Duration: 3 hours **Total marks:80**

N.B.: 1. All questions are compulsory
2. Figures to right indicate full marks
3. Draw structures wherever required.

Q. 1 Answer the following questions (2 marks each) **20 Marks**

i. Write name and structure of one steroidal and one non-steroidal estrogen agonist.

ii. Give structure and use of Ramelteon.

iii. Name and give structure of a reversible acetylcholinesterase inhibitor. Give its use.

iv. Outline any two structural modification in phenylethylamines to increase selectivity giving relevant examples.

v. Write down the example of a prodrug used as anticonvulsant. Give its active metabolite. (structures needed)

vi. Name and give structure of the following: a dual acting opioid b. an opioid used as an antidiarrheal

vii. Classify TCA (tricyclic antidepressants) and write name of one drug in each class (structure not needed).

viii. Give the structure of sulindac. Name the chemical class to which it belongs. Give its metabolism.

ix. Give name, structure and use of a drug having azaspirodecanedione scaffold.

x. Classify the following into selective and non-selective adrenergic blockers and state the receptor: Phentolamine, Labetalol, Prazosin, Propranolol

Q. 2 **i.** Write down the name and structure of Fluoxetine analogue in which linear phenyl propyl amine has been folded into a piperidine ring. Write any four structural changes in the analogue leading to decrease in activity. **6 Marks**

ii. Parallel changes in rigid opioids produce parallel changes in activity. While parallel changes in non-rigid opioid produce non-parallel changes in activity. Explain this statement with a suitable receptor binding model. **3 Marks**

iii. Write methadone metabolism and name the metabolites as active and inactive. **3 Marks**

Q. 3 **i**. Classify antipsychotics with phenothiazine scaffold. Write one example along with structure for each class. Explain development of flurobutyrophenone class. **6 Marks**

ii. Give suitable justification with relevant structures for the following: **6 Marks**

a. Malathion is harmful for insects but not humans.

b. Pralidoxime acts as an antidote for AChE poisoning.

Q. 4 **i.** Outline synthesis of Labetalol with all reagents and reaction conditions. Give the name and therapeutic use of another mixed blocker. **6 Marks**

ii. Give names and structures of two anticholinergic drugs used in treatment of Parkinsons. Discuss their mode of action. **3 Marks**

iii. Justify, "Amantadine inspite of having a polar amino group is used as CNS drug". (structure needed) **3 Marks**

Q. 5 **i.** Give synthesis scheme for Nitrazepam along with all reagents and reaction conditions. **3 Marks**

ii. Explain role of C-3 in pharmacokinetics of benzodiazepines. **3 Marks**

iii. Considering Acetylcholine (ACh) as reference answer the following: **6 Marks**

a. Draw conformation of ACh for interaction with Muscarinic receptors.
b. Effect of β substitution in ACh
c. Effect of modification of only acetyl group in ACh
d. Structure of an antagonist used for Parkinson's disease.
e. Structure of naturally occuring muscarinic antagonist
f. Structure of muscarinic antagonist with an ester group

Q. 6 **i.** Answer the following. **3 Marks**

a. Name and structure of drug that is considered as synthetic derivative of GABA
b. Name and structure of anticonvulsant drug containing triazine ring
c. Name and Structure of anticonvulsant drug belonging to iminostilbene class

ii. Justify with relevant structures, "Oxcarbazepine is preferred over Carbamazepine". **3 Marks**

iii. Classify progestins into two different steroidal classes. Give name and structure of agents belonging to each class along with therapeutic application of the same. What will happen to its activity if methyl group is introduced at 6^{th} position? Give the name and structure the drug with this substitution. **6 Marks**

…….

(3 Hours) **[Total Marks: 80]**

Notes: All questions are compulsory.

The figures to right indicate full Marks.

