The West Bengal University of Health Sciences



WBUHS

PHARMACOLOGY LOGBOOK

for

2nd Phase MBBS students
As per competency based curriculum

Objectives of the Logbook

The logbook in individual disciplines is a mandatory component of the revised MBBS curriculum. To maintain uniformity of structure and standards the University provides this structured logbook to all registered students. The logbook may carry 10 marks weightage in the university final examination.

- 1) The logbook will be a record of the curricular / co-curricular activities of the designated student, who will be responsible for maintaining his / her logbook.
- 2) The logbook will be used to maintain a record of:
 - a. Overall participation & performance in various curricular and co-curricular activities.
 - b. Participation in small group discussion sessions.
 - c. Participation in practical demonstrations (DOAP sessions), skill lab sessions, adverse drug reaction (ADR) reporting sessions, and other procedural skills training.
 - d. Participation in attitude-ethics-communication (AETCOM) sessions.
 - e. Self-directed learning undertaken.
 - f. Record of completion of other pre-determined activities such as ward rounds under faculty supervision.
 - g. Acquisition of certifiable skills (procedural competencies).
 - h. Participation in any co-curricular activities with relevance to pharmacology training such as student seminars, poster presentations, real-world patient / caregiver counselling, etc.
- 3) The student is responsible for getting the entries in the logbook verified and the competencies certified by the faculty in-charge regularly.
- 4) Entries in the logbook will reflect the activities undertaken both within and outside the department (such as in wards, outdoor clinics, vaccination clinics, etc.) and the competencies acquired and as such will have to be scrutinized and endorsed by the head of the department before presentation to university external examiners during the Final Examination.
- 5) Even after the Final Examination the logbook will have to be preserved carefully by the student till completion of the entire MBBS course since it may be required for cross-verification later.

Personal details of the student

Name and address of the college

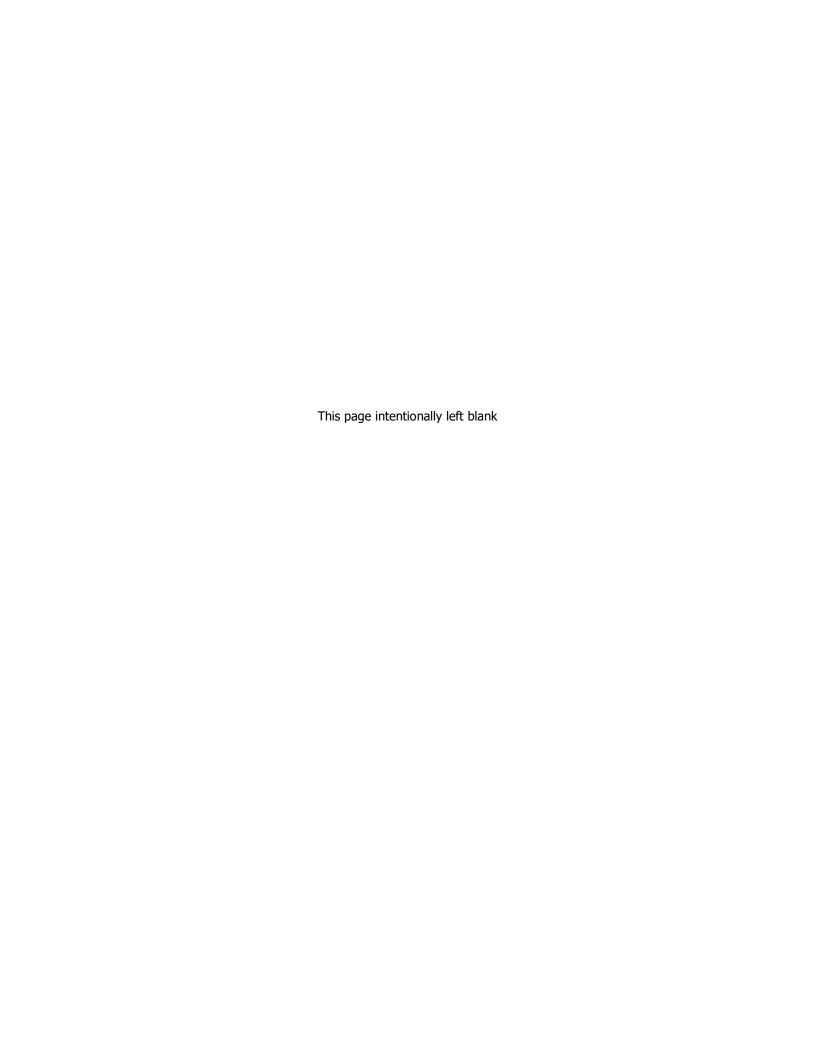
Name of the student	
Date of birth	
Date of admission to MBBS Course	
Date of beginning of the Second Phase	
Reg: No. (College ID)	
Reg. No. (University ID)	
Permanent Address	
Present Address	
E mail ID: (optional)	
Mobile Number: (optional)	
Specimen signature	

