BPHARMA
(SEM VIII) THEORY EXAMINATION 2021-22
PHARMACOVIGILANCE

Time: 3 Hours *Total Marks: 75*

Note: Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt *all* questions in brief. **10 x 2 = 20**

a.	What is drug event monitoring?
b.	List four drugs contraindicated in pregnant and lactating women.
c.	Suggest the requirements for CIOMS form
d.	What is eudravigilance?
e.	What is teratogenicity? Give examples.
f.	What is post marketing safety?
g.	Narrate the minimum criteria required for a valid report?
h.	What is phase IV of clinical trials?
i.	What are the basic objectives of pharmacovigilance planning?
j.	Mention few examples of predictable adverse drug reactions.

SECTION B

2. Attempt any *two* parts of the following: **2 x 10 = 20**

a.	Classify adverse drug reaction. How will you detect and report ADR along with causality assessment scales?
b.	Discuss in detail basic and specialized drug information resources in pharmacovigilance
c.	Discuss in detail of Cohort and case control study. Explain the applications of MedDRA and standard MedDra queries.

SECTION C

3. Attempt any *five* parts of the following: **7 x 5 = 35**

a.	Explain the establishing pharmacovigilance program in the hospital.
b.	What is vaccine safety surveillance? Explain in detail different types of pharmacovigilance methods used for passive and active surveillance.
c.	Discuss in detail establishment and operation of drug safety department in pharmaceutical industry.
d.	Mention the importance aspects of ICH guidelines for expedited reporting.
e.	Write short note on pharmacogenomics in adverse drug reaction
f.	How will you carry out drug safety evaluation in geriatric and pediatric populations?
g.	What is the role of CDSCO in pharmacovigilance? Write a note on ATC classification of drugs.

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Paper Id: 231140 Roll No. | | | | | | | | | | |

B PHARM
(SEM VIII) THEORY EXAMINATION 2022-23
PHARMACOVIGILANCE

Time: 3Hours *Total Marks: 75*

Note: Attemptall Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt *all* questions in brief. **2 x 10 = 20**

(a) Define the adverse drug reaction.

(b) Compute the limitations of detecting ADRs in clinical trials.

(c) Discuss the PSUR.

(d) Classify ADRs according to severity.

(e) List out factors affecting adverse effects of the vaccine.

(f) What is phase IV of clinical trials?

(g) What are CIOMS working groups?

(h) Discuss the cohort study with example.

(i) Discuss the Defined daily doses.

(j) Illustrate the importance of Pharmacogenomics.

SECTION B

2. Attempt any *two* parts of the following: **10 x 2 = 20**

(a) Differentiate betweenadversedrug reactions and adverse events with suitable examples. Explain the mechanisms of Type-A and Type-B ADRs.

(b) Illustrate the vaccine safety surveillance along with the different types of pharmacovigilance methods used for passive and active surveillance.

(c) Explain the drug safety evaluation in pediatrics and geriatrics.

SECTION C

3. Attempt any *five* parts of the following: **7 x 5 = 35**

(a) Characterize the differentmethods ofcausality and severity assessment of ADRs and explain Naranjo's scale.

(b) Demonstrate the prerequisite for setting up a pharmacovigilance center in a CRO and hospital.

(c) Define vaccine. Explain reasons for vaccination failure.

(d) Summarize the ATC classification of drugs with example.

(e) Explore the Pre- marketing and Post-marketing clinical trials.

(f) Illustrate the organization and objectives of ICH.

(g) Explain the Schedule Y of Drugs and Cosmetics Act in brief.

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Subject Code: BP805ET

BPHARM
(SEM VIII) THEORY EXAMINATION 2023-24
PHARMACOVIGILANCE

TIME: 3 HRS **M.MARKS: 75**

Note: Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt *all* questions in brief. **10 x 2 = 20**

a.	What is adverse drugreaction?
b.	Mention the differences between drug toxicity and drug abuse.
c.	What is eudravigilance?
d.	What is drug event monitoring?
e.	List four drugs contraindicated in padiatric patients.
f.	What is post marketing safety?
g.	Narrate the minimum criteria required for a valid report.
h.	Mention the salient features of Phase III of clinical trial.
i.	What do you mean by teratogenicity?
j.	What is ATC classification of drugs?