Q1. A	**Answer the following**	**16M**
i	Explain consulting as a basic element of good clinical practice.	
ii	Enlist ANY FOUR reasons for patient non-compliance.	
iii	Give ANY TWO examples of Type A Adverse drug Reactions (ADR).	
iv	Give any one drug interaction occurring due to alteration in gut flora and justify it.	
v	Justify "Aminoglycosides are required to be used with caution in geriatric patients."	
vi	Justify the need for Therapeutic drug monitoring (TDM) for Digoxin.	
vii	Explain Target Identification and Validation.	
viii	What is the prospective and retrospective study?	
Q1.B	**Fill in the Blanks**	**4 M**
i	Idiosyncrasy is _____type of ADR.	
ii	People with _____ deficiency are at risk of developing haemolytic crisis upon administration of primaquine.	
iii	Chronic alcoholism leads to _____ of microsomal enzyme in liver.	
iv	Absorption of tetracycline _____ on administration with milk.	
Q2	**Answer the following (Any Three)**	**12M**
i	Explain ANY FOUR clinical functions of the pharmacist.	
ii	Enlist the basic elements of good clinical pharmacy practice and explain each element.	
iii	Explain ANY TWO methods of assessment of compliance.	
iv	Explain how supplementary labelling and suitable packaging can improve patient compliance.	

Q3	**Answer the following (Any Three)**	**12M**
i	Explain ANY TWO predisposing factors leading to Adverse Drug Reactions. Add an example for each.	
ii	Explain the Chronic and withdrawal type of adverse drug reactions with an example of each type.	
iii	Discuss Pharmacodynamic drug interactions with suitable examples.	
iv	Write a note with examples of mechanisms of drug interactions altering drug metabolism.	
Q4	**Answer the following (Any Three)**	**12M**
i	Discuss factors altering drug distribution and metabolism in paediatric patients.	
ii	Write a note on reasons for caution for drug therapy in geriatric patients.	
iii	Discuss factors influencing the results of therapeutic drug monitoring.	
iv	Discuss common clinical situations where therapeutic drug monitoring is useful.	
Q 5	**Answer the following (Any Three)**	**12M**
i	Write a short note on lead findings and lead optimization.	
ii	Explain phase 0 and phase 1 trial.	
iii	Discuss the randomized and blinding method of clinical trial.	
iv	Discuss any four ethical principles of clinical trial.	
Q 6	**Answer the following (Any Three)**	**12M**
i	Give applications of Pharmacoepidemiology.	
ii	Discuss cohort studies of Pharmacoepidemiology.	
iii	Give a reason for an increase in health care spending. Add a note on factors affecting drug pricing.	
iv	Discuss the aim, objectives, and principle of Pharmacoeconomic evaluation.	

(3 Hours) **[Total Marks : 80**

1. a. Name properties of rubber material used in parenteral packaging (2)
   b. What is leak test used as evaluation in parenterals (2)
   c. Give merits of sustained release systems (2)
   d. What is validation. Give advantages of validation (2)
   e. Give benefits of novel drug delivery systems (2)
   f. Give principle of floating gastro-retentive systems (2)
   g. Give features of any one erodible ocular insert (2)
   h. Classify liposomes on the basis of their structure (2)
   i. Give mechanism for mucoadhesion (2)
   j. Define bioavailability and bioequivalence (2)

2. a. How is Water for Injection prepared (4)
   b. Write a note on ocular bioavailability (4)
   c. Discuss mechanism of dissolution controlled drug systems (4)

3. a. Discuss air filter used in sterile manufacturing of parenterals (4)
   b. Name evaluation tests for collapsible tubes for ophthalmic products. Discuss any one test. (4)
   c. How are sustained release products evaluated? (4)

4. a. What is Freeze Drying process used in parenterals (4)
   b. Discuss merits of microencapsulation (4)
   c. Explain scale up process for liquid dosage form used by oral route (4)

5. a. Discuss Form-Fill-Seal technology in manufacturing of LVPs (4)
   b. Explain any one design in preparation of transdermal system (4)
   c. Write a note on one compartmental open model (4)

6. a. Discuss salt addition technique in phase separation method for microencapsulation (4)
   b. Give a layout for coated tablet manufacturing unit (4)
   c. Discuss pharmacokinetic parameters in IV bolus of one compartmental open model (4)

Time: 3 Hours **Marks: 80**

N.B.: 1. Figures to right indicate full marks. **Marks**
2. All Questions are compulsory.
3. Draw the diagram wherever necessary.