Competencies to be covered through the practical part of the curriculum

PH1.6	Describe principles of pharmacovigilance & adverse drug reaction reporting systems.
PH1.7	Define, identify, and describe the management of adverse drug reaction.
PH1.8	Identify and describe the management of drug interactions.
PH1.9	Describe nomenclature of drugs i.e. generic, branded drugs.
PH1.0	Describe parts of a correct, complete, and legible generic prescription. Identify errors in prescription and correct appropriately.
PH1.12	Calculate the dosage of drugs using appropriate formulae for an individual patient, including children, elderly, and patients with renal dysfunction.
	SKILLS: Clinical Pharmacy
PH2.1	Demonstrate understanding of the use of various dosage forms (oral/local/parenteral; solid/liquid).
PH2.2	Prepare oral rehydration solution from ORS packet and explain its use.
PH2.3	Demonstrate the appropriate setting up of an intravenous drip in a simulated environment.
PH2.4	Demonstrate the correct method of calculation of drug dosage in patients including those used in special situations.
	SKILLS: Clinical Pharmacology
PH3.1	Write a rational, correct, and legible generic prescription for a given condition and communicate the same to the patient.
PH3.2	Perform and interpret a critical appraisal (audit) of a given prescription.
PH3.3	Perform a critical evaluation of the drug promotional literature.
PH3.4	To recognize and report an adverse drug reaction.
PH3.5	To prepare and explain a list of P-drugs for a given case/condition.
PH3.6	Demonstrate how to optimize interaction with pharmaceutical representative to get authentic information on drugs.
PH3.7	Prepare a list of essential medicines for a healthcare facility.
PH3.8	Communicate effectively with a patient on the proper use of prescribed medication.
	SKILLS: Experimental Pharmacology
PH4.1	Administer drugs through various routes in a simulated environment using mannequins.
PH4.2	Demonstrate the effects of drugs on blood pressure (vasopressor and vasodepressors with appropriate blockers) using computer aided learning.
	SKILLS: Communication (Pharmacology)
PH5.1	Communicate with the patient with empathy and ethics on all aspects of drug use.
PH5.2	Communicate with the patient regarding optimal use of a) drug therapy b) devices c) storage of medicines.
PH5.3	Motivate patients with chronic diseases to adhere to the prescribed management.
PH5.4	Explain to the patient the relationship between cost of treatment and patient compliance.
PH5.5	Demonstrate an understanding of the caution in prescribing drugs likely to produce dependence and recommend the line of management.
PH5.6	Demonstrate ability to educate public & patients about various aspects of drug use including drug dependence and OTC drugs.

Index

Item	Page
Section 1. Clinical Pharmacy	
•	7
A. Dosage forms / Drug delivery devices	7
B. Oral rehydration salts / solution (ORS)	13
C. Pharmaceutical calculations	15
Section 2. Clinical Pharmacology	
A. Prescribing / Prescription review	19
B. Adverse drug reactions and Drug interactions	27
C. Drug promotional literature	35
D. Rational use of medicines	38
Section 3. Experimental Pharmacology	
Experimental pharmacology through computer aided learning (CAL) / Charts	41
Section 4. Attitude-Ethics-Communication (AETCOM)	45
Section 5. Self-directed learning including case scenario based learning through ward rounds / clinic visits	49
Certification of attainment of competencies through practical training	54
Certification of attainment of certifiable skills through practical training	55
Record of other co-curricular activities	55



Section 1. Clinical Pharmacy A. Dosage forms and drug delivery devices

By the end of this module the student must have acquired knowledge and skills pertaining to:

- Medicine label.
- Generic versus branded medicines.
- Enumerating the diversity of dosage forms and drug delivery devices.
- Use of oral solid dosage forms.
- Use of oral liquid dosage forms.
- Use of inhalational drug delivery.
- Use of injections, infusions and implants.
- Use of topical dosage forms.
- Setting up IV infusion.
- Setting up blood transfusion.
- Administration of oxygen.

Carefully remove the label from an expired medicine pack / container of a prescription-only medicine in India and stick it here. Note the various elements in the medicine label.		
Compare and contrast Generic versus Brande		
Generic medicine	Branded medicine	

Enumerate the diversity of dosage forms and	drug delivery devices here.
	L
Draw a schematic diagram of a transdermal	therangutic system (transdermal natch)
Draw a schematic diagram of a transactman	incrapeutic system (transacrinal paten).

Note down the steps in use of the following dosage forms

Metered dose inhaler	Rotahaler [®]
Subcutaneous injection	Intramuscular injection

Note down the steps in use of the following dosage forms

Intravenous injection	Intradermal injection
For door / statement	Paul Julius
Eye drop / ointment	Ear drop
Eye drop / ointment	Ear drop
Eye drop / ointment	Ear drop
Eye drop / ointment	Ear drop
Eye drop / ointment	Ear drop
Eye drop / ointment	Ear drop
Eye drop / ointment	Ear drop
Eye drop / ointment	Ear drop
Eye drop / ointment	Ear drop
Eye drop / ointment	Ear drop
Eye drop / ointment	Ear drop
Eye drop / ointment	Ear drop
Eye drop / ointment	Ear drop
Eye drop / ointment	Ear drop
Eye drop / ointment	Ear drop
Eye drop / ointment	Ear drop

Note down the steps in use of the following dosage forms

Nasal drop	Enema
Rectal suppository	Vaginal suppository

Note down the steps and precautions in setting up

Intravenous infusion	Blood transfusion

Fill-up the following table on oxygen delivery devices used in your hospital

Mode of O₂ delivery	Maximum flow rate	FiO ₂	Other notable features
Nasal cannula / prongs			
Face mask (simple)			
Venturi mask			
NRBM			
(HFNC)			
NIPPV device e.g. BiPAP, CPAP			
Invasive mechanical ventilation (Ventilator)			

