DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE

End Semester Examination – Summer 2022

Course: B. Pharmacy | Sem: VI

Subject Name: Medicinal Chemistry-III | Subject Code: BP601T

Max. Marks: 75 | Date: 13/07/2022 | Duration: 3.45 Hrs.

Instructions –

1. All questions are compulsory
2. Answers to MCQs should be written in full sentences
3. Draw diagrams / figures wherever necessary
4. Figures to right indicate full marks

Q. 1. Multiple Choice Questions (MCQs) = 20 x 1 = 20 (All the questions are compulsory)

i) Basic Nucleus of Cephalosporins and Penicillins is.....
a) Lactone b)Thiazole
c)Lactam Ring d) Beta Lactam Ring

ii)Streptomycin is produced by which of the following organisms?
a) Streptomyces griscus b)Streptomyces fradiae
c)Streptomyces noursei d)Streptomyces nodosus

iii) What is Target for clavulanic acid?
a) Lactamase b) L-alaracemase
c) The transpeptidase enzyme d) Penicillin acylase

iv)Aminoglycosides work by irreversibly binding to the..... ribosomal subunit.
a) 50S b)30S
c)both d)none

v)Benzyl Penicillin is chemical name for which of the following penicillin..?
a) Penicillin-G b)Penicillin-V
c) Penicillin-F d)Phenethicin

vi)Chemically tetracycline is derivative of.....
a) Purine b)Pyridine
c)Octahydronaphthacene d)Phenanthrene

vii)Which is naturally occurring anti-malaria drug?
a) Quinacrine b) Artemisinin
c) Mepacrine d)Mefloquine

viii) Chloroquine can be synthesized by reaction of 4-diethylamino-1-methylbutylamine with?
a) 4,7-dichloroquinoline b) α-naphthol
c)ß-naphthol d) None of the above

ix) What is co-trimoxazole?
a) Sulphamethoxazole + trimethoprim, 3:1

b) Sulfadoxine + pyrimethamine
c) Sulphamethoxazole + trimethoprim, 5:1
d) Sulfacetamide, Sulfathiazine and sulfabenzamide

x) Identification of a new chemical entity as a potential therapeutic agent (From Hit to Lead) is known as

a) Drug discovery
b) Drug development
c) Both of above
d) None of above

xi) In QSAR, study of medicinal chemistry Q stands for

a) Qualitative
b) Quantitative
c) Both
d) Quantam

xii) Identify the metabolite of prontosil responsible for its antibacterial activity?

a) Sulphacetamide
b) Sulphanilamide
c) PABA
d) Probenec

xiii) A combination of medications which applied to treat tuberculosis is

a) 1-thia-4-azabicyclo[3.2.1]heptane
b) 4-thia-1-azabicyclo[3.2]heptane
c) 4-thia-1-azabicyclo[3.2.0]heptane
d) 1-thia-4-azabicyclo[1.2.3]heptane

xiv) Which of the following is noncompetitive inhibitor of the enzyme reverse transcriptase in HIV?

a) Lamivudine
b) Nevirapine
c) Ritonavir
d) Tenofovir

xv)Sulphonamides do not have adverse drug interaction with ……

a) Oral coagulants
b) Sulphonylureas
c) Hydantoin anticoagulants
d) Dihydrofolatereductase inhibitors

xvi) The essential structural unit for the anthelmintic activity of mebendazole is:

a) Benzoyl group
b) Benzimidazole
c) Methyl carbamate
d) Imidazole

xvii) Artemisinin contains the following group in its structure?

a) An endoperoxide
b) An exoperoxide
c) An epoxide
d) An acid hydrazide

xviii) Identify the antibiotic obtained from streptomyces sp. but not having antibacterial property. In fact it is suicide inhibitor of beta lactamases.

a) Azetronam
b) Cilastatin
c) Clavulanic acid
d) Imipenem

xix) Methotrexate is thought to exert its action by…..

