DEPARTMENT OF PHARMACEUTICAL CHEMISTRY

Academic Session January-May 2024

Course Name: B.Pharmacy
Student's Batch: 2020-2024
Semester: VIII
Name of Subject: Pharmacovigilance
Subject Code: BP805T
Faculty In charge: Mrs. Shivani Sharma

HOD

Director cum Principal
Gautam College of Pharmacy
Panipat

Director cum Principal

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Gautam College of Pharmacy
Hamirpur (H.P.)

07.03.2024

HP TECHNICAL UNIVERSITY, HAMIRPUR 177 001, HP

Academic Calendar: 2023-24

Odd Semester: 2023-24 session (*i.e.*, 1st semester of 2023-24)

SN	Event(s)	Date(s)
1	Reporting of Faculty in respective Colleges	27-07-2023
2	Industrial/Institutional/Practical Training:	
	After 2nd Semester: MBA	19-07-23 to 20-08-23
	After 4th Semester: B. Tech. (CSE) & 6th Semester: B. Pharm.	27-07-23 to 27-08-23
	After 6th semester: B. Tech. (All Branches)	27-07-23 to 07-09-23
3	Registration of all students for all courses; **except** 3rd Sem MBA, 5th sem B. Tech.-CSE, 7th sem B. Tech. & 7th sem B.Pharm.	01-08-23 to 03-08-23
4	Commencement of all classes; **except** 3rd Sem MBA, 5th sem B. Tech.-CSE, 7th sem B. Tech. &7th sem B. Pharm.]	02-08-23
5	Induction programme for 1st year students	02-08-23 to 11-08-23
6	*Registration for 3rd Sem (MBA)	21-08-23 to 23-08-23
7	Commencement of classes of 3rd Sem (MBA)	21-08-23
8	*Registration for 5th Sem B. Tech. (CSE) & 7th Sem B. Pharm.	28-08-23 to 30-08-23
9	Commencement of classes of 5th Sem B.Tech. (CSE) & 7th Sem B. Pharm.	28-08-23
10	*Registration for 7th Sem (B. Tech.)	08-09-23 to 11-09-23
11	Commencement of classes of 7th Sem (B.Tech.)	08-09-23
12	Mid-Sem Tests-I (1st Periodical Exams) of all; **except** 3rd Sem MBA, 5th Sem B. Tech.-CSE and 7th Sem of B. Tech. & B. Pharm.	18-09-23 to 21-09-23
13	HPTU Youth Festival	06-10-23 to 08-10-23
14	Mid-Sem Tests-I (1st Periodical Exams) of 3rd Sem (MBA)	27-09-23 to 30-09-23
15	Mid-Sem Tests-I (1st Periodical Exams) of 5th Sem (B.Tech.-CSE) & 7th Sem B. Pharm.	03-10-23 to 06-10-23
16	Mid-Sem Tests-I (1st Periodical Exams) of 7th Sem (B.Tech.)	11-10-23 to 14-10-23
17	Diwali Vacations	09-11-23 to 13-11-23
18	Mid-Semester Tests-II (2nd Periodical Exams) of all courses & semesters	15-11-23 to 18-11-23
19	End of Teaching Work for all semesters	30-11-23
20	• Reporting of Shortage of attendance cases, and • Display of internal assessment awards	02-12-23
21	End Semester Practical Examinations	04-12-23 to 07-12-23
22	End semester Theory Examinations	08-12-23 to 24-12-23
23	Vacations	25-12-23 to 13-01-2024
24	Reporting of Faculty in Respective Colleges	15-01-24

Revised *for* Even Semester of 2023-24 session (*i.e.*, 2nd semester of 2023-24)

SN	Event(s)	Earlier Date(s)	Revised Date(s)
1	Reporting of Faculty in respective Colleges	15-01-2024	No change
2	Registration of UG and PG Courses	16-01-24 to 18-01-24	-do-
3	Commencement of classes	16-01-24	-do-
4	Mid-Semester Tests-I (1st Periodical Examinations)	26-02-24 to 29-02-24	-do-
5	**HPTU Sports Meet**	15-03-24 to 17-03-24	28-03-24 to 30-03-24
6	**Mid-Semester Tests-II (2nd Periodical Examinations)**	03-04-24 to 06-04-24	06-04-24 to 10-04-24
7	**End of Teaching work**	29-04-24	04-05-24
8	▪ Reporting of Shortage of attendance cases, and ▪ Display of internal assessment awards	01-05-24	06-05-24
9	**End Semester Practical Examinations**	02-05-24 to 06-05-24	06-05-24 to 09-05-24
10	**End semester Theory Examinations**	08-05-24 to 22-05-24	13-05-24 to 31-05-24
11	**Vacations**	26-05-24 to 27-06-24	10-06-24 to 12-07-24
12	**Declaration of results of last semester of all courses**	Last Week of July, 2024	First Week of August, 2024
13	**Industrial/Institutional Training of Students: 4 to 6 weeks** (wherever applicable)	24-05-24 to 10-07-24	02-06-24 to 22-07-24
14	Reporting of Faculty in respective Colleges	28-06-24	15-07-24

Dean (Academic) 07.03.24

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COURSE CONTENT

Unit I

Introduction to Pharmacovigilance
- History and development of Pharmacovigilance
- Importance of safety monitoring of Medicine
- WHO international drug monitoring programme
- Pharmacovigilance Program of India(PvPI)

Introduction to adverse drug reactions
- Definitions and classification of ADRs
- Detection and reporting
- Methods in Causality assessment
- Severity and seriousness assessment
- Predictability and preventability assessment
- Management of adverse drug reactions

Basic terminologies used in pharmacovigilance
- Terminologies of adverse medication related events
- Regulatory terminologies

Unit II

Drug and disease classification
- Anatomical, therapeutic and chemical classification of drugs
- International classification of diseases
- Daily defined doses
- International Non proprietary Names for drugs

Drug dictionaries and coding in pharmacovigilance
- WHO adverse reaction terminologies
- MedDRA and Standardised MedDRA queries
- WHO drug dictionary
- Eudravigilance medicinal product dictionary

Information resources in pharmacovigilance
- Basic drug information resources
- Specialised resources for ADRs

Establishing pharmacovigilance programme
- Establishing in a hospital
- Establishment & operation of drug safety department in industry
- Contract Research Organisations (CROs)
- Establishing a national programm

Unit III

Vaccine safety surveillance
- Vaccine Pharmacovigilance
- Vaccination failure
- Adverse events following immunization

Pharmacovigilance methods
- Passive surveillance – Spontaneous reports and case series

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- Stimulated reporting
- Active surveillance – Sentinel sites, drug event monitoring and registries
- Comparative observational studies – Cross sectional study, case control study and cohort study
- Targeted clinical investigations

Communication in pharmacovigilance

- Effective communication in Pharmacovigilance
- Communication in Drug Safety Crisis management
- Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media

Unit IV

Safety data generation

- Pre clinical phase
- Clinical phase
- Post approval phase (PMS)

ICH Guidelines for Pharmacovigilance

- Organization and objectives of ICH
- Expedited reporting
- Individual case safety reports
- Periodic safety update reports
- Post approval expedited reporting
- Pharmacovigilance planning
- Good clinical practice in pharmacovigilance studies

Unit V

Pharmacogenomics of adverse drug reactions

- Genetics related ADR with example focusing PK parameters.

