in this regard, will be entertained after the examination.

Instructions: All Sections are compulsory.

SECTION-A			
In section A attempt all questions		(20*1=20)	
S. No.	Questions	Marks	COs
Q1 (1)	The process of 'Authentication' of herbal material refers to: a) Determining the price b) Verifying the botanical identity c) Assessing the moisture content d) Measuring the particle size	1	CO603T.1
Q1 (2)	Bio-pesticides used in medicinal plant cultivation are derived from: a) Synthetic chemicals b) Natural materials like plants, bacteria, and minerals c) Radioactive elements d) Heavy metals	1	CO603T.1
Q1 (3)	The basic principle of 'Siddha' system of medicine is based on elements. a) Two b) Three c) Five d) Seven	1	CO603T.1
Q1 (4)	Spirulina is a well-known: a) Herb b) Blue-green algae (Cyanobacteria) c) Fungus d) Lichen	1	CO603T.2
Q1 (5)	Herbal cosmetics are preferred by consumers because they are perceived as: a) More expensive b) Fast-acting c) Safer and natural d) Synthetic	1	CO603T.3
Q1(6)	Which novel herbal dosage form is known for improving the absorption of hydrophilic phytoconstituents? a) Tablet b) Syrup c) Phytosome d) Churna	1	CO603T.3
Q1(7)	ICH guidelines for herbal drugs focus on: a) Marketing b) Quality, Safety, and Efficacy c) Pricing d) Packaging	1	CO603T.4
Q1(8)	'Farmers Rights' refer to the rights of farmers to: a) Sell synthetic drugs b) Save, use, and exchange propagated material c) Patent genetically modified crops d) Use any pesticide	1	CO603T.4
Q1(9)	The Curcuma longa patent case was related to the patent on: a) Its cultivation method b) The use of turmeric for wound healing c) Its isolation process d) Its color	1	CO603T.4
Q1(10)	The regulatory body ASU DTAB advises which central government on ASU drugs? a) Ministry of Finance b) Ministry of Ayush c) Ministry of Agriculture d) Ministry of Education	1	CO603T.4
Q1(11)	Good Agricultural Practices (GAP) include: a) Using contaminated water for irrigation b) Using certified seeds and sustainable methods c) Indiscriminate use of pesticides d) Avoiding soil testing	1	CO603T.1
Q1(12)	Which of the following is a solid dosage form in Ayurveda? a) Asava b) Vati (Gutika) c) Arishta d) Kwath	1	CO603T.1
Q1(13)	Fenugreek seeds are known to be beneficial for: a) Skin lightening b) Blood sugar control c) Treating malaria d) Hair growth	1	CO603T.2

Q1(14)	Gums used in herbal formulations primarily act as: a) Sweeteners b) Binders and viscosity builders c) Disintegrants d) Preservatives	1	CO603T.3
Q1(15)	Stability testing parameters for herbal drugs include: a) Only color b) Physical, chemical, and microbiological parameters c) Only taste d) Only odor	1	CO603T.4
Q1(16)	'Bioprospecting' is defined as: a) The illegal theft of biological resources b) The systematic search for useful products from natural sources c) The destruction of forests d) The farming of genetically modified organisms	1	CO603T.4
Q1(17)	Schedule Z of the Drugs and Cosmetics Act specifies: a) GMP for allopathic drugs b) Requirements for Ayurvedic, Siddha, and Unani drugs c) List of banned herbs d) Prices of nutraceuticals	1	CO603T.4
Q1(18)	A major challenge faced by the herbal industry is: a) Lack of consumer interest b) Lack of standardization and quality control c) Overproduction of raw materials d) Shortage of synthetic alternatives	1	CO603T.5
Q1(19)	Under GMP, the 'working space' must be designed to: a) Maximize production speed only b) Prevent cross-contamination and ensure hygiene c) Reduce electricity consumption d) Store marketing materials	1	CO603T.6
Q1(20)	Documentation in herbal drug manufacturing is crucial for: a) Increasing paperwork b) Traceability and quality assurance c) Reducing staff d) Hiding formulas	1	CO603T.6
SECTION-B			
In Section-B attempt any seven questions. (7*5=35)			
Q.2(1)	What are the key steps in the processing of herbal raw materials?	5	CO603T.1
Q.2(2)	Write a short note on Pest Management in medicinal plants using Biopesticides.	5	CO603T.1
Q.2(3)	Discuss the general aspects and market growth of Nutraceuticals.	5	CO603T.2
Q.2(4)	Describe the role of herbs as sources of natural antioxidants in cosmetic products.	5	CO603T.3
Q.2(5)	Compare and contrast the basic principles of Ayurveda and Homeopathy.	5	CO603T.1
Q.2(6)	What is stability testing? Why is it important for herbal drugs?	5	CO603T.4
Q.2(7)	Differentiate between 'Breeder's Right' and 'Farmer's Right'.	5	CO603T.4
Q.2(8)	Explain the potential Herb-Drug interactions of St. John's Wort (Hypericum).	5	CO603T.2
Q.2(9)	List the components of GMP as outlined in Schedule T.	5	CO603T.6
SECTION-C			
In Section-C attempt any two questions. (2*10=20)			
Q.3(1)	Explain the importance of Standard Operating Procedures (SOPs) and health hygiene in a GMP-compliant herbal industry.	10	CO603T.6
Q.3(2)	Discuss the role of nutraceuticals in managing Cardiovascular diseases. Provide specific examples.	10	CO603T.2
Q.3(3)	Explain the preparation and standardization process of Lehya (Avaleha).	10	CO603T.3

