UNDERGRADUATE

ACADEMIC RECORD/ LOGBOOK

PHARMACOLOGY

THE TAMILNADU
Dr. MGR MEDICAL UNIVERSITY
CHENNAI

The TN Dr.M.G.R Medical University

Chennai

Undergraduate Academic Record/LogBook
Department of Pharmacology

Name of the College :

Academic year :

Name of the Student :

Registration No. :

"I thank all the illustrious faculty of Pharmacology inthe Medical Schools of this University for their conscientious effort"

Dr. K. Narayanasamy, M.D., D.M.(Gastro.)

Preface

The new Graduate Medical Education Regulations intends to carry forward the process of The goal of the Graduate Medical Education Regulation (GMER) is to sculpt every medical student into a responsible Indian Medical Graduate who can cater to the needs of the society. The thrust in the new regulations is to make medical education more leamer-centric, patient-centric, gender- sensitive, outcome -oriented and environment appropriate.

Communication and interpersonal skills are imperative in providing quality medical care. Our curriculum achieves this by providing dedicated curriculum time in the form of a longitudinal program based on Attitude, Ethics and Communication (AETCOM) competencies. Foundation Course is to orient medical learners to MBBS programme, and provide them with requisite knowledge, communication (including electronic), technical and language skills.

Electives allow students to get exposed to diverse environment, get a glimpse of future career, to revisit basic sciences of their own interest and indulge in research activities. The Family adoption program aims to provide experimental learning opportunity to Indian Medical Graduates in community-based health care.Skill laboratories have been incorporated into the curriculum for the learners to get an opportunity to observe and learn clinical and communication skills while eliminating the fear of harming patients. The Learner-doctor method of clinical training (Clinical Clerkship) is to provide learners with experience in Longitudinal patient care, by being part of the health care team providing hands-on care for patients.

This academic record / Log book has been prepared based on new NMC guidelines – Competency Based Medical Education Curriculum (CBME) Guidelines – dated 1st August 2023. It should be maintained as a document to record day-to-day academic activities, assessments, grading of assessments and its feedback. Periodic recording of all academic activities should be done by the student and has to be submitted to the faculty in-charge during feedback sessions. This document will incorporate in it all components that are being assessed for the final internal assessment and should be submitted to the concerned department and the examiners. Internal assessment marks will be given after evaluating this document. For subjects spanning across different phases this academic record has to be maintained for that particular subject and has to be evaluated at the end of posting in each phase.

CERTIFICATE

This is to certify that Mr/ Ms…… University Registration No……admitted in the Year ……in…… ……Medical College, ... has satisfactorily attended and completed all academic activities as assigned in this logbook as per the guidelines prescribed under the Tamil Nadu Dr. M.G.R. Medical University in subject of Pharmacology during the period form……..to .....He/She is eligible/NOT eligible to appear in the University Examination.

Counter signed by

Signature of Faculty
Name & Designation

The Professor & HOD of Pharmacology
(signature with date & official seal)

Examiner 1 Date:

Examiner 2 Date:

BACKGROUND OF THE COURSE

Preamble: Pharmacology in medical curriculum is to gain knowledge on various drugs and its application in prescribing appropriate medications, at the right dose, duration and with concern to appropriate cost. The knowledge of the molecular basis of drug action, the adverse effects caused by the medications, its prevention and treatment and the effects of administering two or more drugs to a patient will be learnt in the context of its clinical application. The syllabus and exercises are planned as per UGMER 2023 by NMC.

Goals: The broad goal of Pharmacology curriculum is to train the Indian Medical Graduate (IMG) with the knowledge of scientific basis of therapeutics and the skills of rational prescribing during the second phase of MBBS curriculum.

Objectives: To train medical graduate to attain proficiency in respective domains in core competencies through small group learning sessions.

Knowledge: At the end of the course the student should be able to:

1. Describe Pharmacokinetics and Pharmacodynamics of commonly used drugs
2. Apply the knowledge of indications, contraindications, interactions, and adverse reactions of drugs commonly used in therapeutics
3. Explain the concepts and clinical relevance of Essential medicines, Fixed dose combinations, Over the counter drugs, Herbal medicines, dietary supplements and nutraceuticals

Psychomotor Skills :At the end of the course the student should be able to:

1. Write a rational prescription for a given clinical condition
2. Calculate the dosage in special medical situations such as pregnancy, lactation, children, elderly, and patients with renal dysfunction
3. Apply the concept of rational drug therapy to select P drugs in clinical pharmacology
4. Interpret the clinical presentation & demonstrate management of common poisonings.
5. Recognize and report an adverse drug reaction of commonly used medications
6. Interpret the graph of effects of drugs through Computer Assisted Learning CAL
7. Perform critical evaluation of the Drug Promotional Literature
8. Administer drugs through various routes in a simulated environment

Affective : Attitude, Ethics, Communication: At the end of course student should be able to:

1. Communicate effectively to patient regarding storage and use of prescribed medications
2. Explain patients on the right way to use the various drug formulations
3. Communicate the importance of adherence to medications and motivate the patients
4. Demonstrate an understanding of legal and regulatory aspects of prescription of drugs.
5. Understand and follow the ethics and values while prescribing medications.

Alignment implies the teaching of subject material that occurs under a particular organ system/disease concept from the same phase in the same time frame i.e., temporally.

Integration implies that concepts in a topic / organ system that are similar, overlapping, or redundant are merged into a single teaching session in which subject based demarcations are removed.

The teaching is aligned horizontally and integrated vertically to impart understanding of interactions of drug with drugs, host and disease in order to provide an overall understanding of the context of therapy.

PERSONAL DETAILS

Name of Student (UPPER CASE ONLY)								Affix recent passport size photo			
Date of Commencement of Phase II											
Date of Birth & Age											
Name of Parent/Guardian											
Permanent Address											
Address for Postal Communication											
Aadhar number (Attach copy)											
Landline Phone (Home)											
Mobile Phone (Parent/Guardian)											
Mobile Phone (Parent/Guardian)											
Mobile Phone (Student)											
Email ID (Parent/Guardian)											
Email ID (Student)											

Signature of the Student

Table No. 5 -Distribution of Subject Wise Teaching Hours for II MBBS

Subjects	Lectures	SGL	Clinical postings*	SDL	Total
Pathology	80	165	-	10	255
Pharmacology	80	165	-	10	255
Microbiology	70	135	-	10	215
Community medicine	15	0	0	10	25
FAP**	0	0	30	-	30
Forensic Medicine & Toxicology	12	22	-	08	42
Clinical subjects	59	-	540	-	599
AETCOM	-	29	-	8	37
Sports Yoga & Extra-curricular Activities	-	-	-	20	35
Pandemic Module				28	28
Formative Assessment and Term examinations					
Final total	**316**	**516**	**585**	**104**	**1521**

Ref: 1. UGMEB No.U.14021/08/2023 dated 01/08/2023 Pg.no. 70.

*** 2. UGMEB No.U.14021/08/2023 dated 01/08/2023 Annexure no.3*

*Note : *Clinical postings shall be for 3 hours per day, Monday to Friday.*

There will be 15 hours per week for all clinical postings.