Drug safety evaluation in special population

- Paediatrics
- Pregnancy and lactation
- Geriatrics

CIOMS

- CIOMS Working Groups
- CIOMS Form

CDSCO (India) and Pharmacovigilance

- D&C Act and Schedule Y
- Differences in Indian and global pharmacovigilance requirements

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REFERENCES

Sr. No.	Author(s)	Book Title	Publisher
01	Anoop Kumar Ruchika Sharma	Global Pharmacovigilance	CBS Publishers
02	Dr. S.B. Bhise	Principles of Pharmacovigilance	Nirali Prakashan
03	Guru Prasad Mohanta Prabal Kumar Manna	Textbook of Pharmacovigilance Concept and Practice	PharmaMed Press

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Time Tabl[illegible] Academic Session Jan. 2024-May 2024

LH-1 –B.Pharmacy 2nd Sem.(Sec-A)LH-2 –B.Pharmacy 4th Sem.(Sec-B) LH-3 – B.Pharmacy 4th Sem.(Sec-B) LH-5 – B.Pharmacy 2nd Sem.(Sec-B) LH-6 – B.Pharmacy 8th Sem. LH-7– B.Pharmacy 7th Sem L- LAB,

DAY	SEM/ YEAR	9:00-10:00 am	10:00-11:00am	11:00-12:00noon	12:00-1:00pm	1:00-2:00pm	2:00-3:00pm	3:00-4:00pm	4:00-5:00pm
Monday	B2(S-A)	Biochem. (VK)	POC-I(STK)	HAP-II (SD)	LUNCH	HAP-II (SD)/ Practical batch A (L-11), Biochem. (VK) Practical batch B (L-5) (LT-SP)			
	B2(S-B)	HAP-II (SD)	EVS(Sv.)	Biochem. (VK)		CAP (DP)	Patho (SK)	Library	POC-I(STK)
	B4 (S-A)	Med Chem-I(SH) Prac. B-A (L-1) P'Cog &P'Chem.(PS)Prac.B-B(L-8)				LUNCH	P'Cology (AM)	Med Chem-I (SH)	P'Cog & Phyto (PS)
	B4 (S-B)	P'Cology (AM)	PP-II (AT)	P'Cog & Phyto (KV)	LUNCH	P'Cog & P'Chem (KV) Prac. B-B (L-10)(LT-SKS) PP-II (AT) Practical B-A(L-6)			
	B6	Med. Chem.-III (VD) Prac. B- A (L-1)(LT-SKS), HDT (SK) Prac. B- B (L-10)				LUNCH	QA (P)	Med. Chem (VD)	P'Cology (RK)
	B8	Biostatistics & RM (PR.)	Soc. Pharmacy (RK)	Marketing (Sl.K)		GPAT (Dr. S.K)	Project Work		
Tuesday	B2(S-A)	Biochem. (VK)	POC-I(STK)	HAP-II (SD)	LUNCH	HAP-II (SD)/ Practical batch B (L-11) (LT-SP), Biochem. (VK) Prac. batch A (L-5)			
	B2(S-B)	HAP-II (SD)	EVS(Sv.)	Biochem. (VK)		CAP (DP)	Library	Patho (SK)	POC-I(STK)
	B4 (S-A)	Med.Chem-I(SH)Prac.B-B(L-1)(SKS),P'Cog & P'Chem (PS)Pr.B-A(L-10)(LT-SP)				LUNCH	Med Chem-I (SH)	P'Cology (AM)	P'Cog & Phyto (PS)
	B4 (S-B)	P'Cology (AM)	PP-II (AT)	P'Cog & Phyto (KV)	LUNCH	P'Cog & P'Chem (KV)Prac. B-A (L-10)(LT-SKS) PP-II (AT) Practical B-B(L-6)(LT-SP)			
	B6	Pharmacology (RK)Practical B- B (L-11),HDT(SK) Prac. B- A(L-10)(LT-SP)				LUNCH	P'Ceutical Biotech (PS)	P'Cology (RK)	Med. Chem (VD)
	B8	Biostatistics & RM (PR.)	GPAT (VD)	GPAT (AM)	LUNCH	Marketing (Sl.K)	Project Work		
Wednesday	B2(S-A)	HAP-II (SD)	POC-I(STK)	Patho (SK)		POC-I(STK)/ Pract.B-B(L-5)(LT-SKS) , CAP Practical (DP) Batch-A			
	B2(S-B)	Biochem. (VK) Practical batch A (L-5) (LT-A) CAP Practical (DP) Batch-B				LUNCH	Patho (SK)	Biochem. (VK)	HAP-II (SD)
	B4 (S-A)	P'Cology (AM)	Med Chem-I (SH)	POC-III (VD)	LUNCH	POC-III (VD)	PP-II (AT)	P'Cog. & Phyto. (PS)	CCA
	B4 (S-B)	P'Cog. Phyto.(KV)	PP-II (AT)	P'Cology (AM)		Med Chem-I (SH) Prac. B-A (L-1)(LT-SKS) P'COL.(AM) Practical batch B(L-11) (LT-SP)			
	B6	HDT (SK)	P'Ceutical Biotech.(PS)	Biopharm. (KV)		Pharmacology (RK) Practical B- A (L-11) Med. Chem.-III (VD) Prac.B- B (L-1) (LT-SP)			
	B8	Biostatistics & RM (PR.)	Soc. Pharmacy (RK)	P'Covigillance (Sv.)		CAP(DP) (Lateral Entry) Practical/Project Work		Project Work	
Thursday	B2(S-A)	Patho (SK)	HAP-II (SD)	POC-I(STK)		POC-I(STK) Prac. B-A (L-2) (LT-SKS), CAP Practical (DP) Batch-B			
	B2(S-B)	Biochem. (VK) Practical batch B (L-5) (LT-SKS) , CAP Practical (DP) Batch-A				LUNCH	Biochem. (VK)	HAP-II (SD)	EVS(Sv.)
	B4 (S-A)	P'Cology (AM)	P'Cog & P'chem (PS)	POC-III (VD)	LUNCH	PP-II (AT)	Library	P'Cog. & Phyto. (PS)	CCA
	B4 (S-B)	POC-III (VD)	Med.Chem-I (SH)	PP-II (AT)		Med Chem-I (SH) Prac. batch B(L-1)(LT-SP), P'Cology (AM)Practical batch A(L-1)			
	B6	QA (P)	Biopharm. (KV)	HDT (SK)		QA (P)	Biopharm. (KV)	CCA	P'Cology (RK)
	B8	Biostatistics & RM (PR.)	GPAT (RK)	Marketing (Sl.K)		P'Covigillance (Sv.)	Project Work		
Friday	B2(S-A)	Patho (SK)	Biochem. (VK)	EVS(Sv.)		CAP(DP)	Biochem(VK)	Library	EVS(Sv.)
	B2(S-B)	HAP-II (SD)Prac. B-A (L-11) , POC-I(STK) / Prac. B-B (L-2)(LT-SKS)				LUNCH	POC-I(STK)	Library	HAP-II (SD)
	B4 (S-A)	PP-II (AT) Prac. B-A(L-6)(LT-A), P'COL.(AM)Practical batch B(L-1)				LUNCH	PP-II (AT)	POC-III (VD)	Med Chem-I (SH)
	B4 (S-B)	Med Chem-I (SH)	P'Cog.& P'chem. (KV)	POC-III (VD)	LUNCH	P'Cology (AM)	Library	P'Cology (AM)	CCA
	B6	Med. Chem. (VD)	P'CeuticalBiotech.(PS)	HDT (SK)		P'Ceutical Biotech (PS)	P'Cology (RK)	Library	Biopharm. (KV)
	B8	P'Covigillance (Sv.)	GPAT (Dr. S.K)	Soc. Pharmacy (RK)		CAP (DP) (Lat.Entry)	Project Work		
Saturday	B2(S-A)	EVS(Sv.)	Biochem. (VK)	Patho (SK)	LUNCH	LUNCH	CAP (DP)	Library	HAP (SD)
	B2(S-B)	HAP-II (SD)Prac. B- B(L-11)(LT-SP), POC-I(STK) Prac. B-A(L-2)(LT-SKS)				LUNCH	Patho (SK)	Biochem. (VK)	POC-I(STK)
	B4 (S-A)	PP-II (AT)Practical B-B(L-6)(LT-SKS) P'Cology (AM)Practical B-A(L-11) (LT-SP)				LUNCH	PP-II (AT)	CCA	P'Cology (AM)
	B4 (S-B)	Med Chem-I (SH)	POC-III (VD)	Med Chem-I (SH)	LUNCH	P'Cology (AM)	Library	POC-III (VD)	CCA
	B6	HDT (SK)	Biopharm. (KV)	QA (P)		Med. Chem. (VD)	P'Cology (RK)	QA (P)	QA (P)
	B8	Marketing (Sl.K)	Soc. Pharmacy (RK)	P'Covigillance (Sv.)		CAP (DP) (Lateral Entry)		GPAT (PS)	GPAT (SV)

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Time Table Jan/2024- May/2024:

Day	Semester	9:30-10:30 AM	10:30-11:30 AM	11:30 AM-12:30PM	12:30-1:00PM	1:00-2:00 PM	2:00-3:00 PM	3:00-4:00 PM	4:00-5:00 PM
Monday	B-8				LUNCH				
Tuesday	B-8								
Wednesday	B-8			P'covigillance					
Thursday	B-8					P'covigillance			
Friday	B-8	P'covigillance							
Saturday	B-8			P'covigillance					

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Objectives:

At completion of this paper it is expected that students will be able to (know, do, and appreciate):

- Why drug safety monitoring is important?
- History and development of pharmacovigilance
- National and international scenario of pharmacovigilance
- Dictionaries, coding and terminologies used in pharmacovigilance
- Detection of new adverse drug reactions and their assessment
- International standards for classification of diseases and drugs
- Adverse drug reaction reporting systems and communication in pharmacovigilance
- Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
- Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
- Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India
- ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
- CIOMS requirements for ADR reporting 13. Writing case narratives of adverse events and their quality.