NRBM = Non-rebreather mask / HFNC = High flow nasal cannula / NIPPV = Non-invasive positive pressure ventilation / BiPAP = Bilevel positive airway pressure / CPAP = Continuous positive airway pressure

Teacher's signature	
upon section completion	

Section 1. Clinical Pharmacy B. Preparation and use of Oral Rehydration Solution (ORS)

By the end of this module the student must have acquired knowledge and skills pertaining to:

- Rationale for oral rehydration therapy.
- Composition of ORS with its osmolality.
- Reduced osmolarity ORS.
- Method of preparation using ready-made ORS powder.
- · Correct administration of ORS.
- Assessment of dehydration and rehydration.

Write down the composition of World Health Organization (WHO) recommended ORS.

Original formula	Revised formula (Reduced osmolarity ORS)

Mention the purpose of each component of ORS.

Component	Purpose for inclusion

Clinical assessment of dehydration and rehydration in children – list the salient points.

Clinical characteristic	Changes noted in dehydration when it is			
Clinical Characteristic	Mild to Moderate	Severe		

Note: Assessment is generally to be repeated every 4 hours. Write down pointwise the method of preparation of ORS (using readymade ORS powder), appropriate use in children and the counselling that needs to be done for the caregiver

Teacher's signature upon section completion

Section 1. Clinical Pharmacy C. Pharmaceutical calculations

By the end of this module the student must have acquired knowledge and skills pertaining to:

- Weights and measures used in compounding and dispensing activity.
- Concentration and dilution of liquids and topical medicaments.
- · Stock solutions.
- Dose calculations involving body weight.
- Dose calculations involving body surface area.
- Dose calculation involving parts and proportions.
- Dose calculations involving reconstitution of dry powders.
- Dose calculations involving flow rate of IV preparations.

Weights and measures used in compounding and dispensing activity

Based on discussions held in class fill-up the following tables:

Metric system prefix	Symbol	Multiples of base unit	Mass example	Volume example

used in compounding and dispensing activity	Metric system equivalents

Common household measures	Metric system equivalents

Concentration of liquids and topical medicaments

Based on discussions held in class fill-up the following tables:

Method of expressing concentration	Meaning	Examples
Weight per unit volume		
Weight per given volume		
Percentage concentration w/v		
Percentage concentration v/v		
Percentage concentration w/w		
Ratio or parts		

Dosing of topical medicaments

Based on discussions held in class fill-up the following tables:

Region to be covered	Approximate amount of topical medication required*	Amount in terms of finger tip unit (FTU)
Face and neck		
Trunk (front and back)		
One arm		
One hand		
One leg		
One foot		
Whole body		

^{*} Single light application in adult person

Meaning of FTU	
Examples of medicines whose dose may be expressed in FTU	

Explain the meaning of the following in relation to stock solutions with suitable examples

Stock solution	
Dilution	
Dilution equations	
Alligation	
Dose calculations base	d on body weight and body surface area
Note down examples discuss	

Dose calculations related to infusion

Volume (mL) X Drop factor (drops / mL)

Infusion rate (drops / min) =

Duration of infusion (min)

Remember the following infusion equations given alongside				
Note down examples discussed in class				

Teacher's signature upon section completion

Section 2. Clinical Pharmacology A. Prescribing and prescription review

By the end of this module the student must have acquired knowledge and skills pertaining to:

- Meaning of prescription, the ideal prescription format, common acceptable abbreviations.
- Do's and don'ts in prescription writing.
- Legal issues in relation to prescribing e.g. prescription of narcotics and other controlled drugs, banned drugs, prescribing for sportspersons.
- Prescribing for commonly encountered clinical situations.
- Prescription review, prescription reconciliation and prescription audit.

Define the term prescription
Write down a simple model prescription in the space below and identify its parts

Note down some common abbreviations used in prescriptions with their meaning

Abbreviation	Meaning		Abbreviation	Meaning
				3
State what a	re controlled drugs (in Indian co	nnte	vt) and provid	le some evamples
State Wilat a	condoned drugs (iii Indian Ci	٠د	Ac, and provid	ic some examples
		_		
State what a	re banned drugs (in Indian cont is with reasons for banning	ext)	and provide s	some examples of recently
banned drug	s with reasons for banning			

Practice prescriptions
Clinical scenario
Dung animation
Prescription
Clinical scenario
Prescription

Practice prescriptions
Clinical scenario
Duna animbian
Prescription
Clinical scenario
Prescription

Practice prescriptions	
Clinical scenario	
Prescription	
Trescription	
Clinical scenario	
Prescription	

Practice prescriptions	
Clinical scenario	
Prescription	
Clinical scenario	
Prescription	

Practice prescriptions
Clinical scenario
Duna animbian
Prescription
Clinical scenario
Prescription

Prescription review

Review (critically evaluate) supplied prescriptions under the following heads

Valid signature and date

Format of the prescription

Choice of individual drugs considering indications and contraindications

Dosing of every individual drug (dosage form, individual dose, route, dosing frequency, duration)