16/12/2025

Printing Pages :2

Paper Code: BP604T	A (SVSU:2023-24/R)											
Enrollment No.												

B PHARM

3rd YEAR, VIth SEMESTER, EXAMINATION 2023-24
Biopharmaceutics and Pharmacokinetics (BP604T)

[Time : 3:00 Hours]

[Max. Marks : 75]

I Long Question : Answer Any Two [10×2=20]

1. Illustrate the absorption of drug from non per oral extravascular route.
2. Describe the use of plasma drug concentration-time curves in determining bioavailability.
3. Explain factors causing non linearity in pharmacokinetics. Describe Michaelis –Menten method of estimating pharmacokinetic parameters.

II. Short Question: Answer any Seven [5×7=35]

1. Explain the limitation of pH-partition hypothesis.
2. Explain the BCS classification of drugs with examples.
3. Explain the non renal routes of drug excretion.
4. Give the factors affecting drug Distribution.
5. Explain the theories of dissolution.
6. Calculation of loading and maintenance dose of drugs.
7. Explain the factors affecting drug elimination.
8. Give the difference between catenary and mammillary model.
9. Explain total body clearance.

III. Objectives Question: Answer All Question

1. In which organ the first-pass metabolism of a drug occurs primarily
a) Liver b) Kidneys c) Small intestine d) Stomach
2. Which of the following pH conditions in the GIT is more favorable for the absorption of weak acidic drugs?
a) Acidic pH b) Neutral pH c) Alkaline pH d) Variable pH
3. In which plot, reciprocal of Michaelis-Menten equation is used?
a) Lineweaver- Burk plot. b) Direct linear plot
c) Third graphical method d) None
4. AUC represents the
a) $t_{1/2}$ of the drug b) Amount of the drug absorbed
c) V_d of the drug d) amount of drug excreted in urine
5. Dissolution can be expressed by which equation-
a) Modified Noyes-Whitney's b) Lambert law
c) Handerson Hasselbach equation d). None of above

6. The cell membrane is _____ in nature.
 - a) Impermeable
 - b) Semipermeable
 - c) Permeable
 - d) Permeable to only gases
7. Which one of these is an example of Enteral Route?
 - a) Skin
 - b) IV
 - c) Gastrointestinal
 - d) Inhalation
8. Which is the major process of absorption for more than 90 percent of drugs?
 - a) Facilitated diffusion
 - b) Active transport
 - c) Endocytosis
 - d) Passive diffusion
9. Which kind of molecules cannot pass through a pore transport?
 - a) Low Molecular weight molecules
 - b) Water-soluble drugs
 - c) Molecules up to 400 Dalton
 - d) Molecules greater than 400 Dalton
10. Which one of these is a physicochemical property of Drug substance?
 - a) Drug solubility
 - b) Disintegration time
 - c) Age of patient
 - d) Dissolution time
11. Which cell make up the blood-brain barrier?
 - a) Squamous epithelium cells
 - b) Fat cells
 - c) Red blood cell
 - d) Endothelial cells
12. Which theory takes into account that a thin film is created by the solution of the solid at the solid-liquid interface?
 - a) Interfacial barrier model
 - b) Diffusion layer model
 - c) Surface renewal theory
 - d) Danckwert's model
13. The maximum amount of solute dissolved in a given solvent under standard conditions of temperature, pressure, and pH is known as _____.
 - a) Dissolution rate
 - b) Intrinsic dissolution
 - c) Rate limiting step
 - d) Absolute or intrinsic solubility
14. Which one of the following has a high perfusion rate?
 - a) Fat
 - b) Muscle and skin
 - c) Lungs and kidney
 - d) Bone
15. In equation $X = V_d C$, what does V_d denotes?
 - a) Density
 - b) Volume of blood
 - c) Volume of body
 - d) The volume of the body fluid in which the drug is getting dissolved
16. In which model compartments are joined in series?
 - a) Compartment model
 - b) Caternary model
 - c) Physiologic model
 - d) Mammillary model
17. What is the molecular weight of human serum albumin?
 - a) 5000 Dalton
 - b) 65,000 Dalton
 - c) 60,000 Dalton
 - d) 75,000 Dalton
18. Which is not a prodrug?
 - a) Enalapril
 - b) Levodopa
 - c) Aspirin
 - d) Phenytoin
19. Which drugs deposit in hair shafts?
 - a) Arsenicals
 - b) Tetracycline
 - c) Halogenated hydrocarbons
 - d) Lipophilic drug
20. Prodrugs with two active compounds are known as _____.
 - a) Mixed type prodrugs
 - b) Pro-prodrugs
 - c) Bioprecursors
 - d) Mutual prodrug