Component	Components of evaluataion	Nature of exam
Theory	First sessional exam	Very short question, short essay and long essay questions
	End sessional exam	Very short question, short essay and long essay questions
Overall evaluation	External exam semester wise	Very short question, short essay and long essay questions

Extract Of College Working Days

Year	Month	No. of Working Days/ No of working Periods
2024	January	09
	February	17
	March	12
	April	14
	May	02

Total No of Working Days/ Working Periods: 54

Last Working Day: 04/05/2024

HOD

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GAUTAM COLLEGE OF PHARMACY, HAMIRPUR

COURSE: B. PHARMACY

LESSON PLAN

Class: B. Pharmacy 8th Sem
Subject name: Pharmacovigilance (BP-805 T)
Total No. of Lectures: 45

Sr. No.	Course content	Date	Pedagogy	Assignment	Objectives and Learning Outcomes	Remark
1	**Unit – 1 Introduction to Pharmacovigilance** History and development of Pharmacovigilance	17/01/24	Handwritten notes	**Basic terminologies used in pharmacovigilance**	After completion of the topic the student will understand about the Pharmacovigilance and Adverse drug reactions	Shivani Sharma
2	Importance of safety monitoring of Medicine WHO international drug monitoring programme	18/01/24				Shivani Sharma
3	Pharmacovigilance Program of India (PvPI)	19/01/24				Shivani Sharma
4	**Introduction to adverse drug reactions** Definitions and classification of ADRs	25/01/24				Shivani Sharma
5	Detection and reporting Methods in Causality assessment	24/01/24				Shivani Sharma
6	Severity and seriousness assessment	27/01/24				Shivani Sharma
7	Predictability and preventability assessment	31/01/24				Shivani Sharma
8	Management of adverse drug reactions	31/01/24				Shivani Sharma

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	Basic terminologies used in pharmacovigilance Terminologies of adverse medication related events	01/02/24				Shivani Sharma
10	Regulatory terminologies	02/02/24				Shivani Sharma
11	**Unit-II Drug and disease classification** Anatomical, therapeutic and chemical classification of drugs	03/02/24	PPT/PDF and through out offline / online mode		After completion of the topic the student will learn about the classification of diseases and drug dictionaries used in pharmacovigilance	Shivani Sharma
12	International classification of diseases	07/02/24				Shivani Sharma
13	Daily defined doses International Non-proprietary Names for drugs	08/02/24				Shivani Sharma
14	**Drug dictionaries and coding in pharmacovigilance** WHO adverse reaction terminologies	14/02/24				Shivani Sharma
15	MedDRA and Standardised MedDRA queries	15/02/24				Shivani Sharma
16	WHO drugs dictionary Eudravigilance medicinal product dictionary	16/02/24				Shivani Sharma
17	**Information resources in pharmacovigilance** Basic drug information resources	17/02/24				Shivani Sharma
18	Specialised resources for ADRs	21/02/24				Shivani Sharma
19	**Establishing pharmacovigilance programme** Establishing in a hospital Establishment & operation of drug safety department in industry	22/02/24				Shivani Sharma
20	Contract Research Organisations (CROs) Establishing a national programme	28/02/24				Shivani Sharma
21	**Unit III Vaccine safety surveillance** Vaccine Pharmacovigilance	29/02/24	PPT/PDF and through		After completion of the topic the student will understand about the vaccine's	Shivani Sharma
22	Vaccination failure Adverse events following immunization	06/03/24				Shivani Sharma

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	Pharmacovigilance methods Passive surveillance Spontaneous reports and case series	13/03/24	out offline/ online mode		pharmacovigilance, pharmacovigilance methods and communication in pharmacovigilance	Shivani Sharma
24	Stimulated reporting Active surveillance – Sentinel sites	14/03/24				Shivani Sharma
25	Drug event monitoring and registries	15/03/24				Shivani Sharma
26	Comparative observational studies Cross sectional study	15/03/24				Shivani Sharma
27	case control study and cohort study, Targeted clinical investigations	16/03/24				Shivani Sharma
28	Effective communication in Pharmacovigilance	16/03/24				Shivani Sharma
29	Communication in Drug Safety Crisis management	18/03/24				Shivani Sharma
30	Communicating with Regulatory Agencies, Business Partners Healthcare facilities &Media	20/03/24				Shivani Sharma
31	**Unit IV-Safety data generation** Pre-clinical phase	20/03/24	PPT/PDF and through out offline mode		After completion of the topic the student will learn about the clinical phases and ICH guidelines for pharmacovigilance	Shivani Sharma
32	Clinical phase Post approval phase (PMS)	21/03/24				Shivani Sharma
33	**ICH Guidelines for Pharmacovigilance** Organization and objectives of ICH	23/03/24				Shivani Sharma
34	Expedited reporting Individual case safety reports	23/03/24				Shivani Sharma
35	Periodic safety update reports	27/03/24				Shivani Sharma
36	Post approval expedited reporting	28/03/24				Shivani Sharma
37	Pharmacovigilance planning	04/04/24				Shivani Sharma

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	Good clinical practice in pharmacovigilance studies	05/04/24				Shivani Sharma
39	**Unit V- Pharmacogenomics of adverse drug reactions** Genetics related ADR with example focusing PK parameters.	06/04/24	PPT/PDF and through out offline mode	**Drug safety evaluation in special population** **Paediatrics** **Pregnancy and lactation** **Geriatrics**	After completion of the topic the student will learn about the pharmacogenomics, CIOMS and CDCSO	Shivani Sharma
40	**Drug safety evaluation in special population** Paediatrics	12/04/24				Shivani Sharma
41	Pregnancy and lactation Geriatrics	18/04/24				Shivani Sharma
42	**CIOMS** CIOMS Working Groups CIOMS Form	24/04/24				Shivani Sharma
43	**CDSCO (India) and Pharmacovigilance**	26/04/24				Shivani Sharma
44	D&C Act and Schedule Y	01/05/24				Shivani Sharma
45	Differences in Indian and global pharmacovigilance requirements	07/05/24				Shivani Sharma

Shivani Sharma Assistant Professor

TEACHER INCHARGE

Director cum Principal
Geeta Institute of Pharmacy
Kanipla (Kurukshetra)

PRINCIPAL

[Total No. of Questions - 13] [Total No. of Printed Pages - 2]

May-24-0098

BP-805ET (Pharmacovigilance)

B.Pharm. 8th (PCI)

Time : 3 Hours Max. Marks : 75

The candidates shall limit their answers precisely within the answer-book (40 pages) issued to them and no supplementary/continuation sheet will be issued.

Note : Section A is compulsory. Attempt any two questions from section B. Attempt any seven questions from section C.

SECTION - A
(Compulsory)

1. Answer the following questions in short:

   (a) Define preventable adverse drug reactions.

   (b) Enlist methods of seriousness assessment of ADR.

   (c) Define spontaneous reports and case series.

   (d) Define the term 'daily defined doses'.

   (e) Enlist various adverse events following immunization.

   (f) Define Haemovigilance and Materiovigilance.

   (g) Define post-approval expediting reporting.

   (h) Define phenotype and genotype.

   (i) Enlist various tertiary sources of drug information.