Consolidated Internal Assessment Marks Theory

Name of Faculty /Facilitator:

Name of the Student:

Roll.No **University Reg.No**

I.Formative Assessment Theory			**II. Continuous Internal Assessment**						**Total Marks**
IA **PCT* 1 Theory**	**I.B** **PCT* 2 Theory**	**I.C** **Prelims Theory (Paper I&II)**	**II.A** **Home Assignment**	**II.B** **Continuous class test (LMS**)**	***II.C*** ***Self Directed Learning***			**II.D** **Attendance Theory Min 75%**	
					II.C.1 **Seminar**	**II.C.2** **Museum study**	**II.C.3** **Library Assignment**		
100	**100**	**200**	**15**	**30**	**15**	**15**	**15**	**10**	**500**

Consolidated Internal Assessment Marks Practical

III. Formative Assessment Practical			**IV. Continuous Internal Assessment (Practical)**						**TOTAL MARKS**
			IV.A Log Book (150)				**IV.B** **Journal**	**IV.C Attendance (Practical) Min 80%**	
III.A **PCT* 1 Practical**	**III.B** **PCT* 2 Practical**	**III.C Prelims Practical**	**IV.A.1** **Certifiable skill based (OSPE)**	**IV.A.2** **AETCOM competencies**	**IV.A.3** **SVL***/ **CAL lab activity**	**IV.A.4** **Research**			
100	**100**	**100**	**60**	**30**	**40**	**20**	**40**	**10**	**500**

Ref: UGMEB No.U.14021/08/2023 dated 01/08/2023 Annexure 2, Page 3&4

**PCT- Part Completion Test **LMS-Learning Management System*

****SVL-Simulation Based Virtual Lab activity; CAL- Computer Assisted Learning*

Signature of Professor& HOD
Department of Pharmacology

TIME TABLE PHARMACOLOGY -THEORY & PRACTICAL

I. FORMATIVE ASSESSMENT-THEORY

Theory Assessment	**Max Marks**	**Marks scored**
GP		
ANS		
PNS & CNS		
I.A **1ST PCT**	**100**	
CVS, BLOOD, DIURETICS		
RS, GIT, AUTACOIDS		
I.B **2ND PCT**	**100**	
ENDOCRINE		
CHEMO I		
CHEMO II		
MISCELLANEOUS		
I.C **Model /Prelims** **Paper I & II**	**200**	
TOTAL	**400**	

Signature of Facilitator

BRIEFING ON REFLECTION WRITING BY STUDENT*

1. Students are required to write reflections on overall experience in:

   A. Aligned Integrated Topics (AITo) in Practical exercise
      a) Dosage calculation in Paediatrics
      b) Drug Promotional literature.
      c) Prescription writing
      d) Selection of P-Drug
      e) ADR Reporting
   B. AETCOM
   C. Self-directed Learning, (SDL),
   D. Pandemic Module

2. **For reflections the following structure should be used:**

   A. What happened? (What teaching learning experience did you undertake)

   B. What exactly happened (in your own words)?

      What did you observe? What was your reaction?

      What did other people do e.g. colleague, faculty?

      What are the key aspects of the situation?

   C. So what? (What did you learn from this experience or what change did this session make in your learning of the subject)

   D. What were you trying to achieve?

      What were the reasons for the way you responded?

      What beliefs and values influenced your actions?

      What assumptions did you make?

      What "good" emerged from the situation e.g. for self, others?

   E. What next? (How will you apply this knowledge in future?)

   F. What are the implications for you, others involved? \

      What might you do differently if faced with a similar experience again?

      What would be the consequences of alternative actions for yourself, others?

      What are the best ways of getting further information about the experience should it rise again?

**Ref: Logbook guidelines module for Medical Graduate by NMC*

INDEX

Note : 10 Point Score (6: 3: 1) 6 : Must Know, 3 : Desirable To Know, 1 :Nice To Know.

S.No	Comp.No	Topic	Score	Page. No
1.	PH 1.1	Sources of Drugs (Visit Museum/Chart)	1	
2.	PH 2.1	Dosage Forms & Formulations	6	
3.	PH 1.4	Pharmacokinetic Exercise	3	
4.	PH 2.4	Dosage Calculation	6	
5.	PH 4.1	Routes of Drug Administration	6	
6.	PH 4.1	Special Drug Delivery Systems	6	
7.	PH 3.3	Drug Promotional Literature	3	
8.	PH 2.2	ORS Preparation	6	
9.	PH 4.2	Computer Assisted Learning	3	
10.	PH 3.1	Prescription Writing	6	
11.	PH 3.2	Prescription Audit	6	
12.	PH 3.5	Selection of P-Drug	6	
13.	PH 3.4	ADR Reporting	3	
14.	PH 5.1- 5.7	AETCOM	3	
15.	PH.3.7	Essential Medicine		
16.	PH.8.2	Antimicrobial Stewardship		
17.	Practical	Record of Research		
18.	Practical	Record of Journal Activity		
19.	Theory	Record of Home Assignments		
20.	Theory	Record of Self Directed Learning		
21.	Theory	Pandemic module		

NOTE:

- The record note books must be verified by the facilitator (faculty) at the end of each session: SKILL STATION, OSPE, DOAP etc.
- On completion of each topic a formative assessment will be done and the scores will be documented in the assessment record of the students

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INTRODUCTION

- Pharmacology:(Gr. Pharmakon – drug, and Logos – word) is the study of drugs and its interaction with biological matter in all their aspects.
- Drug: WHO defines a drug as "*a substance or product used or intended to be used to modify or explore physiological systems or pathological states for the benefit of the recipient"*
- Generic Drugs: Drug formulations of identical composition with respect to the active ingredient, i.e., drugs thatmeet current official standards of identity, purity, and quality of active ingredient
- Pharmacy is an independent discipline concerned with the art and science of the preparation,compounding, and dispensing of drugs.
- Pharmacogenetics: The science and study of the inheritance of characteristic patterns of interaction between chemicals (drugs) and organisms. Pharmacogenetics involves identification and description of such patterns, discriminating them from non-heritable patterns, and elucidation of the mechanism of inheritance
- Pharmacognosy is a branch of pharmacy that deals with the identification and analysis of the plantand animal tissues from which drugs may be extracted.

SOURCES OF DRUG INFORMATION

- **Reference books** cover general pharmacology, clinical pharmacology or specialize in pharmacology related areas of contemporary interest. Examples are Goodman and Gilman's *The Pharmacological Basis of Therapeutics*, Bennett and Brown's *Clinical Pharmacology*, Bertram G. Katzung's *Basic and Clinical Pharmacology*, Martindale's *The Extra Pharmacopoeia.*
- **Drug compendia** list drugs available, their generic and brand names; chemical composition; clinical indications and contraindications; warnings, precautions and interactions; side effects; administration and dosage recommendations. Examples are: the annual *Physician's Desk Reference*; *Monthly Index of Medical specialties (MIMS); United States Pharmacopeia Dispensing Information* (USP D1).
- **Pharmacopoeia**: They contain description of chemical structure, molecular weight, physical and chemical characteristics, solubility, identification and assay methods, standards of purity, storage conditions and dosage forms of officially approved drugs in a country. Examples are Indian (IP), British (BP), European (ph.Eur.), United States (USP) pharmacopoeias.

- **Formularies**: list indications, dose, dosage forms, contraindications, precautions, adverse effects and storage of selected drugs that are available for medicinal use in a country. Drugs are categorized by their therapeutic class. Some rational fixed-dose drug combinations are included. Brief guidelines for treatment of selected conditions are provided. While British National Formulary (BNF) also lists brand names with costs, the National Formulary of India (NFI) does not include these. *WHO Model Formulary* is a useful resource.
- **Essential Drugs** are based on a consensus on the treatment of choice for the most common diseases and complaints.
- **Drug Information Centres** are often linked to poison information centres. Health workers and general public can call and get help with questions concerning drug use, intoxications etc. Many major reference data bases, such as *Martindale and Meylers Side Effects of Drugs,* are directly accessible through international electronic networks.
- **Drug Bulletins** promote rational drug therapy, appear at frequent intervals and can be a critical source of information to determine the relative merits of new drugs. A source of unbiased information. Examples are *Drug and Therapeutics Bulletin (UK), Medical Letter (USA), Australian Prescriber (Australia)***.**
- **Index Medicus** covers major reputable journals that publish regularly scientifically validated, peer reviewed articles on treatment.
- **Computerized drug information system** maintain medication profiles for every patient have been developed. Some of these systems include modules to identify drug interactions or contraindications. Some systems include a formulary for every diagnosis, presenting the prescriber with a number of indicated drugs from which to choose, including dosage schedule and quantity. Prescribers can also store their own formulary in the computer.
- **Information from the pharmaceutical industry** is usually readily available through channels of communication: verbal, written and computerized. Usually the pharmaceutical industry uses a ‘multi-track’ approach. This means that information is provided through media/medical representatives; stands at professional meetings; advertisement in journals and by direct mailing.