Essential counselling points

Potential drug-drug interactions

Prescription reconciliation

Reconcile (collate into a single unified prescription) supplied prescriptions from multiple sources but intended for the same patient considering the following points

Individual patient characteristics e.g. age, body weight, contraindications

Clinical severity of the individual symptoms / illnesses / disorders - treatment to be prioritized accordingly

Therapeutic goals

Total pill burden

Economic considerations

Availability of caregiver support

Prescription audit

Scrutinize the supplied prescriptions from an auditing point of view. You may look at:

Formatting and legibility

Signature and date

Inappropriate abbreviations

Number of drugs prescribed

Appropriateness of the drugs selected and their dosing regimens (rationality of the prescription)

Extent of use of branded formulations, injections, antibiotics, inappropriate fixed dose combinations

Extent of use of drugs from recommended essential medicine lists

Potential drug-drug interactions

Potential medication errors

Affordability of the selected drugs

You can consider standard set of indicators e.g. World Health Organization-International Network on Rational Use of Drugs (WHO-INRUD) prescribing indicators for prescription auditing.

Teacher's signature upon section completion

Section 2. Clinical Pharmacology B. Adverse drug reactions and drug interactions

By the end of this module the student must have acquired knowledge and skills pertaining to:

- Meaning of adverse drug reactions (ADRs) and its implications in pharmacotherapy.
- Different types of ADRs with examples, including serious ADRs.
- Pregnancy risk stratification of drugs.
- Meaning of the term pharmacovigilance and various pharmacovigilance strategies.
- Objectives, structure and activities of the pharmacovigilance program of India (PvPI).
- Brief overview of other national adverse event monitoring programs e.g. Herbal pharmacovigilance program, Adverse effects following immunization (AEFI) program, Hemovigilance program of India (HvPI) and Materiovigilance program of India (MvPI).
- Spontaneous reporting of ADRs.
- Basics of causality assessment.
- Meaning of drug-drug interactions and its implications for pharmacotherapy.
- Different types of DDIs with examples.
- Examples of DDI involving modern drugs and herbal medicines.
- Examples of drug-alcohol, drug-smoking, and drug-food interactions.
- Situations that increase risk of ADRs / DDIs like polypharmacy, high alert medication (HAM) and sound alike-look alike (SALA) medication.

Define the terms Adverse Drug Reaction and Drug-drug interaction												
ADR												
DDI												
List examples of												
Type A ADRs												

Type B ADRs	
Serious ADRs	
Serious ADRS	
Pharmaceutical DDIs	
Pharmacokinetic	
DDIs	
Pharmacodynamic	
DDIs	
Harda danan	
Herb-drug interactions	
Food-drug	
Food-drug interactions	

Note down features of the following causality assessment scale

List examples of	World Health Org	ganization-Uppsala Monitoring Center causality categories with features
High alout	List examples of	
High Slove		
medication in the		
ITU setting	ITU setting	
Sound-alike look-		
alike medication that you have come	you have come	
across		

LXCI CISCS UI	it case scenario based mining up of suspected ADK reporting form
Scenario 1	
Scenario 2	
Scenario 3	
Scenario 4	



A. PATIENT INFORMATION 1. Patient leitiels 2. Age at the time of 3. M F Other													Reg. No. /IPD No. /OPD No. /CR No. :							
1. Pat	ient Initials					3. N	1 o	F 🗆 Oth	ner 🗆	AN	AMC Report No. :									
		Ev	ent or Dat	e of E	Birth	4. V	Veight		_Kgs	W	Worldwide Unique No. :									
B. SU	SPECTED A	DVER	SE REAC	TION						12	. Re	leva	nt tests/	laboratory	data with d	ates				
5. Eve	ent/Reaction	start	date (dd/	mm/	yyyy)															
6. Eve	ent/Reaction	stop	date (dd/i	mm/y	yyy)															
6 (A).	Onset Lag 1	ime																		
7. De:	scribe Event	/React	tion with t	treatr	nent de	tails,	if any			13.	. Re	leva	nt medic	al/medicat	on history (e.g. al	lergies, race,			
	11-16-1-16										_		, smokin ry etc.)	g, alcohol u	se, hepatic,	renal (dysfunction,			
											. Se		sness of	the reaction	n: No □ if Y	es □(p	lease tick			
											De	ath	(dd/mm,	/уууу)	□ Cong	enital-	anomaly			
											Lif	e thr	eatening	3	□ Disab	oility				
											los	pitali	ization/P	rolonged	□ Othe	r Med	ically important			
										15.	. Oı	utcor	nes	1, 111						
											Re	cove	ered [□ Recover	ing		lot recovered			
											Fa	tal	[Recover	ed with seq	uelae	□ Unknown			
C. SU	SPECTED N	MEDIC	ATION(S)																
	8. Name		Manufac	turer	Batch N	lo. Ex	p. Dat	Dose	Route		equency Therapy dates						Causality			
S.No	(Brand/Ger	neric)	(if know	vn)	/ Lot N	o. k	(if nown)	used	used	(OD, BI etc.)	Data ctarted				Indication Assessment					
i						1	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			0.0.7				stopped						
ii																				
iii						+					_									
iv*	. Action Tak	on (nl	agen tick)							10 Pag	ctio	on ro	2000250	d after rain	troduction (Inlance	tick)			
as	Drug	-		D	ose	Dose	e not	Not			CCIC	JIIIe	арреате			<u> </u>				
per C	vithdrawn	Dose in	ncreased		luced			applicable	Unknown	Ye	25		No	Effec	t unknown	Dose	(if reintroduced)			
i																				
ii			-											-						
iii	-																			
	oncomitant	medic	al product	inclu	iding se	lf-me	dicati	on and he	erbal remed	lies with	the	rapy	dates (E	xclude thos	e used to tr	eat rea	action)			
S.No	Name (Bra				Dose			te used	Frequen		I			y dates			lication			
					used				BD, e	etc.)		Date		Date						
i											5	tarte	ed .	stopped						
ii					Š.						t									
iii*									0 12											
Addit	tional Infor	matic	n:							D. REP	OR	TER	DETAIL	S						
										16. Nar	ne	and I	Professio	nal Addres	5:					
										Pin:	_		E-ma	il						
											. (w	ith S	TD code							
										Occupa	rtio	n:			_ Signature:					
										17. Dat	e o	f this	report (dd/mm/yy	(v):					
													of Rece							
Conf	dontielite	The	ationt's	idont	itu ie b	old i	n etri	et confid	once and r	1000			Water Street	Sec. 10	hmission	of a re	an ort does not			