a) Interfering with purine synthesis
b) Intracellular formation of an amine adduct
c) Forming a conjugate with nucleic acids
d) Inhibiting the synthesis of folic acid by inhibiting dihydrofolate synthatase

xx) Chloramphenicol has two asymmetric centers. What is the configuration and optical activity of the active form of the antibiotics?

a) D-threo, (-)
b) L-threo, (+)
c) D- erythro, (-)
d) L- erythro, (+)

Q. 2. Long Answers **2 x 10 = 20 (Answer 2 out of 3)**

1. What are antibiotics? Give Chemical Classification of antibiotics with structures. Discuss in brief about Chemistry and SAR of antibiotics containing Penam ring system.

2. Classify antimalarial agents. Discuss SAR and MOA of 4-aminoquinolines and 8-aminiquinolines. Outline the synthetic scheme for Chloroquine.

3. Classify Sulphonamides with structures. Write Chemistry and MOA of Sulpha drugs. Add note of DHFR inhibitor. Give the synthesis of Trimethoprim.

Q. 3. Short Answers **7 x 5 = 35 (Answer 7 out of 9)**

i) Discuss chemistry, SAR and MOA of Tetracycline.

ii) What are anti-mycobacterial agents? Draw the structures of any two anti-tubercular drugs. Outline the synthesis of p-amino salicylic acid.

iii) Write in brief about anthelmintics. Outline synthetic scheme for Mebendazole.

iv) What are aminoglycosides? Write MOA and Chemistry of aminoglycosides.

v) Define Prodrug. Give the Applications of Prodrug with examples.

vi) Classify antiviral agents. Discuss in brief about RTI's.

vii) Discuss chemistry, SAR, MOA of fluoroquinolone antibacterial agents giving synthetic of Ciprofloxacin.

viii) Write a note on combinational chemistry & its applications in drug discovery.

ix) Give chemical classification of antifungal drugs with example.discuss chemistry of Imidazole antifungal

------END OF THE PAPER------

DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE

End Semester Examination – Summer 2022

Course: B. Pharmacy **Sem: VI**

Subject Name: Pharmacology-III **Subject Code: BP602T**

Max. Marks: 75 **Date: 16/07/2022** **Duration: 3.45 Hrs.**

Instructions –

1. **All questions are compulsory**
2. **Answers to MCQs should be written in full sentences**
3. **Draw diagrams / figures wherever necessary**
4. **Figures to right indicate full marks**

Q. 1. Multiple Choice Questions (MCQs) = 20 x 1 = 20 (All the questions are compulsory)

1. If one of the following microorganisms has been proposed as a probable cause of persistent gastritis and peptic ulcer disease.
   A) Campylobacter jejuni
   B) Escherichia coli
   C) Helicobacter pylori
   D) Calymmatobacterium granulomatis

2. If any of those medicine classes is used to treat asthma.
   A) Methylxanthines
   B) M-cholinoblocking agents
   C) Beta2 – stimulants
   D) All of above

3. Select the side-effect characteristic for non-selective beta 2-adrenomimics.
   A) Depression of the breathing centre
   B) Tachycardia
   C) Peripheral vasoconstriction
   D) Dry mouth

4. The mechanism of methylxanthines action is.
   A) Inhibition of the enzyme phosphodiesterase
   B) Beta2 -adrenoreceptor stimulation
   C) Inhibition of the production of inflammatory cytokines
   D) Inhibition of M-cholinoreceptors

5. Choose the drug belonging to membrane stabilizing agents.
   A) Zileutin
   B) Sodium cromoglycate
   C) Zafirlucast
   D) Montelucast

6. Gastric acid secretion is under the control of the following agents EXCEPT.
   A) Histamine
   B) Acetylcholine
   C) Serotonin
   D) Gastrin