Q.1 a Multiple Choice Questions (MCQs) **10**

1. MHLW is a regulatory body of_____ country for regulation of pharmaceuticals and medical devices.
a. South Africa b. Brazil
b. Japan d. Switzerland

2. The national statutory laboratory of Government of India for quality control of drugs and cosmetics is _____
a. Central drugs laboratory b. Central medicines laboratory
b. Indian drugs laboratory d. Indian medicines laboratory

3. CTD stands for _____
a. Common technical document b. Central total documents
b. Complete technical document d. Common team document

4. The ICH medical terminology (MedDRA), the Common Technical Document (CTD) and the development of Electronic Standards for the Transfer of Regulatory Information (ESTRI) is covered under which of the following ICH guidelines?
a. Quality b. Safety
b. Efficacy d. Multidisciplinary

5. The four M's for quality manufacturing are _____
a. Matter, method, machine, manufacturing
b. Material, method, mechanism, manufacturing
c. Material, method, machine, men
d. Material, method, member, management

6. ISO 9001 standards deals with _____
a. Standard operating procedure b. Quality management system
b. Good laboratory practises d. Quantification

7. The GMP certificate for loan licensee is granted _____
a. Only for the category of formulations/ API as that has been granted for the own licensee**.**
b. For categories of formulations/ API other than that granted for the own licensee.
c. No provision for loan licensee
d. For categories of formulations/ API in addition to that granted for the own licensee

8. The Applicant part of ASMF contains the information that the ASMF holder regards as ….....
a. Restricted part b. Confidential c. Public information
d. Non-confidential

9. WTO officially commenced on _____
a. 1st January 1975 b. 1st January 1985
b. 1st January 1995 d. 1st January 2005

10. As per EU guidelines post approval changes including replacement of a chemical active substance by a different salt/ester complex/derivative with the same therapeutic moiety, where the efficacy/safety characteristics are not significantly different is known as _____

a) Type IA variation b. Type IB variation
b) Type II variation d. Extension applications

Q1. B. Each question carries 2 marks **10 marks**

a) Name the regulatory authority of USA, UK, Europe and India
b) Give any two functions of CDSCO.
c) What are main applications of Orange Book?
d) State any two salient features of National Procedure of registration in EU.
e) Give any two important features of TRIPS.

Q. 2. Each question carries 4 marks **12 marks**

a. Explain the role and functions of Central Drugs Laboratory.
b. What is ICH? Give its objectives, roles and responsibilities.
c. Explain the role of pharmacovigilance in ADR monitoring.

Q. 3. Each question carries 4 marks **12 marks**

a. Give the structure and any two functions of FDA.
b. What is types of IND and enlist the basic contents of IND applications.
c. Write a short note on Biologics License Application.

Q. 4. Each question carries 4 marks **12 marks**

a. What is post approval variation as per European regulation? Explain any one on brief.
b. Write short note on Mutual Recognition Procedure as per European regulation.
c. Explain the terms: new drug, hybrid drug, generic, similar biologic

Q. 5. Each question carries 4 marks **12 marks**

a. Enlist types of DMF and discuss any one.
b. Explain multidisciplinary M4 guideline in brief.
c. Illustrate the process of WHO-GMP certification.

Q. 6. Each question carries 4 marks **12 marks**

a. Define bioequivalence. Discuss the regulatory requirement for biowaivers.
b. Define patent and explain the criteria for patentability as per Indian Patent Act.
c. Explain the procedure for obtaining test license (Form 11).

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