Printing Pages :2

Paper Code:BP-605T

B (SVSU:2024-25/R)

Enrollment No.														
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B.PHARM

Third Year Six Semester

Pharmaceutical Biotechnology (BP-605T)

[Max. Marks: 75]

[Time: 3:00 Hours]

(20X1=20)

Q1. Attempt ALL questions.

- 1) For glucose isomerization by immobilized enzyme, the reactor generally used is
 (a) CSTR (b) Plug flow (c) Packed bed (d) Fluidized bed
- 2) An example of Mosaic antigen is
 (a) Virus (b) Bacteria (c) A hapten (d) Protein
- 3) The lowest yield of ATP is in
 (a) Fermentation (b) Aerobic respiration
 (c) Anaerobic respiration (d) Same in (a), (b) and (c)
- 4) T cells are the source of
 (a) Interleukin (b) Interferon (c) Lymphotoxin (d) All
- 5) Some cross reactions with monoclonal antibodies (MAbs) can occur. Unexpected cross reactions occur more frequently with
 (a) IgG (b) Ig MAbs (c) IgE (d) IgA
- 6) The primary B cell receptor is
 (a) IgD (b) IgG (c) IgE (d) IgA
- 7) Small sample antigens molecules are
 (a) Poor (b) Heterophilic (c) Moderate (d) Rich
- 8) Which type of cell actually secretes antibodies?
 (a) Plasma cells (b) Dendritic cells (c) Macrophages (d) T cells
- 9) Tc cells are important in controlling
 (a) Virus infections (b) Allergy (c) Autoimmunity (d) All
- 10) A DNA nucleotide chain has AGCTTCGA sequence of other chain would be
 (a) TCGAAGCT (b) GCTAAGCT
 (c) TAGCATAT (d) GATCCTAG
- 11) A Ribosome is
 (a) Base+Phosphate (b) Ribase+Phosphate
 (c) Base+Phosphate+ribose (d) Ribose+base
- 12) Adenine is
 (a) Purine (b) Pyrimidine (c) Nucleoside (d) Nucleotide
- 13) Amino acid binding site of tRNA is
 (a) 5' end (b) Anticodon loop (c) DHU loop (d) -CCA 3' end
- 14) Base pairs present in one turn of DNA are
 (a) 12 (b) 11 (c) 10 (d) 9
- 15) If a virus is termed "latent", this means it
 (a) Cannot be a retrovirus (b) Has not entered a lytic cycle
 (c) Is easy to develop immunity against it (d) Has not entered a lysogenic cycle

- 16) Distance between two strands of DNA is
 (a) 30Å (b) 20Å (c) 3.4Å (d) 340Å
- 17) Which of the following could be used to grow viruses in the laboratory?
 (a) Chicken eggs (b) Cell culture & WBC (c) Bacteria (d) All
- 18) One bacterial cell passes DNA to a second cell in the process of
 (a) Transformation (b) Transduction (c) Conjugation (d) Replication
- 19) The Latin terms for "break" and "in two" underlie the term
 (a) Transduction (b) Binary fission (c) Transformation (d) Conjugation
- 20) To which of the following domains do viruses belong?
 (a) Archae (b) Eukarya (c) Protista (d) None

Q2. Answer any TWO questions.

(2X10=20)

- Explain complete process of development of hybridoma for monoclonal antibodies.
- Discuss the production process of Streptokinase and Streptodornase. What are their applications?
- Describe the various mode/mechanism of enzyme action in details.

Q3. Answer any SEVEN questions.