7. Select the drug which inhibits peristalsis of GIT.

A) Castor oil
B) Bisacodyl
C) Loperamide
D) Sorbitol

8. The medication on the list below has the potential to reverse gynecomastia
A) Omeprazole
B) Pirenzepine
C) Cimetidine
D) Sucralfate

9. Select the drug stimulating the protective function of the mucous barrier and the stability of the mucous membrane against damaging factors:
A) De-nol
B) Misoprostol
C) Sucralfate
D) Omeprazole

10. Select the mechanism of Metoclopramide antiemetic action:
A) H1 and H2-receptor blocking effect
B) M-cholinoreceptor stimulating effect
C) M-cholinoblocking effect
D) D2-dopamine and 5-HT3-serotonin receptor blocking effect

11. Currently the drug of choice for empiric treatment of typhoid fever is:
A) Chloramphenicol
B) Cotrimoxazole
C) Levofloxacin
D) Ampicillin

12. Clavulanic acid is combined with amoxicillin because
A) It kills bacteria that are not killed by amoxicillin
B) It reduces renal clearance of amoxicillin
C) It counteracts the adverse effects of amoxicillin
D) It inhibits beta lactamases that destroy amoxicillin

13. Penicillins interfere with bacterial cell wall synthesis by:
A) Inhibiting synthesis of N-acetyl muramic acid pentapeptide.
B) Inhibiting conjugation between N-acetyl muramic acid and N-acetyl glucosamine.
C) Inhibiting transpeptidases and carboxypeptidases which cross link the peptidoglycan residues.
D) Counterfeiting for D-alanine in the bacterial cell wall.

14. The most frequent side effect of oral ampicillin is:
A) Nausea and vomiting
B) Diarrhea
C) Constipation
D) Urticaria

15. Select the 3rd generation cephalosporin that can be used only by parenteral route:
A) Cefpodoxime proxetil
B) Ceftizoxime
C) Ceftibuten
D) Cefixime

16. Chloramphenicol inhibits bacterial protein synthesis by:
A) Binding to 30S ribosome and inhibiting attachment of aminoacyl tRNA
B) Binding to 50S ribosome and preventing peptide bond formation

C) Binding to 50S ribosome and blocking translocation of peptide chain
D) Binding to both 30S and 50S ribosome and inducing misreading of mRNA code

17. The aminoglycoside antibiotic causes more hearing loss than vestibular disturbance as toxic effect.

A) Streptomycin
B) Gentamicin
C) Kanamycin
D) Sisomicin

18. The following antineoplastic drug is a mitotic inhibitor and causes metaphase arrest:

A) Busulfan
B) Vincristine
C) Cytarabine
D) Procarbazine

19. Choose the azole antifungal drug which is used only topically:

A) Ketoconazole
B) Fluconazole
C) Itraconazole
D) Econazole

20. Select the drug that acts by inhibiting HIV protease enzyme

A) Zalcitabine
B) Efavirenz
C) Stavudine
D) Nelfinavir

Q. 2. Long Answers) = 2 x 10 = 20 (Answer 2 out of 3)

I. Discuss in detail mode of action, therapeutic uses, adverse effects and drug interactions of tetracycline.

II. Classify antineoplastic agents with example. Explain in detail mode of action, therapeutic uses and adverse effects of alkylating agents.

III. Enumerate drugs used in treatment of tuberculosis. Discuss in detail treatment of tuberculosis.

Q. 3. Short Answers = 7 x 5 = 35 (Answer 7 out of 9)

a) Discuss clinical symptoms and management of barbiturates poisoning.
b) Write a note on teratogenicity.
c) Discuss sexually transmitted diseases and treatment.
d) Classify Antimalarial drugs. Explain MOA of primaquine
e) Explain mechanism of action and therapeutic uses of rifampicin.
f) Explain mechanism of action of griseofulvin and fluconazole.
g) Discuss in detail pharmacology of glucocorticoids.
h) Drugs used in the treatment and management of COPD.
i) Classify antiulcer agents. Explain MOA of Omeprazol

-----END OF THE PAPER-----

DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE

End Semester Examination – Summer 2022

Course: B. Pharmacy Sem: VI

Subject Name: Herbal Drug Technology Subject Code: BP603T

Max. Marks: 75 Date: 19/07/2022 Duration: 3.45 Hrs.