PH 1.1: SOURCES OF DRUGS

Specific Learning Objectives (SLO) At the end of the practical class the student shall be able to:

1. List the various sources of some common drugs and identify them.
2. Define the various terms relating to the science of pharmacology such as pharmacy, toxicology, therapeutics, clinical pharmacology, ethnopharmacology etc.,
3. Museum Visit to familiarize the formulations and sources of drugs. Note down the names of the specimens displayed, the drug obtained from it, the use of the drug and the type of source (plant/mineral/animal etc.)

Sl. No.	Sources	Examples	Part of the Plant / the Animal / any other
1	**Plants**		
2	**Animals**		
3	**Human**		
4	**Microbes**		
5	**DNA recombinant**		
6	**Minerals and Metals**		
7	**Synthetic**		

PH 2.1: DEMONSTRATION OF DOSAGE FORMS

Specific Learning Objectives (SLO) At the end of the practical class the student shall be able to:

1. Identify the dosage form of the drug displayed in museum or Lab.
2. Note the instructions to be given to patients on the proper usage of each dosage form. (Chew, powder, divide, place under tongue etc.,)
3. Write two important advantage /Disadvantage of the dosage form
4. Select the appropriate dosage form for the clinical situation

A. SOLID DOSAGE FORMS

- **Tablet:** It is a commonly used solid dosage form. It consists of active substances along with an excipient (pharmacologically inert substance). Excipients include binders, disintegrants, lubricants, diluents etc. Tablets are of various shapes, size and weight. A tablet may be scored - can be easily broken if smaller dose is required e.g. paracetamol. A tablet that is not scored is difficult to break, e.g. ibuprofen. Tablets may be uncoated or coated (covered with one or more layers of mixture of other substances like resins, gelatin, coloring matter, sugar, etc). Coating of a tablet helps to improve its taste, delay absorption, avoid irritation of the stomach, prevent its degradation in the stomach and improve its stability.
- **Film coated tablet:** The tablet is coated with a thin layer of polymer, e.g. ibuprofen, moxifloxacin, etc.
- **Sugar coated tablet**: Coating of a tablet with sugar helps to improve its taste, e.g. ibuprofen, metronidazole, etc.
- **Enteric coated tablet:** It is coated with material that protects the tablet from disintegration in the acid environment of the stomach. Enteric coating is done to prevent destruction of the drug by gastric acid e.g. enteric coated tablet of erythromycin or to decrease gastric irritation by the drug, e.g. enteric coated tablet of diclofenac, aspirin.
- **Delayed release formulation:** It releases the drug sometime after drug administration. It does not disintegrate in the stomach but in the intestine.
- **Extended release tablet:** It slows the rate of release of active ingredients in the gastrointestinal tract.

- **Sustained release tablet**: In this form, the drug is released slowly over a specified prolonged period of time. This form helps to increase the duration of action of the drug, decreases the frequency of drug administration and improves patient compliance, e.g. sustained release tablets of diclofenac, propranolol, etc.
- **Chewable tablet**: It should be chewed and swallowed. It is suitable for large size tablets, e.g. chewable albendazole tablet for worm infestation.
- **Dispersible tablet**: The tablet disintegrates rapidly within minutes when placed in small amount of liquid (water or milk) to form a stable suspension. An advantage of this is the fast onset of action as compared to a standard tablet. It is useful for children and elderly who find it difficult to swallow a tablet, e.g. aspirin dispersible tablet.
- **Effervescent tablet:** The tablet is to be added to a glass of water just before administration and should be taken immediately. The tablet consists of active substance along with carbonate/bicarbonate and acid. The acids react with bicarbonate in the presence of water to liberate carbon dioxide which breaks down the tablet and produces effervescence. It helps to minimize gastric irritation, e.g. ranitidine hydrochloride effervescent tablet.
- **Mouth dissolving tablet:** It is placed on the tongue, disintegrates / dissolves rapidly within seconds or minutes in saliva without the need for water. It is easy to administer, has rapid absorption, convenient for bedridden, geriatric and pediatric patients and people who are travelling without access to water, e.g. ibuprofen, loratadine, etc.
- **Capsule:** It is a solid dosage form where the active ingredients are enclosed in a stable shell. The shell may be made of gelatin (animal protein) or plant polysaccharides or modified forms of starch and cellulose. A capsule could be –
    - *Hard shelled* - It contains dry powder which includes the active ingredients and excipients, e.g. vit B complex capsules. It consists of two halves, one slipping over the other.
    - *Soft shelled* - It contains oil, e.g. cod liver oil or active ingredient dissolved/suspended in oil, e.g. vit E.
- **Spansule:** It is a capsule containing drug pellets of varying coating and size which disintegrate at different rates, e.g. ferrous sulphate spansule.
- **Troche**: It should be placed in the mouth and sucked. It dissolves slowly in the mouth releasing the active ingredient. It is used for local action, e.g. clotrimazole troche for oral candidiasis.

- **Lozenge:** It should be placed in the mouth and sucked. It dissolves slowly in the mouth releasing the active ingredient. It can be used to soothe irritated mucosa of the throat. It can also be used for systemic effect, e.g. nicotine lozenges reduce withdrawal symptoms and nicotine craving associated with quitting of smoking.
- **Suppository**: A solid dosage form, cylindrical or cone shaped, for introduction into rectum, urethra or vagina, e.g. bisacodyl suppository for constipation.
    - *Pessary:* A vaginal suppository, e.g. nystatin pessary for vaginal candidiasis.
    - *Bougie:* A urethral suppository is called bougie.
- **Powder:** It is the finely divided form of a drug for internal or external use, e.g. oral rehydration salt (ORS) powder for dehydration, antimicrobials in powder form for skin infection**.**

B. SEMISOLID DOSAGE FORMS

- **Ointment:** It is a semisolid preparation usually containing a greasy base meant for application to skin or mucosa, e.g. miconazole ointment for cutaneous candidiasis (topical action). Ointment can also be used for systemic effect e.g. nitroglycerine ointment for angina pectoris.
- **Cream:** It is a semisolid emulsion for external application, e.g. ketoconazole cream for fungal infections. They are of two types - aqueous cream (oil in water emulsion) and oily cream (water in oil emulsion).
- **Paste:** It is a semisolid preparation which is less greasy and has a larger proportion of powdered medicaments as compared to an ointment, e.g. triamcinolone acetonide paste for oral inflammatory conditions.
- **Gel:** It is a colloidal suspension of a solid dispersed in a liquid, e.g.diclofenac gel

C. LIQUID DOSAGE FORMS

- **Mixture:** It is a liquid preparation containing one or more soluble or insoluble ingredients for oral use, e.g. sodium salicylate mixture. A single dose mixture is a draught, e.g. magnesium sulfate mixture for constipation.
- **Emulsion**: It is a mixture of two immiscible liquids (e.g. oil and water), one of which is broken into fine globules and dispersed in the other liquid with the help of an emulsifying agent, e.g. cod liver oil emulsion.
- **Suspension:** It contains one or more insoluble ingredients homogeneously distributed in a liquid, e.g. antacid suspension, amoxicillin suspension. **Shaken well before use**.

- **Syrup:** It is a concentrated sugar solution containing the drug. It is pleasantly flavored and is used to administer bitter, unpalatable drugs, e.g. cough syrup.
- **Elixir:** It is a clear, pleasantly flavored liquid of potent or nauseating drug dissolved in water and ethanol, e.g. promethazine elixir for cough.
- **Linctus:** It is a viscous liquid preparation which should be sipped slowly to allow it to trickle down the throat. It is usually used for relief of cough, e.g. linctus codeine.
- **Gargle:** An aqueous solution used to prevent or treat throat infections, e.g. saline gargle for sore throat.
- **Mouthwash:** An aqueous solution used for rinsing the mouth for oral hygiene, e.g. chlorhexidine mouthwash.
- **Liniment:** It is a fluid or semifluid preparation meant for external application. It is applied to the skin with friction for sprain, joint pain, etc. For example, turpentine liniment. Liniment should not be applied to broken skin or wounds.
- **Lotion:** It is a liquid preparation which is to be applied to the skin without friction, e.g. benzyl benzoate lotion, calamine lotion, etc.
- **Tincture**: It is an alcoholic solution of a non-volatile substance, e.g. tincture of iodine
- **Paint:** It is a liquid preparation for application on the skin or mucosa, e.g. Mandl's paint for sore throat.
- **Irrigation solutions:** They are used for washing wounds or body cavities (procedure is known as irrigation). Water, saline, antiseptic solutions can be used as irrigants.
- **Drops:** Drugs can be administered orally to children in the form of drops, e.g. paracetamol drops. They are also used for instillation of drugs into the eyes, ears and nasal cavity for local action. They contain either anti-inflammatory agents (e.g. diclofenac, flurbiprofen, steroids) or antimicrobials (e.g. ciprofloxacin, gentamicin, acyclovir, fluconazole, etc.). Nasal decongestants (e.g. oxymetazoline, naphazoline, etc.) are available as nasal drops.
- Miotics (e.g. pilocarpine), mydriatics (e.g. atropine), local anaesthetics (lignocaine), etc. are available as eye drops. Ear drops containing glycerol alone or in combination with a surfactant are available to remove cerumen.