   (j) Define drug safety crisis. (10×2=20)

SECTION - B (Long Answer)

2. Describe the GCP principles for Pharmacovigilance studies.

3. Describe the methods for drug safety evaluation in pregnant women.

4. Describe the various methods of causality, predictability and preventability assessment of ADR. (2×10=20)

SECTION - C (Short note)

5. Briefly layout plan and activities of Pharmacovigilance Program of India (PvPI).

6. Describe the establishment and operation of drug safety department in hospital.

7. Describe the ICH guidelines for periodic safety update reports.

8. Briefly describe anatomical, therapeutic and chemical classification of drugs.

9. Describe the methods of generating safety data during clinical phases of drug evaluation.

10. Describe the methods of post-marketing surveillance.

11. Describe the need and approach of effective communication in drug safety management.

12. Describe MedDRA hierarchy system.

13. Describe role of CIOMS working group in pharmacovigilance programme. (7×5=35)

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[Total No. of Questions - 13] [Total No. of Printed Pages - 2]

Jul.-23-0403

BP-805ET (Pharmacovigilance)

B. Pharm. 8th (PCI)

Time : 3 Hours Max. Marks : 75

The candidates shall limit their answers precisely within the answer-book (40 pages) issued to them and no supplementary/continuation sheet will be issued.

SECTION - A
(Compulsory Question)

1. Attempt All the Questions.
   (a) Give full form of MedDRA.
   (b) What do you understand by Geriatrics?
   (c) What do you mean by ATC?
   (d) What is its objective of CIOMS in pharma industry?
   (e) How active surveillance differentiated from passive surveillance?
   (f) What do you mean by D&C act?
   (g) What is drug adherence?
   (h) When did pharmacovigilance programme start in India?
   (i) Write main components of Individual case safety report.
   (j) What are ADRs? (10×2=20)

SECTION - B (Long Answer)
(Attempt any 2 out of 3)

2. Write a detailed note on history and development of pharmacovigilance.

3. What are adverse events following Immunization? How it is important in Vaccine Safety Surveillance?
4. Write a detailed note safety data generation in Clinical phase and post approval phase. (2×10=20)

SECTION - C (Short Answer)
(Attempt any 7 out of 9)

5. What is CRO? Discuss functioning of CROs.
6. Write in detail about objectives and principles of MedDRA.
7. Discuss the scope of pharmacovigilance guidelines in pregnancy and lactation.
8. How will you classify the working groups of CIOMS ?
9. What do you know about ICH guidelines for pharmacovigilance?
10. What do you mean by cross sectional study and cohort study?
11. Discuss the role of communication in pharmacovigilance.
12. Write short notes on Sources of Individual case safety reports.
13. Discuss Eudravigilance in detail. (7×5=35)

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Question bank of Pharmacovigilance (BP805T)

1. Write about need of pharmacovigilance in present scenario.
2. Discuss the objectives and goals of PvPI.
3. Write a detail note on WHO international drug monitoring Programme.
4. Discuss the severity and seriousness assessment of ADR.
5. Discuss the predictability and preventability of ADR.
6. Write a note on Hartwig"s scale and its application.
7. Role of Pharmacist in management of ADRs.
8. Explain in detail the structure and function of PvPI.
9. Elaborate the methods in causality assessment for ADR.
10. Give detailed account on monitoring and reporting system on ADR.
11. Explain the methods for detection and reporting of ADR.
12. Write a note on ATC classification and coding on drugs.
13. Briefly discuss the international classification of disease.
14. Define daily defined dose and international non-proprietary names for drugs.
15. Give account on basic drug information resources and its types.
16. Write a note on specialized resources of ADR with examples.
17. Explain the applications ofMedDRA and standard MedDRA queries.
18. Write a note the scope and development of MedDRA.
19. Discuss in detail about CRO.
20. Outline the features of Eudravigilance-medical product dictionary.
21. Explain the minimum information to be furnished in case reporting form.
22. Explain the drug dictionaries and coding in pharmacovigilance.
23. Write in detail about various resources in pharmacovigilance.
24. Elaborate the establishment of pharmacovigilance program in hospital.
25. Discuss in detail about establishment and operation of drug safety department in pharmaceutical industry.
26. Explain how an effective communication in pharmacovigilance is established?
27. Differentiate between passive surveillance and active surveillance?
28. What are observational studies? Explain cross sectional study with an example?
29. Discuss the role of regulatory agencies in pharmacovigilance?
30. Write a detail note on WHO international drug monitoring Programme?
31. Describe the organization and objectives of International Conference on Harmonization.
32. Describe different factors affecting placental transfer of drugs. What are the various quality measures of drug prescribing in geriatric patients? Write in brief the drug safety evaluation in pediatric patients.
33. What do you mean by MedDRA? Explain in detail with its scope? Write different criteria of Post marketing surveillance (PMS). Mention different types of test available for safety pharmacology.
34. Discuss in detail about the history and development of Pharmacovigilance with the help of Thalidomide and Sulphanilamide tragedy?
35. Write a short note on Stimulated reporting, Registries and Sentinel sites?

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36. Write a short note on Cross- sectional study, case control study and cohort study.
37. Illustrate the Vaccine Safety Surveillance alongwith different types Pharmacovigilance method used for passive and active surveillance.
38. Define vaccine and Explain reason for vaccine failure.
39. List out factors affecting adverse effect of the vaccine.
40. Discuss PSUR.
41. Write about UMC.
42. Write about ICSR.
43. Illustrate the organization and objectives of ICH. Write ICH guidelines for expedited reporting.
44. Explore the pre-marketing and post-marketing clinical trials.
45. What isthe role of CDSCO in pharmacovigilance.
46. Discuss about drug safety evaluation in geriatrics and pediatrics population.
47. Discuss about drug safety evaluation inpregnancy and lactation.
48. Define CIOMS and explain CIOMS working group.
49. Explain genetics related ADRs with example.

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Subject: Pharmacovigilance Faculty: Sanyam Sharma Section:
Class: B. Pharmacy Semester: 8th

Sl.No.	Roll No.	Name	Date	1 17/01	2 18/01	3 19/01	T 4 20/01	5 20/01	6 25/01	7 27/01	T 8 27/01	9 31/01	10 01/02	11 02/02	T 12 03/02
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01	2001331400 2	Ravinder		1	1	2	3	4	5	6	7	8	9	9	10
02	2001331400 3	Abhay Sharma		1	2	3	4	4	4	5	6	7	7	8	9
03	2001331400 4	Abhay Sharma		1	1	2	2	3	4	4	5	5	6	7	8
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06	2001331400 7	Aneesh kumar		0	1	1	2	3	4	4	5	5	6	7	7
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08	2001331400 9	Anjali Sharma		1	2	3	4	5	6	6	7	8	9	9	10
09	2001331401 0	Ankita		1	2	2	3	4	4	5	6	7	8	9	9
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11	2001331401 3	Anurag Thakur		0	1	1	2	3	3	4	5	6	7	8	9
12	2001331401 4	Arya Sharma		1	1	2	3	4	5	6	7	7	8	9	10
13	2001331401 5	Ashish Patial		1	2	3	4	5	6	7	7	8	9	10	10
14	2001331401 6	Ayush Balihar		1	2	3	4	4	5	6	7	8	8	9	10
15	2001331401 7	Barkha		1	2	3	4	5	6	6	7	8	9	9	10
16	2001331401 8	Dikshit Rana		0	1	1	2	3	3	4	5	5	6	7	8
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21	2001331402 3	Karan Thakur		1	2	3	4	5	6	7	8	9	10	10	11
22	2001331402 4	Komal Choudhary		1	2	3	3	4	5	6	7	8	9	10	10
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24	2001331402 6	Mahender Singh		0	1	1	2	3	3	4	5	6	6	7	8
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Sl.No.	Roll No.	Name	Date	13 01/02	14 01/02	15 02/02	T 16 05/02	17 10/02	18 15/02	19 16/02	T 20 19/02	21 17/02	22 23/02	23 21/02	T 24 25/02
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30	2001331403 2	Nilika kumari		10	11	12	12	13	14	15	15	16	17	18	19

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Subject..... Faculty..... Section.....
Class..... Semestor.....