Instructions –

1. **All questions are compulsory**
2. **Answers to MCQs should be written in full sentences**
3. **Draw diagrams / figures wherever necessary**
4. **Figures to right indicate full marks**

Q. 1. Multiple Choice Questions (MCQs) = 20 x 1 = 20 (All the questions are compulsory)

i) Dissolution test is done to check

a) Hardness b) Weight variation

c) Absorption of drug in blood d) Concentration of drug in formulation

ii) Shodhana and Marana processes are associated with ..... formulation.

a) Avaleha b) Bhasma c) Aristas d) Gutika

iii)Undesired plants in the field are known as

a) Herbs b) Weeds c) Cover crops d) Buffers

iv).....practiced and introduced surgery in Ayurveda.

a) Charaka b) Nagarjuna c) Dhanwantari d) Sushrut

v) Ashwagandha exhibits therapeutic activity due to the presence of .....

a) Withanolides b) Atropine c) Diosgenin d) Catechin

vi) Stevia is an example of.....

a) Natural binder b) Natural colorant c) Natural thickener d) Natural sweetener

vii) Full form of IPR

a) Intellectual Property Rights b) Indian Property Rights

c) Intellectual Personal Rights d) Intellectual Property Reserve

viii) ..... is not a member of ASU DTAB.

a) Drug controller of India b) Director of CDL

c) Pharmacognosist appointed by Central government d) President of PCI

ix) Spreadability test is performed for.....formulation.

a) Tablet b) Syrup c) Cream d) Shampoo

x) Most popular Indian herbal industry Dabur was established in....

a) 1920 b) 1884 c) 1832 d) 1882

xi) As per ICH guidelines sub section Q1B deals with...

a) Stability testing of new dosage form b) Stability data evaluation

c) Photo stability testing d) Stability testing of new drug

xii) Churna is the formulation of the category .....

a) Shampoo b) Powder mixture c) Tablet d) Cream

xiii) In the case study of Neem, patent was claimed for ..... activity.

a) Antiseptic b) Antiviral c) Antiulcer d) Fungicidal

xiv) Regulation in production of ASU drugs is done by

a) Schedule Z b) Schedule P c) Schedule O d) Schedule N

Xv) Alcohol content of Asava/Arishta is in the range of.....

A) 8-12 % v/v B) 20-25 % v/v C) 15-20 % v/v D) 4-7 % v/v

xvi) Hypericin is the chemical constituent of .....

a) Ashwagandha b) St.John's wort c) Ephedra d) Ginseng

xvii)Dr.Samuel Hahnemann did the experiments on his own healthy body with the drug.....

a) Rauwolfia b) Fenugreek c) Cinchona d) Ginseng

xviii) Azadirachtin is one of the potent components of

a) Neem b) Turmeric c) Tulsi d) Kava-kava

xix) Full form of ICH.

a) Indian Council for Harmonisation b) International Council for Harmonisation

c) International Course for Harmonisation d) Indian Course for Harmonisation

xx).....is NOT an Ayurvedic formulation.

a) Bhasma b) Gutika c) Syrup d) Lehya

Q. 2. Long Answers = 2 x 10 = 20 (Answer 2 out of 3)

i) Explain Asava and Arishta with its method of preparation and standardization parameters.

ii) Discuss the Part-I components of GMP (Schedule T) for ASU drugs.

iii) Highlight the role of Nutraceuticals in Diabetes. Mention the significance of Amla and Ashwagandha as health food.