- **Spray:** The drug is delivered in the form of fine droplets into the oral cavity (e.g. lignocaine, nitroglycerine), nasal cavity (e.g. oxymetazoline, desmopressin) and on the skin (e.g. diclofenac).The drug thus delivered acts locally or systemically.
- **Enema:** It is a liquid preparation to be administered into the rectum. It can be -
    - *Evacuation enema* - to evacuate the bowel contents, e.g. soap and water enema.
    - *Retention enema* - the drug containing fluid is retained in the rectum, e.g. prednisolone enema for ulcerative colitis.

D. INJECTIONS, AMPOULES OR VIALS

- **Injection solution** – It consists of drug/drugs dissolved in a solvent or a mixture of miscible solvents. It is ready for use and administered as such, e.g. regular insulin.
- **Injection suspension** – It consists of solid, insoluble particles dispersed in a liquid phase and is ready for use, e.g. lente insulin
- **Injection powder for solution** – The powder has to be mixed with a diluent (reconstituted) to form a solution and then administered, e.g. benzyl penicillin G.
- **Injection powder for suspension** – The powder is reconstituted to form a suspension before injection, e.g. benzathine penicillin G.
- **Injection, powder, lyophilized, for solution** –This is a sterile freeze dried (lyophilized) preparation of the drug which is mixed with a diluent to form a solution. It is then injected, e.g. carboplatin lyophilized powder.
- **Injection, powder, lyophilized, for suspension** - This is a sterile freeze dried (lyophilized) preparation of the drug which is mixed with a diluent to form a suspension, e.g. phentolamine mesylate lyophilized powder.
- Examples of **diluents** - sterile water, 5% dextrose in water, 0.9% normal saline, etc. Instructions for reconstitution and administration should be carefully read and followed. Suspensions should never be administered intravenously.
- **Ampoule:** It is a small, sterile, sealed glass container containing the drug solution for injection, e.g. adrenaline, atropine. It contains a single dose of a drug.
- **Vial:** It is a small, sterile, glass bottle closed with a stopper containing drug in powder form/aqueous solution/suspension for injection, e.g. lignocaine, benzathine penicillin G, etc. It contains single or multiple doses of a drug.

DOSAGE FORMS- MODEL EXERCISE

(1Sheet per Exercise**)**

Exercise No: 1. ORAL SOLID DRUG FORMULATIONS

Tablets, Capsules

1. What are the different types of tablets? Give one example for each.
2. Mention the advantages & disadvantages of enteric, film and sugar coated tablets?
3. Differentiate effervescent tablets and chewable tablet ?
4. Differentiate capsule and spansule?

Exercise. No: 2. ORAL LIQUID DRUG FORMULATIONS

Syrup, Suspension and Elixir.

1. Mention two differences between syrup and suspension
2. What are the advantages and disadvantages of oral liquid formulation?
3. What is the volume of one teaspoon and one table spoon?
4. Steps to prepare a suspension from powder for suspension?

Exercise. No: 4 PARENTERAL DRUG FORMULATIONS

Ampoule, Vial – Single dose, Multi Dose, Depot preparation, Infusion ,

1. Identify the different forms of Parenteral formulation
2. What are depot preparations? Give one example.
3. Select the appropriate - Parenteral route with Relevance to Drug and clinical scenario?

Exercise. No: 5 TOPICAL DRUG FORMULATIONS

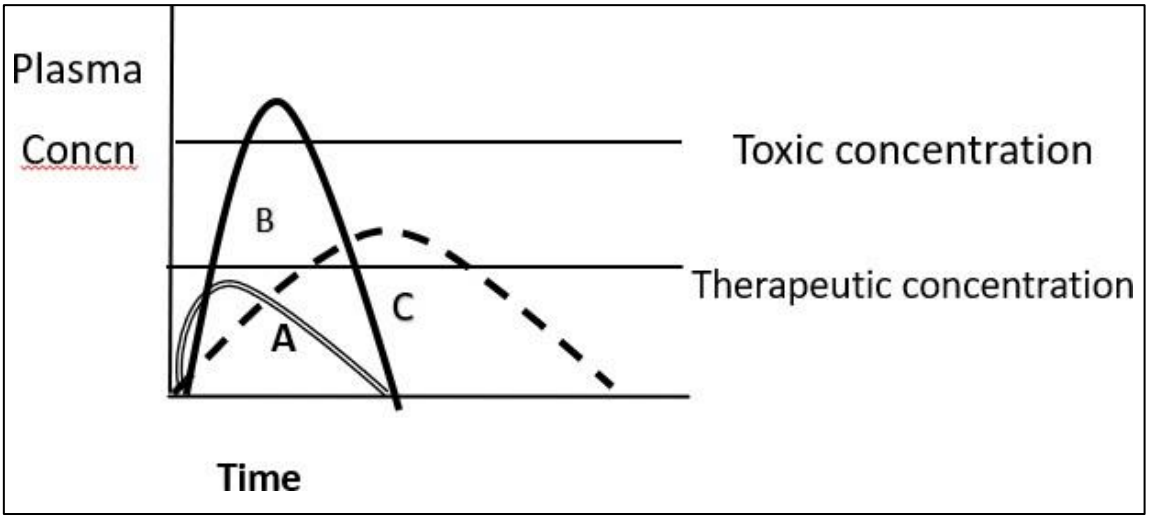
1. Identify Pessary & Suppository Give one example.
2. Mention the disadvantages

Exercise. No: 6 TOPICAL DRUG FORMULATIONS

1. Compare the composition and use of ointment , gel , cream , emulsion, lotion liniment ?
2. Communicate the patient regarding the application of topical formulation with a clinical scenario ?

PH 1.4 PHARMACOKINETIC EXERCISE

Exercise :1 Bioavailability

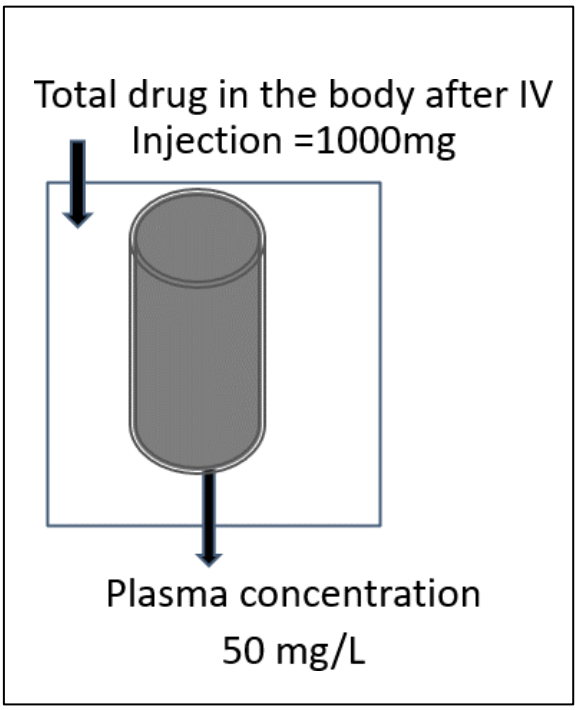


The above chart shows the comparison of the serum level curve of three formulations of a hypnotic compound. Note: A, B and C - Three different formulations,