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

^{*}use separate page for more information

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reaction by Healthcare Professionals INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India) Ministry of Health & Family Welfare, Government of India Sector-23, Raj Nagar, Ghaziabad-201002

A. PATIENT INFORMATION 1. Patient leitiels 2. Age at the time of 3. M F Other													Reg. No. /IPD No. /OPD No. /CR No. :								
1. Pa	tient Initials					3.1	Мп	F 🗆 Oth	ner 🗆	A	AMC Report No. :										
		Ev	ent or Da	te of E	Birth	4. \	Weight		Kgs	V	Worldwide Unique No. :										
B. SU	ISPECTED A	DVEF	SE REAC	TION				1	2. R	elevar	nt tests/	labo	oratory d	lata with da	ates	1					
5. Ev	ent/Reaction	start	date (dd/	mm/	уууу)																
6. Ev	ent/Reaction	stop	date (dd/	mm/\	(vvv)																
	Onset Lag T																				
	scribe Event		tion with	treatr	ment de	tails.	, if any			1	3. R	elevar	nt medic	cal/n	nedicatio	n history (e.g. all	ergies, race,			
											_		smokin y etc.)	ig, al	cohol us	e, hepatic/	renal	dysfunction,			
											4. Se		ness of	the r	reaction:	No □ if Ye	es □(p	lease tick			
											D	eath (dd/mm,	/ууу	y)	□ Conge	enital-	anomaly			
											Li	fe thr	eatening	g		□ Disab	ility				
					Hos	spitali	zation/P	rolo	nged	□ Other	Med	cally important									
				1	5. 0	utcon	nes														
					R	ecove	red [□ R	ecoverir	ng		ot recovered									
											Fa	atal		□ R	ecovere	d with sequ	ıelae	□ Unknown			
C. SL	ISPECTED N	NEDIC	ATION(S)		_															
8. Name Manufacturer Batch No				lo. E	xp. Dat	Dose	Route	Freque (OD.						Indication		Causality					
S.No	(Brand/Ger	eric)	(if kno	wn)	/ Lot N	o. k	(nown)	used	used	etc.		Date started		Date stopped		Assessm		Assessment			
i														эторрец							
ii						1															
iii						+			-												
iv*	Action Tak	on /nl	naco tick)							10 Pr	acti	on ro	annaara	daf	tor roint	roduction (nleass	+ick)			
as	Drug	en (pi	ease tick)	_	ose	Dos	e not	Not	1	10. Ke	acti	on re	appeare	o an	ter reinti	roduction (piease	tick)			
	withdrawn	Dose in	ncreased		luced			applicable	Unknown	,	Yes No		No	Effect ur		unknown Dose (i		(if reintroduced)			
i			Ų.	reduced changed applicable																	
ii			4																		
iii			-					-						_			-				
	oncomitant	medic	al produc	t incl	iding se	lf-me	edicatio	on and he	rhal remed	ies with	the	rany	dates (F	velu	de those	used to tre	eat rea	action)			
S.No	Name (Bra			c mere	Dose		_	te used	Frequen		LIIC	пару	Therap			used to the		ication			
		,			used		22.5		BD, e			-			ate						
											_	starte	d	sto	pped						
i							-				+										
iii*											$^{+}$										
Addi	tional Infor	matic	n:							D. RE	POF	RTER	DETAIL	s							
															Address:						
										Pin:			E-ma TD code	_							
													TD code	_		Signature:					
													235			18050					
														_	mm/yyyy	y):					
										Sig. a	nd I	Name	of Rece	iver	-						

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

^{*}use separate page for more information



SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reaction by Healthcare Professionals INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India) Ministry of Health & Family Welfare, Government of India Sector-23, Raj Nagar, Ghaziabad-201002