Q. 3. Short Answers = 7 x 5 = 35 (Answer 7 out of 9)

i) Illustrate different Good Agricultural practices in cultivation of medicinal plants.

ii) Write a brief note on herbs used in skin care herbal cosmetics.

iii) Investigate the possible side effects and interactions of the drug Hypercium and Ginseng.

iv) Explain the Phytosomes as Novel dosage forms.

v) Brief the term Biopiracy. Elucidate patent case study of Curcuma.

vi) Describe the composition and functions of ASU DTAB.

vii) Recognize the present scope and future prospects of Herbal drug industry in India.

viii) Write a note on Herbs as significant natural excipients.

ix) Mention the basic principles involved in Ayurvedic system of medicine.

DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE

End Semester Examination – Summer 2022

Course: B. Pharmacy | Sem: VI

Subject Name: Biopharmaceutics & Pharmacokinetics | Subject Code: BP604T

Max. Marks: 75 | Date: 22/07/2022 | Duration: 3.45 Hrs.

Instructions –

1. **All questions are compulsory**
2. **Answers to MCQs should be written in full sentences**
3. **Draw diagrams / figures wherever necessary**
4. **Figures to right indicate full marks**

Q. 1. Multiple Choice Questions (MCQs) = 20 x 1 = 20 (All the questions are compulsory)

i) Drug absorption by passive diffusion is

a) Non ionic diffusion b) Energy dependent

c) Uphill transport d) Saturable

ii) Acidic drugs mainly bind to

a) α- Acid glycoprotein b) Antigens

c) human serum albumin d) Vitamin A

iii) In general, the presence of food in the gastrointestinal tract (GIT) reduces the rate and extent of drug absorption due to

a) Enhanced presystemic drug elimination

b) High viscosity of the GIT contents

c) Increased adsorption of the drug on the Gl contents

d) Increased dissolution of the drug in the GI contents

iv) Calculate the volume of distribution of drug, when 300 mg dose is administered showed the initial blood drug concentration of 30 microgram/mL?

a) 9 L b) 10 L c) 100 L d) 90 L

v) Gaseous and volatile substances are excreted through one of the following routes.

a) Dermal b) Pulmonary

c) Renal d) Salivary

vi) Which is NOT a marker for renal drug excretion?

a) Creatinine b) Glucose

c) Inulin d) Probencid

vii) One of the following is the phase II drug biotransformation reaction?

a) Acetylation b) Deamination

c) Hydrolysis d) Reduction

viii) Conjugation with Glutathione useful for

a) water soluble metabolite formation b) detoxification

c) enhancing biological half life d) Reduction

ix) What does the word "open" mean in the one compartment open model?

a) Unidirectional input and output b) The drug readily mixes with the blood

c) The drug easily enters d) Easy absorption

x) In one compartment open model drug disposition, the drug is eliminated by one of the following patterns:

a) Biexponentially b) Nonexponentially

c) Triexponentially d) Monoexponentially

xi) In one compartment open model drug disposition, the assigned one compartment is:

a) Body b) Blood

c) Gastrointestinal tract d) Liver

xii) In which of the model peripheral compartments are connected to a central compartment in series?

a) Caternary model b) Physiologic model

c) Compartment model d) Mammillary model

xiii) Steady state plasma concentration (Css) depends on following factors except

a) Clearance b) Dosing interval c) Dose d) Elimination half life

xiv) Total systemic clearance in two compartment open model is calculated by

a) hybrid first order constants for slow elimination phase and apparent volume of distribution

b) hybrid first order constants for slow elimination phase and Clearance

c) hybrid first order constants for slow elimination phase and AUC

d) hybrid first order constants for slow elimination phase and rapid distribution phase

xv) The dosing interval depends on one of the following

a) Apparent volume of distribution b) AUC

c) Clearance d) Plasma Elimination half life

xvi) The loading dose of a drug is based upon the desired plasma drug concentration and

a) Time taken for complete elimination

b) Percentage of drug excreted unchanged in urine

c) Percentage of drug bound to plasma protein

d) Apparent volume of distribution

xvii) One of the following statements is correct with respect to non-linear pharmacokinetics.