Sl.No.	Roll No.	Name	Date	1 17/01	2 18/01	3 19/01	4 20/01	5 24/01	6 25/01	7 27/01	8 28/01	9 31/01	10 01/02	11 02/02	12 03/02
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36	20013314039	Prafull		0	1	1	2	3	4	4	5	6	7	8	9
37	20013314040	Priya Suleja		1	1	2	3	3	4	4	5	5	6	7	8
38	20013314041	Priyanshu Sharma		0	1	2	3	4	4	5	6	7	7	8	9
39	20013314042	Rahul Thakur		1	1	2	3	4	4	5	6	7	8	8	9
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43	20013314046	Shivam Thakur		1	2	3	4	5	6	7	7	8	9	10	10
44	20013314047	Siya Rana		1	1	2	3	4	4	5	6	7	8	9	10
45	20013314048	Sourav Thakur		0	1	2	2	3	4	5	6	7	8	8	9
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48	20013314051	Tanvi Kapil		1	2	3	3	4	4	5	6	7	8	9	10
49	20013314052	Vikas		1	1	2	3	3	4	5	6	7	8	9	9
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53	21023314002	Anjana kumari		1	2	3	3	4	5	5	6	7	8	9	10
54	21023314003	Rajesh		0	1	1	2	3	4	4	5	6	7	7	8

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	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	
	28/02	29/02	13/03	14/03	15/03	16/03	20/03	21/03	22/03	23/03	25/03	1/03	27/03	03/04	04/04	05/04	06/04	08/04	12/04	15/04	24/04	29/04	29/04		
31	19	20	21	22	23	24	25	26	27	28	29	30	1	32	33	34	35	36	38	39	40	41	42	43	31
32	19	20	21	22	22	23	24	25	26	27	28	29	30	31	32	33	34	36	37	38	39	40	41	42	32
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54	19	20	21	22	23	24	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	54

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	49	50	51	52	53	54	55	56	57	58	59	61	62	63	64	65
	25/04	26/04	27/04	21/04	04/05	04/05										
31	44	45	46	47	48	49										
32	43	44	45	46	47	48										
33	43	44	45	46	47	48										
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35	45	46	47	48	49	50										
36	44	45	46	47	48	49										
37	44	45	46	47	48	49										
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42	44	45	46	47	49	50										
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46	43	44	45	46	47	48										
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52	45	46	47	48	49	50										
53	45	46	47	48	49	50										
54	42	43	44	45	46	47										

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1st Sessional Examination March (2024)

B. Pharmacy 8th Sem

Subject: Pharmacovigilance (BP-805T)

Time allowed: 1:30 hours Max. Mark's: 30

Note: i. Section A is compulsory.

ii. Attempt any two questions from Section B.

iii. Attempt any one questions from Section C.

Section-A (10×1=10)

Q.1 a) Define PvPI.

b) Define INN.

c) Define WHOADR.

d) Define Eudravigilance.

e) Define CROs.

f) Define vaccine failure.

g) Define Spontaneous reporting.

h) Differentiate ADR & ADE

i) Enlist methods of causality assessment.

j) Enlist basic drug 8information resources in Pharmacovigilance

Section-B (2x5=10)

Q.2 a) Define MedDRA & give its classification with example.

b) Write down specialize resources for ADRs.

c) Define AEFI & classify them.

Section-C (1×10= 10)

Q.3 a) Write down history and development of Pharmacovigilance in detail.

b) Define ATC classification of drug and write down classification of ADRs.

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2nd Sessional Examination April (2024)

B. Pharmacy 8th Sem

Subject: Pharmacovigilance (BP-805T)

Time allowed: 1:30 hours **Max. Mark's: 30**

Note: i. Section A is compulsory.

ii. Attempt any two questions from Section B.

iii. Attempt any one questions from Section C.

Section-A (10×1=10)

Q.1 a) Define GCP.

b) Define PSUR.

c) Define ICSR.

d) Define registries.

e) Define stimulated reporting.

f) Define passive surveillance.

g) Define cross-sectional study.

h) Define expedited reporting.

i) Define schedule Y in D&C act.

j) Enlist the role of communication in pharmacovigilance.

Section-B (2x5=10)

Q.2 a) Define CIOMS and classify its working groups.

b) Define CDSCO and write down its functions.

c) Define ICH and write down its guidelines for pharmacovigilance.

Section-C (1×10= 10)

Q.3 a) Write down drug safety evaluation in geriatrics, pregnancy and lactation in detail.

b) Write a detailed note on safety data generation in clinical phase and post approval phase.

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3rd Sessional Examination May (2024)

B. Pharmacy 8th Sem

Subject: Pharmacovigilance (BP-805T)

Time allowed: 1:30 hours **Max. Mark's: 30**

Note: i. Section A is compulsory.

ii. Attempt any two questions from Section B.

iii. Attempt any one questions from Section C.

Section-A (10×1=10)

Q.1 a) Define Passive surveillance.

b) Define ICD.

c) Define WHO drug dictionary.

d) Define Vaccine Pharmacovigilance.

e) Define CROs.

f) Define Cohort study.

g) Define PSUR.

h) Define PMS.

i) Define Pediatrics.

j) Define schedule Y in D&C act.

Section-B (2x5=10)

Q.2 a) Define MedDRA & give its classification with example.

b) Define CIOMS and classify its working groups.

c) Define AEFI & classify them.

Section-C (1×10= 10)

Q.3 a) Write a detailed note on safety data generation in Pre-clinical phase and clinical phase.

b) Write down history and development of Pharmacovigilance in detail.

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Gautam College of Pharmacy Hamirpur (H.P)-177001
Award Sheet (Theory) B. Pharmacy VIIIth semester
(Session January 2024 – April 2024)

Name of Subject. Pharmacovigilance Subject Code BP.805.T..... Teacher: Shivani Sharma

Sr. No.	Name of Student	University Roll No.	I Marks obtained/ 15	II Marks obtained/ 15	III Marks obtained/ 15	Avg. of best two out of 15
1.	RAVINDER KUMAR	20013314002	08	09	—	09
2.	ABHAY SHARMA	20013314003	08	11	—	10
3.	ABHAY SHARMA	20013314004	10	11	—	11
4.	AMAN KUMAR	20013314005	11	10	—	11
5.	AMANJEET THAKUR	20013314006	05	08	11	10
6.	ANEESH KUMAR	20013314007	03	0	10	07
7.	ANIRUDH SHARMA	20013314008	09	1	12	11
8.	ANJALI SHARMA	20013314009	11	12	—	12
9.	ANKITA	20013314010	11	09	—	10
10.	ANUJ SHARMA	20013314011	05	08	12	10
11.	ANURAG THAKUR	20013314013	08	08	—	08
12.	ARUN SHARMA	20013314014	08	08	—	08
13.	ASHISH PATIAL	20013314015	15	14	—	14
14.	AYUSH BALIHAR	20013314016	06	11	—	09
15.	DEEPIKA	20013314017	14	15	—	15
16.	DIKSHIT RANA	20013314018	05	08	11	10

17.	DIPALI THAKUR	20013314019	13	09	—	11
18.	HARSH ROUHAN	20013314020	05	11	—	08
19.	ISHA	20013314021	09	09	—	09
20.	JYOTI SHARMA	20013314022	10	12	—	11
21.	KARAN THAKUR	20013314023	08	11	—	10
22.	KOMALCHOUDHARY	20013314024	11	11	—	11
23.	KRITIKA SHARMA	20013314025	11	12	—	12
24.	MAHENDER SINGH	20013314026		Ab		
25.	MANISHA	20013314027	13	Ab	—	07
26.	MOHIT SHARMA	20013314028	08	Ab	12	10
27.	MOHIT SHARMA	20013314029	15	15	—	15
28.	MUSKAN	20013314030	15	14	—	15
29.	NAVEEN SHARMA	20013314031	03	10	—	07
30.	NITIKA KUMARI	20013314032	01	Ab	13	07
31.	NITIN KAUNDAL	20013314033	Ab	Ab	13	07
32.	OM	20013314034	Ab	Ab	13	07
33.	PARMOD KUMAR	20013314035		Absent		
34.	PAYAL RANA	20013314036	15	15	—	15
35.	POORNIMA	20013314038	11	10	—	11
36.	PRAFUL	20013314039	01	Ab	12	07