Questions:

1. Which formulation is effective & safe? Explain?
   Formulation C is effective and safe as the serum level is attained and maintained in therapeutic concentration. But Formulation A levels below therapeutic concentration, not effective. Formulation B attains toxic concentration, not safe.
2. Mention 4 factors affecting bioavailability of a drug.
   First pass metabolism, Route of administration, Host factor- Age, G.I disease
3. Name four drugs having poor bioavailability. Indicate their route of administration
   Exenatide - S.C , Sumatriptan- Nasal, Gentamycin -IM, Nitroglycerin-Transdermal

Exercise :2 Volume of Distribution



Questions:

1. Define aVd?

   aVd is defined as the volume that would accommodate all the drug in the body, if the concentration throughout was the same as in the plasma

2. Calculate the (aVd) volume of distribution?

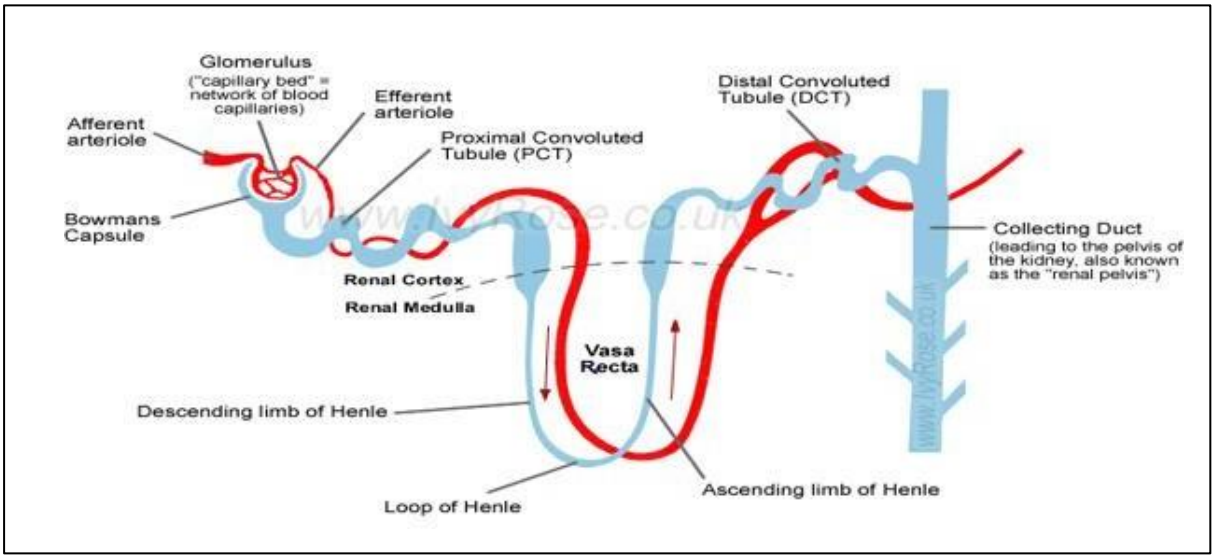
   aVd= Dose administered i.v = 1000 = 20 L/Kg

   Plasma concentration 50

3. What is the clinical significance of aVd?

   In case of poisoning, drugs with high Vd are not easily removed by hemodialysis. Pathological states e.g congestive cardiac failure may alter Vd of drugs and result in toxicity.

Exercise :3 Drug Excretion- Kidney



Questions:

1. How changes in pH affect tubular reabsorption?

   Since pH of the urine is acidic, all acidic drugs remain nonionised and are reabsorbed. If pH of the urine is made alkaline, acidic drugs are ionized. lonized drugs are not reabsorbed and are excreted.

2. Write the clinical application of the above principle?

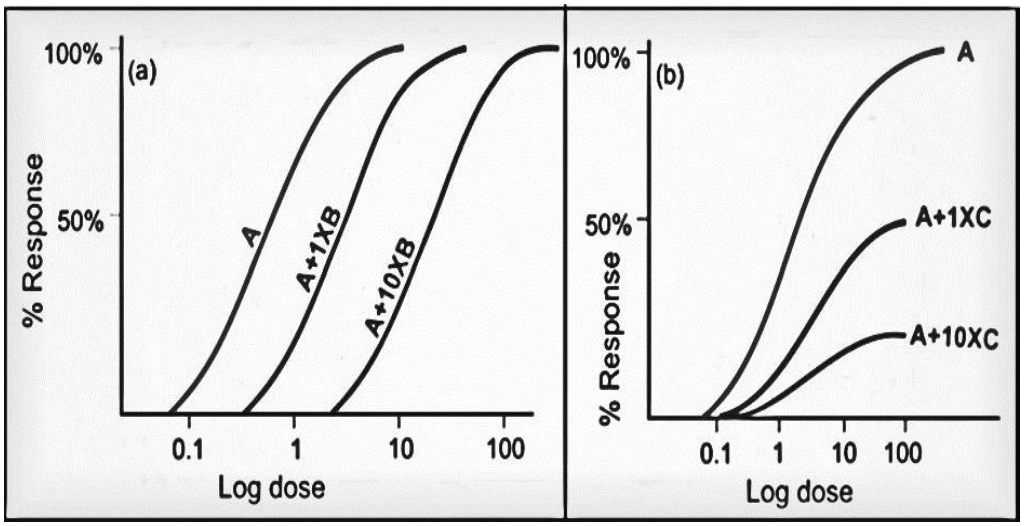
   Excretion of weakly acidic drugs like salicylate or barbiturate can be increased, if the pH of the urine is made alkaline by giving sodium bicarbonate or sodium citrate. Hence alkalinization of urine is useful in salicylate or barbiturate poisoning

3. What is the clinical importance of tubular secretion?

   In the tubular secretion processes, drugs utilizing the same active transport mechanisms compete with each other. Probenecid competitively inhibits the tubular secretion of penicillin and amoxycillin, thereby increasing the plasma half life and effectiveness of of penicillins in infections. Probenecid inhibits the tubular reabsorption of uric acid, hence, excretion of uric acid is increased.

   Thiazide diuretics inhibit the tubular secretion of uric acid, increases uric acid concentration in the body, precipitates gout in susceptible individuals.

Exercise :4 Drug Antagonism



Questions:

1. What are the different types of antagonism? Give example

   Physical antagonism - eg. Charcoal adsorbs alkaloids in alkaloidal poisoning

   Chemical antagonism - eg.BAL (Chelating agent) forms insoluble complexes with lead, arsenic

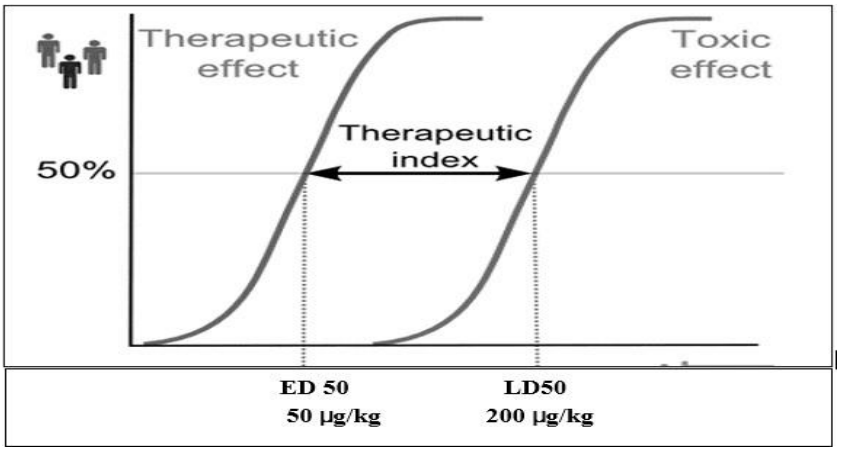
   Physiological or functional antagonism - effect of Histamine(vasodilatation) and noradrenaline(vasoconstriction) on BP

   Pharmacological or pharmacodynamic antagonism - Atropine and Acetylcholine for competitive antagonism, Flumazenil and BZD for noncompetitive antagonism
2. How will you prove surmountable antagonism?