a) First order b) First order followed by zero order

c) Pseudo first order d) Zero order

xviii) Xenobiotic means

a) foreign to body b) Produced by bacteria

c) produced by xerophytes d) synthesized in the body

xix) The volume of distribution of a drug is

a) an expression of total body volume

b) a measure of total fluid volume

c) a relationship between the total amount of drug in body and plasma concentration of drug

d) proportional to bioavailability of the drug

xx) What is the reason of complicated penetration of some drugs through Blood brain barrier?

a) High lipid solubility of drug

b) High endocytosis degree in a brain capillary

c) Absence of pores in the brain capillary endothelium

d) Meningitis

Q. 2. Long Answers) = 2 x 10 = 20 (Answer 2 out of 3)

i) Describe One compartment open model. Deduce the monoexponential equation of disposition of drugs. Illustrate assessment of Pharmacokinetic parameters after IV bolus administration of drug for One compartment open model.

ii) Define absorption. List factors influencing absorption of drugs. Discuss physicochemical factors in detail.

iii) Define Bioavailability and bioequivalence. Explain Pharmacokinetic & Pharmacodynamic Methods of assessing bioavailability.

Q. 3. Short Answers = 7 x 5 = 35 (Answer 7 out of 9)

i) List USP *In vitro* dissolution test apparatus and illustrate any 4 apparatus.

ii) Compare active and passive transport of drug absorption mechanism.

iii) Differentiate between loading dose and maintainance dose.

iv) Describe physiological models.

v) Illustrate Phase I metabolism reactions with example.

vi) Explain Wagner Nelson method for estimation of Ka.

vii) Illustrate factors causing Non-linearity in pharmacokinetics with example of drugs.

viii) Explain protein binding of drugs.

ix) Explain mechanism of renal excretion. State the equation of renal clearance. List factors affecting renal excretion of drugs.

------END OF THE PAPER------

DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE

End Semester Examination – Summer 2022

Course: B. Pharmacy | Sem: VI

Subject Name: Pharmaceutical Biotechnology | Subject Code: BP605T

Max. Marks: 75 | Date: 30/07/2022 | Duration: 3.45 Hrs.

Instructions –

1. All questions are compulsory
2. Answers to MCQs should be written in full sentences
3. Draw diagrams / figures wherever necessary
4. Figures to right indicate full marks

Q. 1. Multiple Choice Questions (MCQs) = 20 x 1 = 20 (All the questions are compulsory)

i) . .....biosensors are based on the principle of sound vibrations.

a) Piezoelectric b) Optical

c) Calorimetric d) Potentiometric

ii)Which type of restriction endonucleases is used most in genetic engineering?

a) Type I b) Type II

c) Type III d) Type IV

iii) A segment of DNA that reads the same from forward and backward is called .....

a) palindromic DNA b) complementary DNA

c)plasmid DNA d)copy DNA

iv) Which of the following is not included in immobilization process?

a) Absorption b) Adsorption

c) Entrapment d) Cross-linking

v) Most commonly used plasmid vector in genetic engineering is .....

a) pBR 322 b)pBR 328

c) pBR 232 d) pBR 832

vi) Name the class of immunoglobulin which has a pentameric structure?

a) IgE b) Ig G

c) Ig A d) IgM

vii)Restriction endonucleases are utilised in genetic engineering as.....

a) Molecular build up at nucleotides

b) Molecular degradation to DNA break up

c) Molecular cement for combining DNA

d) Molecular scalpels for cutting DNA

viii)What will be the consequence of not having an origin of replication (ori) in the vector?

a) If an ori is absent, replication of vector would not take place

b) As the cells divide after taking up the vector, both the daughter cells would be having the vector

c) A colony of transformed colonies is observed

d) The vector won't be taken up by the cell

ix)The hybridomas are made by_____.