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37.	PRIYA GULERIA	20013314040	14	Ab	15	15
38.	PRIYANSHU SHARMA	20013314041	04	08	11	10
39.	RAHUL THAKUR	20013314042	04	05	11	08
40.	ROHIT CHAUHAN	20013314043	02	05	11	08
41.	SAHIL KUMAR	20013314044	03	05	10	08
42.	SHIVAM	20013314045	05	08	08	08
43.	SHIVAM THAKUR	20013314046	10	10	—	10
44.	SIYA RANA	20013314047	08	10	12	11
45.	SOURAV THAKUR	20013314048	03	Ab	10	07
46.	SUMIT THAKUR	20013314049	05	09	10	10
47.	TANUJ KUMAR	20013314050	04	0	09	07
48.	TANVI KAPIL	20013314051	06	08	11	10
49.	VIKAS	20013314052	06	08	12	10
50.	ABHISHEK	21023314001	10	11	—	11
51.	ANJNA KUMARI	21023314002	09	13	—	11
52.	RAJESH KUMAR	21023314003	08	08	—	08
53.	AFTAB POSWAL	20012614003	08	10	—	09
54.	NAMRATA	20013214027	08	10	—	09
Signature of Subject Incharge			Shivani Sharma	Shivani Sharma	Shivani Sharma	Shivani Sharma

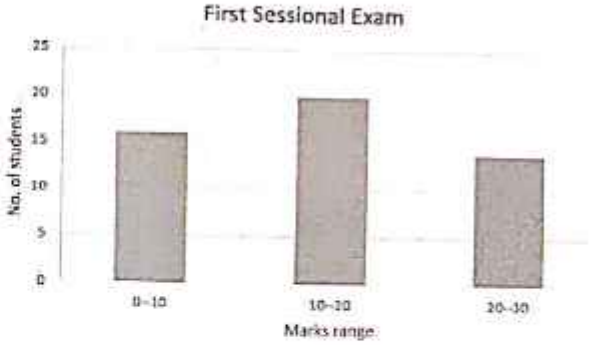
Signature of Examination Incharge

Signature of Academics Incharge

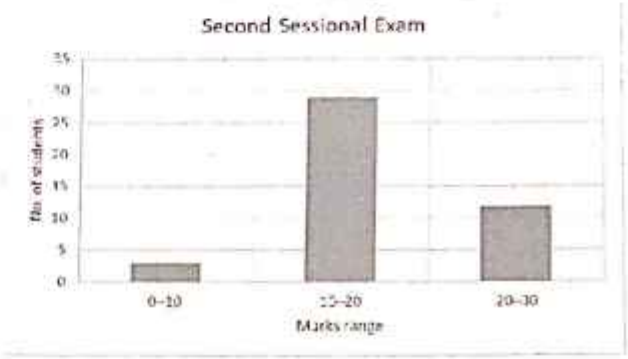
Signature of Director

Internal Exam Result and Result Analysis

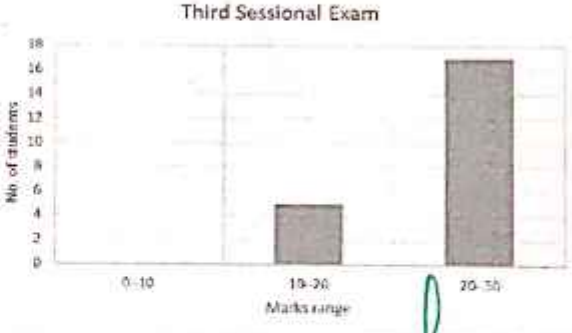
1st Sessional Exam Total number of students: 54 Present: 50 Absent:04	
Range of marks	No of students
0-10	16
11-20	20
20-30	14



2nd Sessional Exam Total number of students: 54 Present: 44 Absent: 10	
Range of marks	No of students
0-10	03
11-20	29
20-30	12



3rd Sessional Exam Total number of students: 22 Present: 22 Absent: 00	
Range of marks	No of students
0-10	0
11-20	05
20-30	17



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Gautam College of Pharmacy

Submitted to
Mrs. Shivani

10/10

Submitted by
Mr. Mohit Sharma
Course – Bpharmacy
Sem – 8th
Roll.no – 2001331402 9

Topic – Basic Terminology used in Pharmacovigilance

Shivani sharma
18/03/24

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Date –

Absolute Risk :—

Risk in a population of exposed person; The probability of an event affecting members of a particular population (e.g. 1 in 1000). Absolute risk can be measured over time (Incidence) or at a given time (Prevalance)

Adverse Events :—

Any untoward medical occurance that may present during the treatment with a pharmaceutical product but which does not have nessarily have a causal relationship with this treatment

Allopathy :—

Non-traditional, western scientific Therapy usually using synthesized ingredients, but may also contain a purified active ingredients extracted from a plant or other natural source

Association

Events associated in time but not necessarily linked as cause and effect Or Association of one effect & another effect

Tuberculosis → 1° effect Diuretic → Associated effect → Low B.P.

Attributable Risk or

Diff. b/w the risk in exposed population (absolute risk) & risk in an unexposed population.

Benefit :— Estimated gain for an individual or a population

Benefit-risk analysis :—

It refers to examination of favourable (beneficial) & unfavourable result of undertaking a specific course of action

(Compliance) – Mean & [illegible] adherence to prescriber's instruction

Control group

Comparison group in drug – trials not beings given the studied drug.

Cohort Event Monitoring

Is an active surveillance tool that is used to monitor & document ADR's experienced by patients who have been enrolled to investigate the effect of prescribed medication

Phocomelia

A rare congenital deformity in which the hands or feet are attached close to the trunk. The limbs were underdeveloped or absent

→ This is the side effect of Thalidomide taken during early Pregnancy

Phyto therapy –

Phyto + therapy
Plant ↳ Treatment

→ Scientific treatment using plant extract or material's

Placebo –

An inactive substance (called a sugar pill) given to a group being study to compare results with effect of active drug.

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Poly pharmacy :-

Use of more than 1 drug, some time prescribed by different practioners

Post - marketing

The stage when a drug is generally available in the market

Pre - disposing factors

Any aspect of patient history (other than the drug) whose explain reported adverse event (genetic factor, diet, Alc consump: Disease history polypharmacy or use of herbal medicine)

Prescription event Monitoring

System created to monitor ADR in a population. Prescribed are requested to report all events, regardless of whether they are suspected ADR for identified patient receiving a specified drug or (convent event monitoring)

POM (Prescription drug monitoring)

Medicinal product available to public only on prescription

Prevalance :- No of existing case in a defined population at a given point in a time.

Prophylaxis :- Prevention are protective

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Biological Products :-

Medical Product prepared from biological material of human, animal or microbiological origin (such as blood product, Vaccine, Insulin)

Causal Relationship :-

Means
↳ a relationship b/w one phenomenon or event (A) and another (B) in which A precedes & causes B

↳ Eg PV :- A medicine caused AR

Syn- Causality

Causality assesment :- It is a method used for estimating the strength of relationship b/w drug exposure & occurrence of ADR

Caveat Document

Comflow

Software developed by UMC for

- collection
- Analysis of data
- Incoherent Event monitoring

Cohort Event Monitoring

It is study of events that occurs during the use of modern

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Compliance :- Mean's patient's adherence to prescriber's instruction

Control group

Comparison group in drug - Individuals not being given the studied drug.

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⇒ Scientific treatment using plant extract or materials

Placebo :-

An inactive substance (called a sugar pill) given to a group being study to compare results effect of active drug.

Vigi Base

The name of WHO ICSR Database
Global

Vigiflow – ICSR Management System
↓
Created & Maintained
by UMC

→ It is used for Report analysis & facilate sending report to vigibase

WHO-ART Terminology for coding Clinical information in relation to drug therapy

↓
maintained by UMC

Vigimed :- Allows rapid exchange of Information and opinion on drug safety matters around the world as well as UMC NPC

Vigisearch

- A Search service for accessing ICSR Stored in vigibase database offered by UMC to National PV centre & other third part enquirers

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Page No. _____ | Date: / /20

GAUTAM COLLEGE OF PHARMACY

HAMIRPUR

TOPIC — Basic Terminologies Used In Pharmacovigilance.

SUBJECT — Pharmacovigilance.

SUBMITTED BY

ANUJ SHARMA
B.Pharm 8th Sem
2001331401 11

SUBMITTED TO

MRS. SHIVANI SHARMA.

Shivani Sharma
18/03/24

07/10

Director cum Principal
Gautam College of Pharmacy
Hamirpur (H.P.)