A. PA	TIENT INF				Reg. No. /IPD No. /OPD No. /CR No. :													
1. Pat	ient Initials		Age at the			3.	М 🗆	F 🗆 Oth	ner 🗆	AMC Report No. :								
Event or Date of Birth 4. Weight Kgs										Worldwide Unique No. :								
B. SU	SPECTED	ADVER	SE REAC	TION				12. Relevant tests/ laboratory data with dates										
5. Eve	nt/Reactio	n start	date (dd/	mm/	уууу)													
6. Eve	nt/Reactio	n stop	date (dd/	mm/y	yyyy)													
6 (A).	Onset Lag	Time																
7. Des	cribe Even	t/React	tion with	treatr	ment de	tails	, if any			13. Relevant medical/medication history (e.g. allergies, race,								
											-		, smokin ry etc.)	g, a	lcohol us	e, hepatic/	renal (dysfunction,
											4. Se		sness of	the	reaction:	No □ if Ye	es □(p	lease tick
											D	eath	(dd/mm	/yyy	y)	□ Conge	enital-	anomaly
											Li	fe thr	reatening	g		□ Disab	ility	
											Hos	spital	ization/F	rolo	onged	□ Other	Medi	cally important
										1	5. 0	utcor	mes					
											R	ecove	ered [Recoverin	ng		ot recovered
											Fa	atal		□ F	Recovere	d with sequ	ielae	□ Unknown
C. SU	SPECTED	MEDIC	ATION(S)	I	_												
SNo	8. Name		Manufac		Batch N	lo.	xp. Dat	Dose	Route	Freque (OD, I			Therap	py dates Date		Indication		Causality
(Brand/Generic) (if known) / Lot No				o. known) used			used	etc.		Date started Stopped			Ass		Assessment			
i																>		
iii				- 4		+		-										
iv*				-		+												
-	. Action Ta	ken (pl	ease tick)							10. Re	acti	ion re	appeare	d af	ter reint	roduction (please	tick)
as	Drug	Dose in	ncreased	D	ose	Dos	se not	Not	Unknown		es		No		Effect	unknown	Dose	(if reintroduced)
	vithdrawn	Dose II	icreaseu	rec	luced	cha	inged	applicable	Olikilowii	<u>'</u>	63		140		Effect	ulikilowii	Duse	(ii reiliti oduced)
i																		
iii																		
iv																		
				t inclu	_	lf-m	_				the	erapy				used to tre		
S.No	Name (B	rand/G	eneric)		Dose		Rou	te used	Frequen BD, e		-	Date	Therap	_	ates ate		Ind	ication
used									00,0			starte			opped			
i											I							
ii											+					1		
iii*	ional Info	rmatic	n:						12	D DE	DO!	OTED	DETAIL	•				
riddic	ional ime	· · · · · · · · · · · · · · · · · · ·												_	Address			
													TD code			Signature:		
										17. Da	ite o	of this	report	(dd/	mm/yyy	y):		
													of Rece					

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

^{*}use separate page for more information

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reaction by Healthcare Professionals INDIAN PHARMACOPOEIA COMMISSION(National Coordination Centre-Pharmacovigilance Programme of India) Ministry of Health & Family Welfare, Government of India Sector-23, Raj Nagar, Ghaziabad-201002

										_								
A. PATIENT INFORMATION										_	Reg. No. /IPD No. /OPD No. /CR No. :							
1. Pa	tient Initials		Age at the ent or Dat		3. M 🗆 F 🗆 Other 🗅					AMC Report No. :								
			an or pate or bi		711.211	4. WeightKgs					Worldwide Unique No. :							
B. SUSPECTED ADVERSE REACTION										12. Relevant tests/ laboratory data with dates								
5. Event/Reaction start date (dd/mm/yyyy)																		
6. Ev	ent/Reaction	stop	date (dd/	mm/y	7999)													
6 (A)	Onset Lag T	ime																
7. Describe Event/Reaction with treatment details, if any										 Relevant medical/medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction, past surgery etc.) 								
											14. Seriousness of the reaction: No □ if Yes □(please tick anyone)							
											□ Death (dd/mm/yyyy) □ Congenital-anomaly							
										☐ Life threatening ☐ Disability								
										□Hospitalization/Prolonged □ Other Medically important								
											15. Outcomes							
										□ R	ecove	ered	□ F	Recoverin	g		ot recovered	
											□ Fa	atal	[□ R	Recovered	d with sequ	uelae 1	□ Unknown
C. SL	ISPECTED N	IEDIC	ATION(S)														
	8. Name		Manufac	turer	Batch N	lo. Exp. Da		Dose	Route		uency	Causa			Causality			
S.No	(if				used	used used		, BD	Date started		Date Indicati topped		Assessment					
i															opped			
ii																		
iii				-		_						_						
iv*	Action Tak	an (nl	ease tick)						<u> </u>	10.5	Doacti	on re	annoaro	d of	tor rointr	oduction (nlaaca	tick)
as	Drug	ен (ри	ease tick)		ose	Dose r	not	Not		10.1	neacti	onre	appeare	uai	terremu	ouucuon (piease	tick)
per C			e increased		uced	chang		applicable	Unknown		Yes	'es No		Effect un		nknown Dos		(if reintroduced)
i																		
ii			-				_										-	
iii			- 4				\dashv										-	
	oncomitant i	nedic	al produc	t inclu	iding se	lf-medi	cati	on and he	rbal remed	ies wi	ith the	erapy	dates (E	xclu	de those	used to tre	eat rea	action)
S.No	Name (Bra				Dose			te used	Frequen				Therap					lication
	u				used	d			BD, etc.)						ate			
i						-			_			starte	ed	sto	opped			
ii					3						+					7		
iii*									9 172			- 1 -						
Addi	tional Infor	matic	n:							D. R	REPOR	RTER	DETAIL	s				
										16.1	Name	and I	Professio	onal	Address:			
Di							Dia	n: E-mail										
											I. No. (with STD code)							
									ccupation:Signature:									
											. Date of this report (dd/mm/yyyy):							
																/):		
Conf	identiality	The r	ationt's	ident	ity ic b	eld in	strie	t confide	ance and				of Rece			hmission	of a re	eport does not

constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission

*use separate page for more information

of an ADR report does not have any legal implication on the reporter.