   Reversible competitive or equilibrium competitive antagonism is the surmountable type of antagonism. Here, the antagonism can be overcome (surmounted) and the maximum response of agonist can be attained if concentration of agonist is increased.
3. Give an example for Irreversible Antagonism?

   Phenoxy Benzamine Antagonist versus Agonist Adrenaline.

Exercise :5 Therapeutic Index



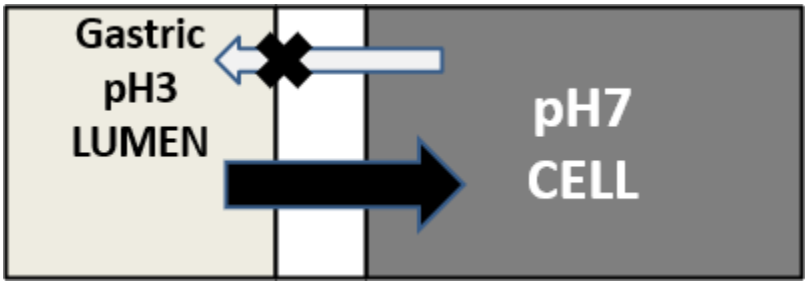
Questions:

1. What is ED50 ? Calculate from the above data.
   ED 50 also known as Median Effective Dose, is the dose that produces the specified effect in 50% of individuals. In the above graph ED 50 value- 50 µg/kg
2. What is LD50 ? Calculate from the above data.
   LD 50 also known as Median Lethal Dose is the dose which kills 50% of recipients. In the above graph LD 50 value- 200 µg/kg
3. Calculate the Therapeutic Index from the above data

   Therapeutic Index = $\frac{LD50}{ED50} = \frac{200}{50} = 4$

4. Write the Clinical significance for drugs with high and low Therapeutic Index.
   Therapeutic Index is the index of safety of the drug. Drugs with high T.I (>1) are more safer than drugs with low T.I (<1).

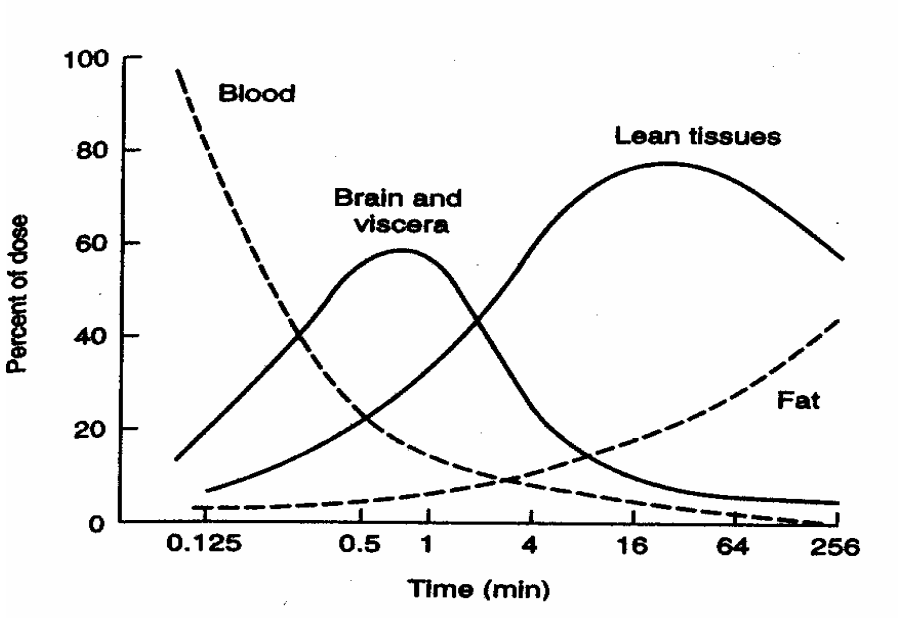
Exercise :6. ION TRAPPING



Questions:

1. Define the above phenomena?
2. List 4 drugs which show ion trapping?
3. Explain the site of absorption of acidic and basic drugs?

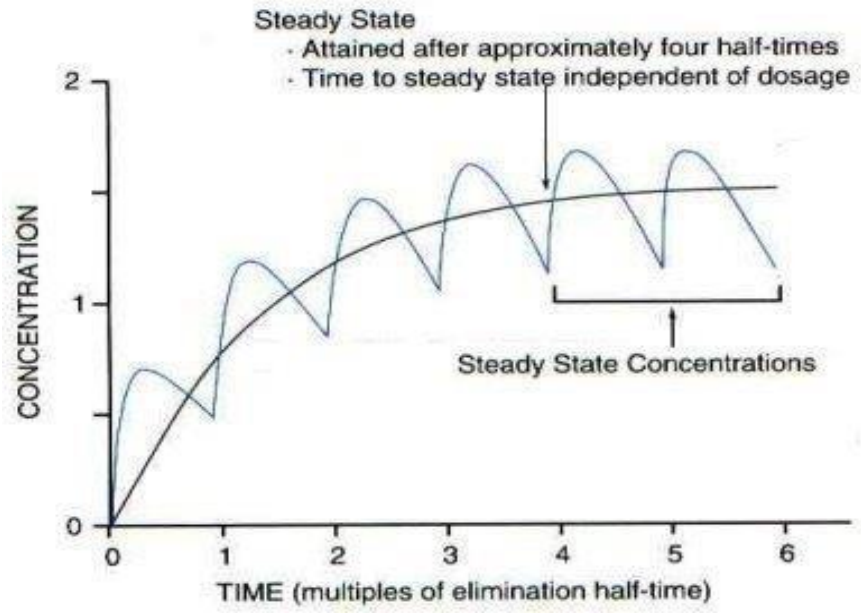
Exercise :7: DRUG REDISTRIBUTION



Questions:

1. What is redistribution?
2. How redistribution influences the duration of action of thiopentone?
3. How repeating the dose alters the half- life of drugs with redistribution?
4. Name the other drugs which may undergo redistribution?

Exercise : 8 - $t_{1/2}$ AND STEADY STATE PLASMA CONCENTRATION



Questions:

1. Define half life of a drug.
2. Give 2 example each for drugs with short half life & long half life?
3. For Drug A the half life is 2 hours
   a) What is the frequency of dosing of Drug A ?
   b) Calculate the time required for Drug A to achieve steady state plasma concentration?

Exercise: 9 Kinetics of Elimination

1. 100mg of drug A was given intravenously and the serum level of drug was measured every 2 hrs. The levels were 50mg, 25 mg, 12.5mg, 6.25mg, 3.125mg respectively. What does this signify?
2. Calculate (t½) for drug A?
3. When does a drug shift from first order to zero order kinetics? Give example.

Exercise :10 FDC- Fixed Drug Combination

A 26 year old female patient with UTI was prescribed Tab. Cotrimoxazole twice daily for 5 days along with Syrup.Citralka.

1. What are the drugs present in Tab.Cotrimoxazole?
2. What is the advantage of this combination?

PH 2.4: CALCULATION OF DRUG DOSAGE

Specific Learning Objective: At the end of session the learner should be able to :

1. Calculate the quantity of drug present in a given solution
2. Appreciate the importance of calculating the total quantity of drug and its conversion from the percentage to molar solutions for individualization of therapy.
3. Able to calculate the daily dose and the total dose for the course of treatment
4. Select a suitable drug for prescription for a given scenario and able to explain the rationale.
5. Formulation of choice for a given clinical situation in Paediatric /Geriatric /Pregnancy and in patients having hepatic and renal dysfunction.

Drug concentrations are expressed as: weight (mg or g) for solid medicaments; for liquid formulations like syrups, injections and the drug concentration can be expressed in two ways :

1. Weight in volume (W/V) - mg or g or U in ml, e.g. dopamine 200mg / 5ml, insulin 40U/ml, 5% dextrose solution (5g in 100 ml).
2. Volume in volume (V/V) - e.g. 70% ethyl alcohol (70ml of absolute alcohol in 100ml of it's aqueous solution).

In semisolid medications like ointments, gel, creams, the drug concentration is expressed as weight per weight W/W e.g. Benzoic acid 12%.