Teacher's Remarks:

Teacher's Signature _____

Chitra

BASIC TERMINOLOGIES USED IN PHARMACOVIGILANCE

ABSOLUTE RISK – Risk in a population of exposed persons, the probability of an event affecting members of a particular population (e.g 1 in 1,000) absolute risk can be measured over time or at a given time

ADVERSE EVENT :- It can also be called as adverse experiences Any unintended, untoward or un-expected, medical incidence, clinical investigation undergoing in a patient administered with the medical drug, which might or might not necessarily have any casual relationship with the drug.

ADVERSE DRUG REACTION (ADR) – As per WHO, adverse drug rexn can be defined as any response to a drug which is noxious and unintended & which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of or afor the modification of physiological function.

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ASSOCIATION :- Events associated in time but not necessarily linked as cause and effect.

BENEFIT RISK ANALYSIS — It refers to examination favourable (beneficial) and unfavourable results a specific course of action.

BIOLOGICAL PRODUCT — medical product prepared biological material of human, insulin, animal & microbiological origin (such as blood product, vaccine

CAUSALITY ASSESSMENT — The evaluation of the likelihood that a medicine was the causative agent of an observed adverse reaction. Causality assessment is usually made according established algorithms.

CAUSAL RELATIONSHIP — It means a relationship b/w one phenomenon or event (A) & another (B) in which precedes and cause B. In pharmacovigilance — a medicine causing an adverse rxn.

CEM FLOW — Software developed by UMC for collection & analysis of data in cohort event monitoring.

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VIGI BASE — The name of the WHO Global ICSR Data base is called Vigi Base.

VIGIMED — Share point based conferencing facility exclusive to member countries of the WHO Programme for international drug monitoring for fast communication of topical pharmacovigilance issues.

VIGIFLOW — It is Complete ICSR management system create and maintained by UMC. It is web based & build to adhere to the ICH E2B standard. It can be used the national data base for Countries in the WHO as it incorporates tools for report analysis & facilitates sending reports to Vigi Base.

VIGIMINE — A statistical tool within Vigisearch with statistical material calculated for all drug AUR (combinations) available in Vigi Base. The main include the disproportionality measure (IC value) in different ways & useful filter capabilities

VIGISEARCH — A search service for accessing ICSR stored in the vigibase database offered by the UMC to national pharmacovigilance centres & other third party inquiries

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WHO – ART – This is the terminology for coding clinical information in relation to drug therapy. WHO ART is maintained by UMC.

PANI – FLOW – Software developed by UMC for collection and analysis of data in relations of vaccination in the pandemic situation.

Rechallenge – It is a point at which the recipient administered repeats a medicine once the previous dose is extracted out.

Dechallenge – It indicates the withdrawl of a drug from patient. It is that condition at which the adverse effects might disappear, get reduced, or the continuity might get broken down.

INDIVIDUAL CASE SAFETY REPORT (ICSR) –

It is a document containing complete information associated to an individual case. This is provided by a primary source to describe alleged adverse reactions related to the administration of one or more medicinal products to a particular patient at a certain point of time.

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Teacher's Signature _____

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Hanamkonda (H.D.)

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PRESCRIPTION ONLY MEDICINE (POM)

The Therapeutic drug or medicinal product becomes available to the public only on showing prescription.

SERIOUS ADVERSE EVENT OR REACTION —

It can be defined as any unintended or untoward medical intervention at any dose resulting in significant disability or life threatening death.

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Teacher's Remarks:

Teacher's Signature _____

CO/PO AND CO/PO MAPPING:

SESSIONAL EXAM -1					
Code: BP-805T Subject: PHARMACOVOGILANCE Semester: 8 MM:30					
Date: March-2024 Duration: 1:30 hrs Staff: Mrs. SHIVANI SHARMA					
Q.No.		Marks	CO	BL	PO
	Answer any 1				
1	Write down history and development of Pharmacovigilance in detail.	10	BP805T.1	L1, L2 & L4	PO1, PO6 & PO11
2	And Define ATC classification of drugn and write down classification of ADRs	10	BP805T.1	L1 & L2	PO1, PO6 &PO11
	Answer any 2				
1	Define MedDRA & give its classification with example.	5	BP805T.1	L1 & L2	PO1, PO6 &PO11
2	Write down specialize resources for ADRs.	5	BP805T.1	L1 & L2	PO1, PO6 &PO11
3	Define AEFI & classify them.	5	BP805T.3	L1, L2 & L3	PO1, PO4, PO6 &PO11
	Attempt all				
1	Short ans questions	1	BP805T.1, BP805T.3,	L1, L2 & L3	PO1,PO3, PO4, PO6 &PO11

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CO-Course Outcome:

BP805T.1	Students have to learn about Basic terminologies of Pharmacovigilance.
BP805T.3	Students learn about the Adverse drug reactions.

PO-Programme Objectives:

1.	Pharmacy Knowledge	7.	Pharmacological Ethics
2.	Planning Abilities	8.	Communication
3.	Problem Analysis	9.	The Pharmacist & Society
4.	Modern Tool Usage	10.	Environment &Sustainability
5.	Leadership Skill	11.	Life Long Learning
6.	Professional Identity		

CO/PO ATTAINMENTS

CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO 11
BP805T.1	3	-	3	3	-	3	-	-	-	-	3
BP805T.2	3	-	3	3	-	3	-	-	-	-	3
BP805T.3	3	-	-	-	-	3	-	-	-	-	3
BP805T.4	3	-	-	-	-	3	-	-	-	-	3

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AttainmentofPO's

CourseoutcomemappingwithProgramoutcome(PO)

PO1		Level of Mapping	PO's Assessment	PO's Attainment
CO1	83	3	90%	Yes
CO2	93	3		
CO3	94	3		
CO4	90	3		
PO3				
CO1	83	3	88%	Yes
CO2	93	3		
CO3	00	0		
CO4	00	0		
PO4				
CO1	83	3	88%	Yes
CO2	93	3		
CO3	00	0		
CO4	00	0		
PO6				
CO1	83	3	90%	Yes
CO2	93	3		
CO3	94	3		
CO4	90	3		
PO11				
CO1	83	3	90%	Yes
CO2	93	3		
CO3	94	3		
CO4	90	3		

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Note: Correlation levels 1, 2 or 3 as defined below: 1: Slight (Low) 2: Moderate (Medium)

3: Substantial (High) '--' Indicates there is no correlation.

CO/POAttainments

Attainments of POs and COs for First Sessional

TableNo.1Assessmentof course outcome

CourseOutcome	CO1		CO2		CO3		CO4	
	Q	Avg.%	Q	Avg.%	Q	Avg.%	Q	Avg.%
Measure	Q1	-	Q1	-	Q1	97	Q1	-
	Q2	83	Q2	-	Q2	-	Q2	-
	Q3	-	Q3	98	Q3	-	Q3	-
	Q4	-	Q4	92	Q4	-	Q4	-
	Q5	75	Q5	-	Q5	90	Q5	-
	Q6	90	Q6	90	Q6	-	Q6	90
Total Average		83		93		94		90

Mechanism for the attainment of CO:

The student performance in continuous assessment exams is verified for each question.

$$CO\ Assessment\ (Direct) = \frac{\text{Number of students reached in answering the question}}{\text{Number of students attempted the question}}$$

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***PO'sAttainment=morethan 70%=Yes,Lessthan 70%=No**

PO1 Direct Assessment = $\frac{\Sigma(\text{level of mapping of PO with CO} \times \text{Average of CO attainment})}{\Sigma(\text{level of Mapping of PO with CO})}$

PO'sAssessment=446/5=89%

SESSIONAL EXAM -2					
Code: BP805T	**Subject: PHARMACOVIGILANCE**		**Semester: 8**		**MM:30**
Date: April-2024	**Duration: 1:30 hrs**			**Staff: Mrs. SHIVANI SHARMA**	
Q.No.		**Marks**	**CO**	**BL**	**PO**
	Answer any 1				
1	Write down drug safety evaluation in geriatrics, pregnancy and lactation in detail.	10	BP-805T.3	L1, L2,L3 & L4	PO1, PO3, PO4, PO6 & PO11
2	Write a detail note on safety data generation in clinical phase and post approval phase.	10	BP-805T.1	L1, L2,L3 & L4	PO1, PO3, PO4, PO6 & PO11
	Answer any 2				
1	Define CIOMS and classify its working group.	5	BP-805T.2	L1, L2,L3 & L4	PO1, PO3, PO4, PO6 & PO11
2	Define CDSCO and write down its functions.	5	BP805T.3	L1 & L2	PO1, PO6 &PO11
3	Define ICH and write down its guidelines for pharmacovigilance.	5	BP805T.3	L1, L2,L3 & L4	PO1, PO3, PO4, PO6 & PO11
	Attempt all				
1	Short ans questions	1	BP805T.1, BP805T3, BP805T.2	L1, L2,L3 & L4	PO1, PO3, PO4, PO6 & PO11

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CO-Course Outcome:

BP805T.2	Know about information resources in pharmacovigilance.
BP805T.3	Students learn about the Vaccine safety surveillance.
BP805T.5	Student learn about the Safet data generation.