SECTION B

2. Attempt any *two* parts of the following: **2 x 10 = 20**

a.	
b.	Discuss the importanceof safety monitoring of medicine. Highlight the salient features of the Pharmacovigilance Program of India (PvPI)
c.	How will you set up the establishment & operation of drug safety department in industry? Mention its rationale of such set up.
	Discuss in detail of Cohort and case control study. Explain the applications of MedDRA and standard MedDra queries.

SECTION C

3. Attempt any *five* parts of the following: **7 x 5 = 35**

a.	Suggest some examples ofvaccination failure.How will you control such failures in future?
b.	Mention the importance aspects of ICH guidelines for expedited reporting
c.	What is the role of CDSCO in pharmacovigilance? Write a note on ATC classification of drugs
d.	How will you carry out drug safety evaluation in pregnant woman and geriatric patients?
e.	Write short notes on CIOMS
f.	Suggest the role of genetics related ADR with examples
g.	Write short note on pharmacogenomics on adverse drug reaction

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BPHARM
(SEM VIII) THEORY EXAMINATION 2024-25
PHARMACOVIGILANCE

TIME: 3 HRS **M.MARKS: 75**

Note: **1.** Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt *all* questions in brief. **10 x 2 = 20**

a.	Write in short about the importance of safety monitoring of Medicine.
b.	What are CROs ?
c.	Expand PvPI. When did PvPI established in India?
d.	What is vaccination failure?
e.	What is the importance of Schedule Y in Pharmacovigilance?
f.	Write the names of at least *four* International Non-proprietary drugs.
g.	On what basis drugs are classified?
h.	What is cohort analysis?
i.	What is the importance of CIOMS form?
j.	What Good clinical practices to be followed in pharmacovigilance studies?

SECTION B

2. Attempt any *two* parts of the following: **2 x 10 = 20**

a.	Elaborate Adverse drug reaction reporting systems and communication in pharmacovigilance.
b.	Expand ICH guidelines. Write in detail about the ICH guidelines for Pharmacovigilance.
c.	How safety data is generated at pre-clinical, clinical and post market level under vigilance program in India?

SECTION C

3. Attempt any *five* parts of the following: **7 x 5 = 35**

a.	Write a note on adverse events following immunization.
b.	Write the mission, objectives, structure, function and reporting methods of PvPI.
c.	Enlist some differences in Indian and global pharmacovigilance requirements.
d.	Write a note on MedDRA.
e.	Enlist some genetics related ADR with example.
f.	What are the parameters for drug safety evaluation in Pregnancy and lactation?
g.	How will you manage and report any adverse drug reaction?

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BPHARM

(SEM. VIII) THEORY EXAMINATION 2025-26

PHARMACOVIGILANCE

TIME: 3 HRS M.MARKS: 75

Note: 1. Attemptall Sections. If require anymissingdata;then choose suitably.

SECTION A

1. Attemptall questions in brief. 10 x 2 = 20

a.	Defineadverse drugreaction.
b.	List four drugs contraindicated in pregnant and lactating women
c.	Suggest the requirements for CIOMS form
d.	Mention the basic CIOMS requirements for ADR reporting.
e.	Why is safety monitoring of medicine so important in the current context.
f.	What is Type C adverse reaction?
g.	Why is drug safety monitoring important for a geriatric patient?
h.	Define pharmacogenomics.
i.	What is post marketing safety?
j.	Narrate the minimum criteria required for a valid report?

SECTION B

2. Attempt anytwo parts of the following: 2 x 10 = 20

a.	Classifyadversedrug reaction. Howwill youdetect and report ADR along with causality assessment scales?
b.	Enumerate the various phases of clinical trials. Write short notes on good clinical practice in pharmacovigilance studies
c.	Suggest the various ICH guidelines in pharmacovigilance studies. How will you conduct post approval expedited reporting process?

SECTION C

3. Attempt anyfive parts of the following: 7 x 5 = 35

a.	Discuss in detail basic and specialized druginformation resources in pharmacovigilance
b.	Highlight the significance of Pharmacovigilance Program of India
c.	What is vaccine safety surveillance? Explain in detail different types of pharmacovigilance methods used for passive and active surveillance
d.	Discuss in detail establishment and operation of drug safety department in pharmaceutical industry.
e.	What is the role of CDSCO in pharmacovigilance? Write a note on ATC classification of drugs
f.	What are the salient features of effective communication in pharmacovigilance particularly with regulatory agencies
g.	Write short notes on “EudraVigilance medicinal product dictionary”