Teacher's signature upon section completion

Section 2. Clinical Pharmacology C. Drug promotional literature

By the end of this module the student must have acquired knowledge and skills pertaining to:

- Strategies of drug promotion.
- Codes of ethical drug promotion.
- Types of drug promotional literature.
- Critically appraising promotional literature distributed by pharmaceutical companies responding to text / graphs / statistical data / images / referencing.
- Responding to the individual conveying promotional messages.

List the drug promotional strategies which you can think of							
Are you aware of any guidelines or codes for ethical drug promotion?							

List the types of drug promotional literature that you have been shown or that which you can think of
State some of the ways that you may be misled through drug promotional literature

Name some impartial sources of drug information			
What do you think are the pros and cons of interacting with representatives of			
pharmaceutical sales personnel (medical representatives)?			

Section 2. Clinical Pharmacology D. Rational use of medicines

By the end of this module the student must have acquired knowledge and skills pertaining to:

- Rational use of medicines (RUM) and its three pillars essential medicines list (EML), formularies, standard treatment guidelines (STG).
- Framing of an EML for a given health facility / healthcare scenario.
- Sources of drug information.
- Extracting information from non-commercial and commercial formularies.
- Basic steps in promulgation of Standard Treatment Guidelines (STG).
- Steps in exercising the P-drug concept.

State the definition of the following terms

Rational use of medicines
Essential medicines list
Formulary
Standard treatment guidelines or protocols
Provide examples of EML that you have come across and identify the factors that determine inclusion of a particular medicine in such a list

Identify 10 to 12 essential medicines that may be required in the following scenarios

A primary health control in wirel area	
A primary health centre in rural area	A religious mela likely to draw a huge crowd
A university class field trip into a tropical forest	Emergency department crash cart
A diliversity class field trip files a displical forest	Lineigency department crash care
State some sources of drug information, include	ling examples of formularies
, 	
Identify the kind of drug information that may	be available from patient package inserts /
patient information leaflets and drug formular	ies
PPI / PIL	Formulary
	1 ormalary

Highlight sequential steps in the development of STGs			
Give examples of STGs that you have come across			
State what is P-drug concept and highlight sequential steps in the selection of P-drugs			

Section 3. Experimental Pharmacology Through computer aided learning (CAL) / Charts

By the end of this module the student must have acquired knowledge and skills pertaining to:

- Interpretation of graphically presented pharmacokinetic information (e.g. plasma concentration time curves).
- Interpretation of graphically presented pharmacodynamic concepts (e.g. log dose response curves).
- Anesthetized cat / dog experiments related to autonomic and cardiovascular pharmacology.
- Isolated tissue experiments related to autonomic, gastrointestinal, and neuromuscular pharmacology.
- Rabbit eye experiments.

If space is inadequate for the following sections affix additional pages

Draw the following graphs / charts (or paste output from computer aided learning experiments) illustrating PK-PD concepts

Date

learning experiments) mustrating FR-FD conce	pts Date
Plasma concentration time curve for an orally administered drug	Plasma concentration time curve demonstrating attainment of steady state
Plasma concentration time curve for an IV drug not showing distribution phase	Plasma concentration time curve for an IV drug not showing distribution phase

Dose response curve	Log dose response curve
Log dose response curves showing competitive	Log dose response curves showing non-competitive
antagonism	antagonism
Log dose response curves showing potentiation	Other PK or PD related chart

Draw the following graphs / charts (or paste output from CAL experiments) illustrating effect of drugs on blood pressure in an anesthetized animal Date __

Effect of pressor agents	
_	
Effect of depressor agents	
Lifect of depressor agents	
Effect of a blocker	
Dale's vasomotor reversal	
Tachynhylavis	
Tachyphylaxis	
Tachyphylaxis Nicotinic action of acetylcholine	

Draw the following graphs / charts (or paste the output from computer aided learning experiments) illustrating effect of drugs in isolated tissue experiments Date _____

Experimental system parameters	
Effect noted (graphical)	
Experimental system parameters	
Effect noted (graphical)	
Experimental system parameters	
Effect noted (graphical)	

Fill-up the following table on the basis of rabbit eye experiments observed Date _____

Eye	Agent	Pupil diameter	Light reflex	Corneal reflex	Intraocular pressure	Other effects (e.g. lacrimation)	Remarks
Test							
Control							
			1		ı	ı	
Test							
Control							
Test							
Control							

	Time spent
cation issues raised through th	his scenario?
y, raised through this scenario	0?
,,	
ed?	
and ord ord order	
esoived and why?	
	Video Group discussion cation issues raised through the group this scenarion of the group discussion issues raised through this scenarion of the group discussion issues raised through this scenarion of the group discussion is a content of the group discussion is a conte

Date of discussion	Time spent
Scenario in brief	
How was it presented? ☐ Role play ☐ Video ☐ Group discussion	
What are the attitude and communication issues raised through the	his scenario?
What are the ethical dilemmas, if any, raised through this scenario	o?
	-
How were issues / dilemmas resolved?	
Were any issues / dilemmas left unresolved and why?	