(7X5=35)

- Define Michaelis-Menten equation and discuss the role of double reciprocal plot.
- Discuss process of protoplast fusion.
- Elaborate standardization and storage process of BCG vaccine.
- Explain plasmids and their role in biotechnology.
- Explain about Penicillinase. How penicillin can be obtained by fermentation process?
- Discuss method of standardization of broad spectrum antibiotics.
- Define any two (i) Antigens (ii) Haptens (iii) Activase.
- Give a detailed account on immobilisation by adsorption, Complexation and chelation.
- Explain PCR and reverse PCR.

Printing Pages :2

Paper Code:BP-606T

A (SVSU:2024-25/R)

Enrollment No.														
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B. PHARM
3rd YEAR, 6th SEMESTER EXAMINATION
Quality Assurance (BP606T)

[Time : 3:00 Hours]

[Max. Marks : 75]

I Long Question : Answer Any Two [10×2=20]

1. Discuss in-detail the salient features of GMP
2. Discuss the objectives and scope of GCP in Pharmaceutical industry.
3. Discuss in detail the principles of TQM.

II. Short Question: Answer any seven [5×7=35]

1. Explain the steps involved in ISO 9000 registration.
2. What is CTD and explain module -2.
3. Write the significance of personnel hygiene in pharmaceutical industry.
4. Describe the equipment selection and purchase procedure.
5. Explain the protocol for conduct of non-clinical laboratory study.
6. Explain the quality control tests for containers and rubber closures.
7. Discuss the handling of return goods.
8. Explain the importance and scope of validation.
9. Explain the concept of QA and QC.

III. Multiple Choice Question: Answer All [1x20=20]

1. Oil should not be sterilized by

- | | |
|-----------------------------|---------------------------|
| A. Moist heat sterilization | B. Dry heat sterilization |
| C. Radiation sterilization | D. Gaseous sterilization |

2. Which quality is measured as a foundation of requirement:

- | | |
|-------------|----------------|
| A. Software | B. Programmers |
| C. Hardware | D. None |

3. While setting Quality objective, _____ to be considered.

- | | |
|-----------------------------|---------------------------|
| A. Material quality | B. Feedback |
| C. Development of standards | D. Customer Satisfaction. |

4. Select which option is not true about SQA:

- A Evaluations to be performed
- B. Documents that are produced by the SQA team.
- C. Audits & reviews to be performed by the team
- D. None.

5. Control chart is a:

- | | |
|----------------------------|-------------------------|
| A. Process monitoring tool | B. Process control tool |
| C. Both (a) and (b) | D. None |

6. Software quality assurance consists of which function of management:

- | | |
|------------------------|-----------------------|
| A. Reporting functions | B. Auditing functions |
| C. both a and b | D. None |

7. Which of the following is not included in prevention cost:

- A. Formal technical reviews
- B. Equipment calibration and maintenance
- C. Test equipment reviews
- D. None

8. Capacity planning is concerned with:

- A. How much labour required?
- B. How many machines required ?
- C. None
- D. Both

9. Process control is carried out:

- A. During production
- B. Before production.
- C. After production control
- D. All of the above

10. Total Quality Management (TQM) focuses on

- A. Employee
- B. Customer
- C. Both (a) and (b)
- D. NONE

11. Select which one is not an External failure costs

- A. Testing
- B. Helpline support
- C. Warranty work
- D. Complaint resolution

12. The objective of ISO-9000 family of Quality management is:

- A. Customer satisfaction.
- B. Employee satisfaction
- C. Skill enhancement
- D. Environmental issues

13. P-D-C-A stands for

- A. Plan-Do-check-Act
- B. Plan-Do-correct-Act
- C. Proceed-Do-check-Act
- D. Proceed-Do-correct-Act

14. Physical dimension of equipment and accessories- comes under which qualification?

- A. Design qualification (DQ)
- B. Installation qualification (IQ)
- C. Operational qualification
- D. Performance qualification (PQ)

15. TQM Stands for :

- a. Total Quality Management
- b. Total Quality Material
- c. Total Quality Measurable
- d. None of these

16. GLP Means:

- a. Good Laboratory Protocols
- b. Good Laboratory Practices
- c. Good Laboratory Planning
- d. None of these

17. What does QA and QC stand for:

- a) Quality Assurance and Queuing Control
- b) Quality Adjustment and Quality completion
- c) Quality Assurance and Quality control
- d) Quality Adjustment and Queuing control

18. Which of the following option is correct regarding QA and QC:

- a) QC is an integral part of QA
- b) QA is an integral part of QC
- c) QA and QC are independent to each other
- d) QC may or may not depend on QA

19. GCP Means:

- a. Good clinical practice
- b. Good clinical patient
- c. Good client practice
- d. None of these

20. Which of the following is an example of QA:

- a) Verification
- b) Software testing
- c) Validation
- d) Documentation