AIKTC/KRRC/SoP/ACKN/QUES/2019-20/ **Date:** 25/01/23

School: SoP-CBCS **Branch:** SoP **SEM:** VIII

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	Pharmaceutical Chemistry III	BPH_C_801_T			
2	Pharmaceutics IV	BPH_C_802_T		✓	
3	Pharmacovigilance.			✓	
4					
5					

Note: SC – Softcopy, HC - Hardcopy

(Shaheen Ansari)
Librarian, AIKTC

05/12/22

Paper / Subject Code: 14210 / Pharmacovigilance Optional

Sem - VIII CBCS ATKT

Duration: 3 Hrs. **Marks: 80**

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

Q.1 Multiple choice questions **20 M**

1. The Uppsala Monitoring Center as collaborating center for international drug monitoring is founded in the year.
A. 1991
B. 1978
C. 1950
D. 1965

2. The CDSCO initiated a nationwide pharmacovigilance programme of India (PVPI) in
A. August 2010
B. June 2010
C. July 2010
D. July 2001

3. This type of ADR is characterized by the delayed occurrence even after the cessation of treatment……
A. End of dose
B. Delayed
C. Bizzare
D. Augmented

4. An unusual pharmacological response which cannot be explained by the action of a single drug but may be caused by two or more drugs……
A. Pharmacologic
B. Intolerance
C. Drug interaction
D. Hypersensitivity

5. This type of adverse reaction requires no antidote therapy or prolongation of hospitalization……
A. Moderate
B. Mild
C. Severe
D. Chronic

6. Among the following who can report adverse reaction
A. Health care professionals
B. Patients
C. Drug manufacturers
D. All of the above

7. According to the classification of pediatric population, Infants and Toddlers have age range of:……
A. 0 to 28 days
B. 28 days to 23 months
C. 1 to 2 years
D. 2 to 11 years

8. Geriatrics are involved in ..... phase of clinical trials.

A. Phase I
B. Phase II
C. Phase III
D. Phase IV

9. Which of the following is Passive Surveillance method of pharmacovigilance –

A. Spontaneous reports.
B. Sentinel site
C. Drug event monitoring.
D. Registries

10. In this comparative observational study, data collected on a population of patient at a single point in time (or Interval of time) regardless of exposure or disease status

A. Case control study
B. Cross sectional study
C. Cohort study
D. Case series

11. In this comparative observational studies population-at-risk for the disease is followed over time for the occurrence of the disease.....

A. Cohort study
B. Case series
C. Case control study
D. Cross sectional study

12. The Yellow card form used for spontaneous reporting in which of the following country.....

A. South Africa
B. United Kingdom
C. Japan
D. Ethiopia

13. How many system organ classes are included in MedDRA?

A. 23
B. 26
C. 28
D. 30

14.....is person responsible for the conduct of the clinical trial at a trial site.

A. Investigator
B. Monitor
C. Clinical research coordinator
D. Sponsor

15. An epidemic that becomes unusually widespread and even global in its reach is referred to as .....

A. Pandemic
B. Spanish flu.
C. Endodermic.
D. Hyperendemic.

16. Absolute risk is.....

A. Probability of an event affecting members of particular population
B. Risk in a population of unexposed person
C. Ration of risk in exposed population and risk in unexposed population
D. Comparison between outcome frequency measurements

17. ICH is.....

A. The International Council of Harmonization for Technical Requirements for Pharmaceuticals for Human Use.
B. The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use.
C. The International Council for Harmonization of Technical Requirements for Pharmaceutical products in Human Use.
D. The International Council of Harmonization of Technical Requirements for Pharmaceuticals in Human Use.

18. Guidelines for Safety Data Collection are provided by .....ICH guideline.

A. E16
B .E18
C. E19
D .E17

19. D & C act was passed in the year.....

A.1951
B.1980
C.1940
D.1947

20. .....is the Regulatory Authority of India.

A. Indian Council of Medical Research
B. Drug Price Control Order
C. Indian Society for Clinical Research
D. Central Drugs Standard Control Organization

Q.2. A. Answer <u>ANY ONE</u> of the following **12 M**

a. Enlist the different manifestations of adverse drug reactions & explain the role of pharmacist in detection & management of ADR.
b. Explain hierarchy of MedDRA & types of drug utilization studies.

Q.2.B. Answer <u>ANY FOUR</u> of the following **48 M**

1. a) Give Pharmacovigilance historical perspective during thalidomide era.
   b) Write a note on Pharmacovigilance Programme of India.

2. a) Give the pharmacological classification of ADR.
   b) Define ADR. Enlist the risk factors for ADR.

3. a) Explain the pharmacogenomics of adverse drug reactions with example.
   b) Write a note on drug safety evaluation in Pediatric & Geriatric patients.

4. a) Give a comparative account of cross sectional studies and cohort studies.
   b) Explain in detail spontaneous reports as a method of pharmacovigilance.

5. a) Give the organization and objectives of ICH.
   b) Explain periodic safety update report.

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02/12/22

Paper / Subject Code: 14209 / Clinical Pharmacy

Sem-VIII CBCS R-19 ATKT

(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.	

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28.11.22

Paper / Subject Code: 14207 / Pharmaceutics- IV

Sem - VIII CBGS

(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)