Percentage solution:

Weight / volume- 1g of solute in 100ml of solvent is 1% W/V.

Volume / volume -1ml of solute in 100ml of solvent is 1% V/V.

Weight / weight -1g of solute in 100g of solvent is 1% W/W

Dose Calculation can be done based on body weight and body surface area. Weight based calculation are more popular.

Based on weight (mg per kg body weight.)

$$\text{Individual Dose} = \frac{\text{Body weight (kg)}}{70} \times \text{Average adult dose}$$

Based on Body Surface Area

$$\text{Individual Dose} = \frac{\text{Body surface area in square metre}}{1.73} \times \text{Adult dose}$$

Based on Body Surface Area (BSA) in m^2 is calculated by using Mostellers formula.

$$\text{BSA in } m^2 = \frac{\sqrt{Height(cm) x Weight(kg}}{3600}$$

This method is more cumbersome and dose calculations by this method is used only for a limited number of drugs e.g. anticancer drugs.

Pediatric dose calculation can be done based on age, weight and BSA

- Based on age (Young 's formula)

$$\text{Child Dose} = \frac{\text{Age of child in years}}{\text{Age} + 12} \times \text{adult dose}$$

- Dose calculation based on weight and BSA can be done using above formulae

In patients with renal failure dose: calculation is based on creatinine clearance

Cockroft – Gault's formula used to calculate creatinine clearance as follows:

$$\text{Creatinine clearance } \left(\frac{\text{ml}}{\text{min}}\right) (\textbf{for males}) = \frac{[140 - \text{age (years)}] \times \text{Weight (kg)}}{72 \times \text{serum creatinine (mg/dl)}}$$

For Estimated CR.Clearance values in Females, multiply by 0.85.

Dose adjustment:

Creatinine clearance (ml/min)	Dose reduction
50-70	1.5 times
30-50	2.0 times
10-30	3.0 times
05-10	6.0 times

Mole: A mole is molecular weight expressed in grams. For e.g. molecular weight of sodium bicarbonate ($NaHC0_3$) is 84. So, 1 mole of sodium bicarbonate contains 84g.

Molar solution: One molar solution can be defined as one mole of a substance dissolved in 1 litre of solution, (1 mole/L.) For example, 1 molar $NaHCO_3$ represents 84 g of sodium bicarbonate dissolved in 1 litre of distilled water.

Calculation of intravenous infusion drip rate : It is mandatory that the students learn the basic steps of calculating the Dose, Dilution and Rate for administering drugs as Intravenous infusion, in emergency clinical conditions. Physician must calculate the quantity of drug present in solution before administration.

The infusion rate will not differ in case of total dose administration (e.g., infusion rate of quinine will remain the same for a 30, 50 or 70 kg patient since it is given in the dose of 10 mg/kg in 500 ml of 5% dextrose solution which is to be administered over a period of 4Hrs.

The infusion rates will differ when drugs are to be given at the **specified rates** (e.g., infusion rate of aminophylline will differ for a 30, 50 or 70 kg patient since it is to be given in the dose of 1 mg/kg/hr in 500 ml of normal saline). The dose of drugs is calculated per minute or per hour.

Diluting fluid: Selection of a suitable I.V. fluid is necessary for infusion based on chemical compatibility, stability and to manage side effects of the drug. For example, 10% dextrose solution is being used for quinine infusion. Dopamine infusion is given with 5% dextrose (acidic pH) solution for its compatibility and stability.

Solution can be expressed in form of ratio or percentage

Percentage: means part per 100

25% solution - means 25 gm in 100 ml

1: 1000 solution means-1 gm in 1000 ml

Calculating intravenous flow rates

Step 1- Total amount of solution / number of hours= number of ml/hour

Step 2- ml/hour = ml/60 minutes = ml/minute

Step 3- ml/minute = number of drops / minute

1 ml = 16 drops

Basic data for percentage calculation (metric system)

Weight / weight 1g of solute in 100g of solution is 1 %w/w

Weight / volume 1g of solute in 100 ml of solution is 1% w/v

Volume / volume 1ml of solute in l00ml of solution is 1 *% v/v*

MODEL EXERCISE

1. Calculate the dose requirement of Injection Amikacin for a 65 year old male weighing 50kg, with serum creatinine of 2mg/dL provided Inj. Amikacin normal Dose is 15mg/kg/day.

a. Write the formula for estimating the Creatinine clearance using Serum creatinine value

b. Calculate the dose required for the above patient.

c. If the clinical picture is that of a female with same values what is the dose of amikacin recommended?

a. Cockcroft- Gault Formula for Estimated Creatinine clearance:

$$\text{Estimated Creatinine clearance} = \frac{140 - \text{Age in years}}{72 \times \text{serum creatinine(mg/dl)}} \times \text{weight in kg}$$

$$= \frac{140-65}{72\times2} \times 50 = 26 \text{ ml/min.}$$

b. Dose requirement of Inj. Amikacin for the above Patient

Dose for this patient weighing 50 kg = 15 x 50 =750 mg/day

$$\text{Dose in mg Renal dysfunction} = \frac{\text{Normal dose}}{\text{Normal Cr. Cl}} \times \text{Cr. Cl in renal insufficiency(ri)}$$

$$\frac{750}{} = \frac{}{120} \times 26 = 162$$

Dose for male in Renal insufficiency= 162 mg/ day (80mg 12 Hrly)

c. Female = Male Estimated Cr. Cl × 0.85 = 26 x 0.85= 22.1 ml/min

$$\text{Dose in mg Renal dysfunction} = \frac{\text{Normal dose}}{\text{Normal Cr. Cl}} \times \text{Cr. Cl in renal insufficiency(ri)}$$

$$\frac{750}{} = \frac{}{120} \times 22 = 137$$

Dose for female with Renal Insufficiency = 137 mg/day (60 mg 12 Hrly)

2. Calculate the parenteral iron required for a patient weighing 60 kg with Hemoglobin level of 7gm/dl in blood. (Normal Hb level = 14 gm/dl)

   Requirement of iron in mg = 4.4 x body weight x Hb deficit in gm/dl

   = 4.4 x 60 x (14 - 7) = 4.4 × 60 x 7= 4.4 × 420= 1848 mg/dL

   Iron is available as 2 ml ampoule (1 ml = 50 mg).100 mg is present in 1 ampoule.

   So, 19 Ampoules for I.M. injections are needed on alternative days.

3. A 60 year old male patient with 50kg body weight develops thrombotic stroke. Calculate the dosage of mannitol to be prescribed to this patient.

   (Mannitol is available as 20% solution.

   Dose = 1g/kg in two divided doses

   Dose required =1 x 50 = 50g, 50 / 2 = 25g twice a day.

   20% mannitol = 20 g in 100ml.

   Therefore 50 g, $= \frac{50X100}{20}$ = 250 ml per day, 125 ml twice a day.

4. Calculate the amount of fluids to be infused to a 50 kg patient with 20% burns.

   The amount of fluids to be infused =4 x body weight x % of burns

   = 4 × 50 × 20 = 4000 ml.

   The preferred fluid is Ringer lactate.

   Half of the amount to be given in first 8 hrs.

   The remaining to be given in next 16 hrs.

   So 2000 ml i.e. 4 pints in first 8 hrs and remaining 2000 ml in next 16 hrs.

5. Calculate the amount of oral Paracetamol drops formulation for a 4 months old febrile infant weighing 5 kg. The given formulation contains 100 mg of paracetamol in 1 ml. (Dose: 15 mg/kg/dose)

   Dose of paracetamol required per dose = 15 mg x Wt in Kg = 15 × 5 = 75 mg/dose

   100 mg Paracetamol in 1 ml (16 drops)

   75 mg Paracetamol in 0.75 ml (12 Drops)

   So 12 drops /dose given 6th hourly.