a) Fusing T cells with myeloma cells b) Fusing T helper cells with myeloma cells

c) Fusing B cells with myeloma cells d) Fusing B memory cells with myeloma cells

x)Cell-mediated immunity is carried out by_____While humoral immunity is mainly carried out by_____

a) B cells/T cells b) Epitopes/Antigens

c) T cells/B cells d) Antibodies/Antigens

xi)Type IV hypersensitivity is also called as_____.

a) Immediate hypersensitivity b) Delayed hypersensitivity

c) Cytotoxic hypersensitivity d) Immune complex hypersensitivity

xii)Which immunoglobulin is responsible for humoral sensitivity and histamine release?

a) IgE b) IgM

c) IgG d) IgA

xiii)_____ technique is used for amplification of RNA molecules

a) Nested PCR b) Real time quantitative PCR

c) Anchored PCR d) Reverse Transcription PCR (RT-PCR)

xiv)The transfer of genetic material from one bacterium to another via virus is called.....

a) Transformation b) Conjugation

c) Recombination d) Transduction

xv)Which of the following characteristics is not true of a plasmid?

a) It is a circular piece of DNA. b) It is required for normal cell function.

c) It is found in bacteria. d) It can be transferred from cell to cell.

xvi)The mutation which will not affect the length of a protein is_____.

a) Nonsense mutation b) Missense mutation

c) Frame shift mutation d) Reverse Mutation

xvii)Which of the following technique is suitable for identifying mRNA molecule in a sample

a) Western blotting b) Southern blotting

c) Eastern blotting d) Northern blotting

xviii) The chemical nature of humulin produced by rDNA technology is .....

a) lipid b) protein

c) polysaccharide d) nucleic acid

xix)A period during which the growth rate of cells gradually increases is known as _____.

a) Lag phase b) Stationary phase

c) Log phase d) Deceleration phase

xx)It is necessary to have _____in the nutrient medium for the production of Vitamin B12.

a) Manganese b) Phosphate

c) Cobalt d) Calcium

Q. 2. Long Answers Questions (Answer 2 out of 3) (2 x 10) = 20

i) Define enzyme immobilization. Elaborate different methods of enzyme immobilization and give their applications.

ii)Describe the steps involved in r-DNA technology and its application in detail.

iii) Illustrate immuno-blotting technique? Discuss in detail the different methods of immuno-blotting techniques.

Q. 3.Short Answers Questions (Answer 7 out of 9) (7 x 5) = 35

i)Define the cloning vector. Explain the different types of cloning vectors.

ii)Illustrate Hybridoma technology and give the role of HAT medium in monoclonal antibody production.

iii)State the mutation and comment on different types of mutation.

iv) Discuss the structure and functions of different types of MHC.

v)Explain in detail the construction of a typical fermenter with a suitable diagram.

vi) Define biosensor. Illustrate the components and types of biosensors.

vii) Write a note on PCR technique

viii) Elaborate in detail any four methods of gene transfer along with diagrams.

ix) Compare different types of hypersensitivity reactions.

-----END OF THE PAPER-----

DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE

End Semester Examination – Summer 2022

Course: B. Pharmacy **Sem: VI**

Subject Name: Pharmaceutical Quality Assurance **Subject Code: BP606T**

Max. Marks: 75 **Date: 28/07/2022** **Duration: 3.45 Hrs.**

Instructions –

1. **All questions are compulsory**
2. **Answers to MCQs should be written in full sentences**
3. **Draw diagrams / figures wherever necessary**
4. **Figures to right indicate full marks**

Q. 1. Multiple Choice Questions (MCQs) = 20 x 1 = 20 (All the questions are compulsory)

1) NABL accreditation has a validity period of _____ years.