PO-Programme Objectives:

7.	Pharmacy Knowledge	7.	Pharmacology Ethics
8.	Planning Abilities	8.	Communication
9.	Problem Analysis	9.	The Pharmacist & Society
10.	Modern Tool Usage	10.	Environment &Sustainability
11.	Leadership Skill	11.	Life Long Learning
12.	Professional Identity		

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CO/PO ATTAINMENTS

CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO 11
BP805T.1	3	-	3	3	-	3	-	-	-	-	3
BP805T.2	3	-	3	3	-	3	-	-	-	-	3
BP805T.3	3	-	3	3	-	3	-	-	-	-	3
BP805T.4	3	-	3	3	-	3	-	-	-	-	3

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Note: Correlation levels 1, 2 or 3 as defined below: 1: Slight (Low) 2: Moderate (Medium)

3: Substantial (High) '--' Indicates there is no correlation.

Attainments of POs and COs for Second Sessional

TableNo.1Assessmentof courseoutcome

CourseOutcome	CO1		CO2		CO3		CO4	
	Q	Avg.%	Q	Avg.%	Q	Avg.%	Q	Avg.%
Measure	Q1	85	Q1	-	Q1	-	Q1	85
	Q2	93	Q2	93	Q2	-	Q2	93
	Q3	97	Q3	97	Q3	-	Q3	97
	Q4	-	Q4	-	Q4	93	Q4	-
	Q5	94	Q5	94	Q5	-	Q5	94
	Q6	97	Q6	97	Q6	97	Q6	97
Total Average		93		95		95		93

Mechanism for the attainment of CO:

The student performance in continuous assessment exams is verified for each question.

$$CO\ Assessment\ (Direct) = \frac{\text{Number of students reached in answering the question}}{\text{Number of students attempted the question}}$$

AttainmentofPO's

CourseoutcomemappingwithProgramoutcome(PO)

PO1		Level ofMapping	PO's Assessment	PO's Attainment
CO1	93	3	94%	Yes
CO2	95	3		
CO3	95	3		
CO4	93	3		
PO3				
CO1	93	3	94%	Yes
CO2	95	3		
CO3	95	3		
CO4	93	3		
PO4				
CO1	93	3	94%	Yes
CO2	95	3		
CO3	95	3		
CO4	93	3		

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PO6				
CO1	93	3	**94%**	**Yes**
CO2	95	3		
CO3	95	3		
CO4	93	3		
PO11				
CO1	93	3	**95%**	**Yes**
CO2	95	3		
CO3	95	3		
CO4	97	3		

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PO1 Direct Assessment = $\frac{\Sigma(\text{level of mapping of PO with CO} * \text{Average of CO attainment})}{\Sigma(\text{level of Mapping of PO with CO})}$

***PO'sAttainment=morethan 70%=Yes,Lessthan 70%=No**

PO'sAssessment=470 / 5=94%

SESSIONAL EXAM -3					
Code: BP805T	**Subject: PHARMACOVIGILANCE Semester: 8 MM:30**				
Date: May 2024	**Duration: 1:30 hrs**			**Staff: Mrs. SHIVANI SHARMA**	
Q. No.		**Marks**	**CO**	**BL**	**PO**
	Answer any 1				
1	Write a detail note on safety data generation Pre-clinical and clinical phases.	10	BP-805T.1	L1, L2,L3 & L4	PO1, PO3, PO4, PO6 & PO11
2	Write down history and development of pharmacovigilance in detail	10	BP-805T.3	L1, L2,L3 & L4	PO1, PO3, PO4, PO6 & PO11
	Answer any 2				
1	Define MedDRA & give its classification with example.	5	BP-805T.1	L1, L2,L3 & L4	PO1, PO3, PO4, PO6 & PO11
2	Define CIOMS and classify its working group.	5	BP805T.2	L1 & L2	PO1, PO6 &PO11
3	Define AEFI & classify them.	5	BP805T.3	L1, L2,L3 & L4	PO1, PO3, PO4, PO6 & PO11
	Attempt all				
1	Short ans questions	1	BP805T.1, BP805T2, BP805T.3	L1, L2,L3 & L4	PO1, PO3, PO4, PO6 & PO11

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CO-Course Outcome:

BP805T.1	Students learn about ICH Guidelines for Pharmacovigilance.
BP805T.2	Know about Pharmacovigilance methods
BP805T.3	Students learn about the Drug safety evaluation in special population.
BP805T.5	Student learn about the CDSCO

PO-Programme Objectives:

1.	Pharmacy Knowledge	7.	Pharmacology Ethics
2.	Planning Abilities	8.	Communication
3.	Problem Analysis	9.	The Pharmacist & Society
4.	Modern Tool Usage	10.	Environment &Sustainability
5.	Leadership Skill	11.	Life Long Learning
6.	Professional Identity		

CO/PO ATTAINMENTS

CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO 11
BP805T.1	3	-	3	3	-	3	-	-	-	-	3

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BP805T.2	3	-	3	3	-	3	-	-	-	-	3
BP805T.3	3	-	3	3	-	3	-	-	-	-	3
BP805T.4	3	-	3	3	-	3	-	-	-	-	3

Note: Correlation levels 1, 2 or 3 as defined below: 1: Slight (Low) 2: Moderate (Medium)

3: Substantial (High) '--' Indicates there is no correlation.

Attainments of POs and COs for Second Sessional

TableNo.1Assessmentof courseoutcome

CourseOutcome	CO1		CO2		CO3		CO4	
	Q	Avg.%	Q	Avg.%	Q	Avg.%	Q	Avg.%
Measure	Q1	85	Q1	-	Q1	-	Q1	85
	Q2	93	Q2	93	Q2	-	Q2	93
	Q3	97	Q3	97	Q3	-	Q3	97
	Q4	-	Q4	-	Q4	93	Q4	-
	Q5	94	Q5	94	Q5	-	Q5	94
	Q6	97	Q6	97	Q6	97	Q6	97
Total Average		93		95		95		93

Mechanism for the attainment of CO:

The student performance in continuous assessment exams is verified for each question.

$$CO\ Assessment\ (Direct) = \frac{\text{Number of students reached in answering the question}}{\text{Number of students attempted the question}}$$

AttainmentofPO's

CourseoutcomemappingwithProgramoutcome(PO)

PO1		Level of Mapping	PO's Assessment	PO's Attainment
CO1	93	3	94%	Yes
CO2	95	3		
CO3	95	3		
CO4	93	3		
PO3				
CO1	93	3	94%	Yes
CO2	95	3		
CO3	95	3		
CO4	93	3		

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PO4				
CO1	93	3	**94%**	**Yes**
CO2	95	3		
CO3	95	3		
CO4	93	3		
PO6				
CO1	93	3	**94%**	**Yes**
CO2	95	3		
CO3	95	3		
CO4	93	3		
PO11				
CO1	93	3	**94%**	**Yes**
CO2	95	3		
CO3	95	3		
CO4	93	3		

***PO'sAttainment=morethan 70%=Yes,Lessthan 70%=No**

PO1 Direct Assessment = $\frac{\Sigma(\text{level of mapping of PO with CO} * \text{Average of CO attainment})}{\Sigma(\text{level of Mapping of PO with CO})}$

PO'sAssessment=470 / 5=94%

24. Faculty Feedback: APPENDIX

Shivani Sharma Shivani Sharma

NAME AND SIGN OF FACULTY **HOD** **PRINCIPAL**

Principal
Gautam College of Pharmacy
Hamirpur (H.P.)