Date of discussion	Time spent
Scenario in brief	
How was it presented? ☐ Role play ☐ Video ☐ Group discussion	
What are the attitude and communication issues raised through the	his scenario?
What are the ethical dilemmas, if any, raised through this scenario	n?
what are the ethical dileminas, if any, raised through this scenario	o:
How were issues / dilemmas resolved?	
Were any issues / dilemmas left unresolved and why?	

Date of discussion	Time spent
Scenario in brief	
How was it presented? ☐ Role play ☐ Video ☐ Group discussion	
What are the attitude and communication issues raised through the	his scenario?
What are the ethical dilemmas, if any, raised through this scenario	n?
what are the chical anominas, it any, raised amough this seeman	.
How were issues / dilemmas resolved?	
Were any issues / dilemmas left unresolved and why?	

Topic
Торіс
Time spent
Resources used
Salient learning points
Торіс
Time spent
Resources used
Salient learning points

Торіс
Time spent
Resources used
Salient learning points
Tauta
Topic
Time spent
Resources used
Salient learning points

Case based learning through	gh ward round / clinic visit
Ward / Clinic	Date & time spent
Clinical case scenario in brief	·
Pharmacological treatment offered with therapeu	tic objectives for the various drugs used
Filarmacological treatment offered with theraped	tic objectives for the various drugs used
Any adverse drug reactions noted	
, a	
Potential drug-drug interactions	Potential medication errors
Totalida drug drug interdections	Totalida medication errors
Any other observations of note	

	Case based learning through	gh ward round	/ clinic visit
Ward / Clinic	<u> </u>		Date & time spent
Clinical case scena	rio in brief		
Pharmacological tr	eatment offered with therapeu	tic objectives for	the various drugs used
	·		-
Any adverse drug r	eactions noted		
Potential drug-dru	g interactions	Potential medic	ation errors
Any other observat	tions of note		
•			

Case based learning through	gh ward round / clinic visit
Ward / Clinic	Date & time spent
Clinical case scenario in brief	·
Pharmacological treatment offered with therapeu	tic objectives for the various drugs used
That macological deadliche offered with therapea	tic objectives for the various arags asca
Any adverse drug reactions noted	
,	
Potential drug-drug interactions	Potential medication errors
. occinian and and microconcini	- Coolina moundation on ord
Any other observations of note	

Case based learning through	gh ward round / clinic visit
Ward / Clinic	Date & time spent
Clinical case scenario in brief	·
Pharmacological treatment offered with therapeu	tic objectives for the various drugs used
Pharmacological treatment offered with therapeu	tic objectives for the various drugs used
A durant durant de la constant de	
Any adverse drug reactions noted	
Potential drug-drug interactions	Potential medication errors
Any other observations of note	
,	

Certification of attainment of competencies through practical training

Competency addressed	Type of activity	Date done	Attempt First (F) / Repeat (R) / Remedial (R)	Rating Below expectation (B) / Meets expectation (M) / Exceeds expectation	Decision of faculty Completed (C) / Repeat (R) / Remedial (Re)	Faculty initials with date	Feedback received Student initials

Certification of attainment of certifiable skills through practical training

SN	Skill	Minimum no. of times to be performed successfully	Date certified	Full signature of faculty certifying	Remarks, if any
1	Write a rational, correct and legible generic prescription for a given condition and communicate the same to the patient. (Competency PH 3.1)	5			
2	Perform and interpret a critical appraisal (audit) of a given prescription. (Competency PH 3.2)	3			
3	Recognize and report an adverse drug reaction. (Competency PH 3.4)	3			
4	Prepare a list of essential medicines for a healthcare facility. (Competency PH 3.7)	3			

Record of other co-curricular activities

SN	Activity e.g. Seminar / Symposia, Conference / Integrated lecture series / Workshop	Dates	Initials of student	Initials of faculty	Remarks, if any
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					

LOGBOOK CERTIFICATE

This is to certify that the candidate Mr. / Ms
bearing University Reg. No, admitted to
(college)
in the year has satisfactorily completed / not yet completed all
assignments / requirements mentioned in this logbook for second phase MBBS course in the
subject of Pharmacology / AETCOM during the period from to
and he / she is ELIGIBLE / NOT ELIGIBLE to appear for the
summative (University) examination as on date given below.
Signature of Eaculty wit date
Signature of Faculty wit date
Signature of Faculty wit date Name and designation
Name and designation
Name and designation Countersigned by Head of the Department with date
Name and designation Countersigned by Head of the Department with date
Name and designation Countersigned by Head of the Department with date Name and seal
Countersigned by Head of the Department with date Name and seal Signature of Principal / Dean of the College with date
Name and designation Countersigned by Head of the Department with date Name and seal