a) 1 b) 2 c) 3 d) 4

2) The …… is a process of assurance that the specific system, premises or equipment are able to achieve the predetermined acceptance criteria to confirm the attributes.

a) Validation master plan b) Calibration

b) Evaluation d) Qualification

3) ISO Certification is valid for _____ years.

a) 1 b) 2 c) 3 d) 4

4) Which guideline stands for evaluation of stability data?

a) Q1B b) Q1C c) Q1D d) Q1E

5) P-D-C-A stands for…..

a) Proceed-Do-Check-Act b) Plan-Do-Check-Act

c) Plan-Do-Correct-Act d) Prepare-Do-Check-Act

6) Physical dimension of equipment and accessories comes under which qualification?

a) Operational qualification (OQ) b) Installation qualification (IQ)

c) Performance qualification (PQ) d) Design qualification (DQ)

7) _____ airlock is mainly used in Parenteral manufacturing areas.

a) Cascade airlock b) Sink airlock

c) Bubble airlock d) Hermetical airlock

8) For Hydrolytic resistance test, at least _____ number of containers to be used for the 5 ml capacity glass containers.

a) 20 b) 10 c) 5 d) 3

9) Fragmentation test applicable to butyl rubber closures, the total number of fragments is NMT____.

a) 5 b) 10 c) 15 d) 20

10) As per USFDA, Microbiological limit for clean area class 1000 is _____ cfu/ft^3.

a) <1 b) <2 c) <3 d) <5

11) Non-clinical laboratory study records must be retained for at least ____ years, when application for research is approved by FDA.

a) 1 b) 2 c) 3 d) 5

12) _____ validation is performed on already completed process.

a) Prospective b) Concurrent c) Retrospective d) Qualification

13) Non-clinical laboratory study protocol is signed and approved by _____

a) Study Director b) Sponsor c) QA Unit d) Both a & b

14) ____ is degree of closeness of a series of measurement obtained using multiple samples of same substance.

a) Accuracy b) Precision c) Specificity d) Linearity

15) Waste which is potentially dangerous to human health is called as.....

a) Non-hazardous waste b) Hazardous waste

b) Inert substances waste d) Biomedical waste

16) _____ means an action taken to resolve a problem with therapeutic goods having deficiencies in quality, efficacy or safety.

a) Qualification b) Drug recall c) Quality review d) Complaint

17) As per CDSCO, Class II Drug recall should be completed within _____

a) 3 days b) 10 days c) 30 days d) 7 days

18) _____ audit is performed to assess the GMP & cGMP compliance.

a) External audit b) Internal audit c) Regulatory audit d) Operational audit

19) Product quality complaint should be investigated within_____ days

a) 5 b) 3 c) 10 d) 7

20) Only complaint sample shows OOS result, due to improper storage and retained sample meets specifications, this complaint is categorized as_____

a) Confirmed complaint b) Non-confirmed complaint

c) Counter complaint d) Tamper complaint

Q. 2. Long Answers = 2 x 10 = 20 (Answer 2 out of 3)

1. Describe process of harmonization and elaborate the ICH stability testing guidelines.
2. Write in detail about Analytical Method Validation. Give process of Calibration of pH meter.
3. Explain the quality control tests for glass containers and rubber closures.

Q. 3. Short Answers = 7 x 5 = 35 (Answer 7 out of 9)

1. Explain the process of Complaint Handling.
2. Describe Elements of QbD.
3. Explain principles and procedure for NABL accreditation.
4. Write a note on Training and Personnel health and hygiene. Explain in short Maintenance of sterile areas.
5. Give an account of purchase specifications and maintenance of stores for raw materials.
6. Discuss the Protocol for Conduct of a Nonclinical Laboratory Study and Records and Reports per GLP.
7. Write a note on Quality Audit and Master Formula Record.
8. Differentiate between QA & QC. Enlist the steps for registration for ISO 9000.
9. Write a short note on Good Warehousing Practice.

------END OF THE PAPER------