Reflections of the Learner

PH 4.1: ROUTES OF DRUG ADMINISTRATION

A. PARENTERAL

Specific Learning Objective: At the end of the session the learner should be able to

1. Identify the volumes of syringe and needle required for IM, IV Bolus injection.
2. Select the appropriate route for a given medication.
3. **DEMONSTRATE THE STEPS AND PERFORM THE PROCEDURE INDEPENDENTLY IN A MANNEQUIN**. *(Not Enumerate)*

GENERAL CHECK LIST IN USE OF PARENTERAL DRUGS :-

1. **Expiry dates:** Check the expiry dates of each item including the drug.
2. **Drug:** Ensure that the vial or ampoule contains the right drug in the right strength.
3. **Sterility:** During the preparation procedure, material should be kept sterile. Wash your hands prior to preparing the injection. Disinfect the skin over the injection site.
4. **No bubbles:** Ensure that there are no air bubbles in the syringe, important in intravenous injections.
5. **Prudence:** Once the protective cover of the needle is removed extra care is needed. Do not touch anything with the unprotected needle. Once the injection has been given take care not to prick yourself or somebody else.
6. **Waste:** Make sure that contaminated waste is disposed of safely.
7. **Size of needles , volume of syringe in different routes :**

Route	Syringe (ml)	Needle (gauge)
Intradermal	0.1-1	26-27
Subcutaneous	1-2	24-26
Intramuscular	up to 5ml	22-24
Intravenous	any volume	16-22
Transfusion of blood	-----	15-16
Collection of blood	-----	18-19

ASPIRATING FROM AMPOULES (GLASS, PLASTIC)

Materials needed: Syringe of appropriate size, needle of required size, ampoule with required drug or solution, gauze.

Technique

1. Wash your hands.
2. Put the needle on the syringe.
3. Remove the liquid from the neck of the ampoule by flicking it or swinging it fast in a downward spiraling movement.
4. File around the neck of the ampoule.
5. Protect your fingers with gauze if ampoule is made of glass.
6. Carefully break off the top of the ampoule (for a plastic ampoule twist the top/ampoule breaker).
7. Aspirate the fluid from the ampoule.

8. Remove any air from the syringe.
9. Inject.
10. Clean up; dispose of working needle safely; wash your hands.

ASPIRATING FROM A VIAL

Materials needed: Vial with required drug or solution, syringe of the appropriate size, needle of right size (IM, SC, or IV) on syringe, disinfectant, gauze.

Technique

1. Wash your hands.
2. Disinfect the top of the vial.
3. Use syringe with volume twice the required amount of drug / solution, add needle.
4. Suck up as much air as the amount of solution needed to aspirate.
5. Insert needle into (top of) vial and turn upside-down.
6. Pump air into vial (creating pressure).
7. Aspirate required amount of solution and 0.1 ml extra. Ensure needle tip is below the fluid surface.
8. Pull the needle out of the vial.
9. Remove possible air from the syringe.
10. Inject.
11. Clean up; dispose of waste safely; wash your hands

DISSOLVING DRY MEDICINE

Materials needed: Vial with dry medicine to be dissolved, syringe with right amount of solvent, needle of right size (IM, SC, or IV) on syringe, disinfectant, gauze.

Technique

1. Wash hands.
2. Disinfect the rubber cap (top) of the vial containing the dry medicine.
3. Insert the needle into the vial, hold the whole unit upright.
4. Suck up as much air as the amount of solvent already in the syringe.
5. Inject only the fluid into the vial, not the air!
6. Shake.
7. Turn the vial upside-down.
8. Inject the air into the vial (creating pressure).
9. Aspirate the total amount of solution (no air).
10. Remove any air from the syringe.
11. Inject.
12. Clean up; dispose of waste safely; wash hands

Handling a syringe

Task: Load the following volumes of the drug from the vial with the appropriate syringes following aseptic techniques:

a) 0.2ml b)1.5ml c)4.5ml d)7.0ml

Components of Task

- Choose the appropriate syringe for the volume
- Choose the needle of appropriate size for the desired route

- Aseptic technique while opening the packet/handling the syringe
- Loading the syringe with aseptic technique

SUBCUTANEOUS INJECTION

Requirements: Syringe, drug, short and 25 Gauge needle, antiseptic lotion, cotton wool, adhesive tape

Procedure:

1. Wash hands
2. Reassure the patient and explain the procedure
3. Uncover the area to be injected (upper arm, upper leg, abdomen)
4. Clean the injection site by rubbing the skin with cotton wool soaked in antiseptic lotion in a circular motion starting from the centre and moving outwards
5. Pinch fold of the skin
6. Insert needle at the base of the skin fold at an angle of 20-30 degrees
7. Release the skin
8. Aspirate briefly, if blood appears withdraw the needle, replace it with a new one and start again from step 4
9. Inject slowly in 0.5 -2 minutes
10. Withdraw needle quickly, press sterile cotton at the site and fix with adhesive tape
11. Dispose the waste, clean up and wash your hands.

INTRAMUSCULAR INJECTION

Requirements: Syringe, drug, 22/23/24 gauge needle antiseptic lotion, cotton wool, adhesive tape .

Procedure:

1. Wash hands
2. Reassure the patient and explain the procedure
3. Uncover the area to be injected (lateral upper quadrant of the gluteus maximus/ lateral side of the thigh/ deltoid muscle
4. Clean the area with a cotton wool soaked in antiseptic lotion in a circular motion starting from the centre
5. Ask the patient to relax the muscle
6. Insert the needle at an angle of 90 degrees
7. Aspirate to see if blood appears, if not, inject slowly (less painful)
8. Withdraw needle swiftly
9. Press sterile cotton wool onto the injection site. Fix with adhesive tape
10. Dispose the waste, clean up and wash your hands

INTRAVENOUS INJECTION

Requirements: Syringe, drug, needle (long and gauge 20), antiseptic lotion, cotton wool, adhesive tape and tourniquet

Procedure:

1. Wash hands
2. Reassure the patient and explain the procedure
3. Uncover the arm completely, support the arm

4. Apply the tourniquet above the median cubital vein and wait for the vein to become prominent
5. Clean the area with antiseptic lotion
6. Stabilize the vein by pulling the skin taut, insert the needle at an angle of 35 degrees
7. Puncture the skin and enter into the vein for 3-5mm
8. Aspirate to see if blood appears if so, loosen the tourniquet inject very slowly and check for swelling
9. Withdraw needle swiftly, press sterile cotton wool into the opening and fix with adhesive tape
10. Reassure the patient, clean up the area dispose the waste safely and wash your hands.

SETTING UP an IV LINE and FIXATION

Requirements: Drug/fluid for infusion , needle (long and gauge 18/20),IV Cannula, Infusion set, antiseptic lotion, cotton wool, adhesive tape, tourniquet

Procedure:

1. Adopt Aseptic technique when opening infusion set
2. Checking drug name, date of expiry, patient ID,
3. Positioning of the patient, selection of vein
4. Skin preparation
5. Injection technique and confirmation of position
6. Strapping the needle in place
7. I.V fluids to be checked for impurities
8. Adjusting flow rate
9. Monitoring the patient

MODEL EXERCISE

NOTE:

- *Facilitator must teach these sessions as **DOAP** ,*
- *Observe the student's performance in Mannequin with relevant communication*
- *Enter the proficiency level in academic record and scores for the individual routes in assessment record (ranging as mentioned against each route)*

1. A 35 years old male presents with high grade fever and vomiting. Physician has prescribed Inj.Paracetamol. Select the parenteral route, requirements and **demonstrate** in mannequin in the above scenario and present instructions to the patient about the procedure.

   Facilitator's Observation of Demonstration (Tick in the appropriate box)

Date	Needs Improvisation (Plan remedial session)	Average	Satisfactory

Signature of Facilitator

2. A 27 year old male presents to emergency clinic with active convulsions select the drug from the emergency tray, required syringe and **demonstrate** the steps in mannequin , with relevant communication. Facilitator's Observation of Demonstration (Tick in the appropriate box)

Date	Needs Improvisation (Plan remedial session)	Average	Satisfactory

Signature of Facilitator:

3. A 18 yrs old female present with severe dehydration due to vomiting and diarrhoea, select the fluids and device required, and **demonstrate** the steps with relevant communication.Facilitator's Observation of Demonstration (Tick in the appropriate box)

Date	Needs Improvisation (Plan remedial session)	Average	Satisfactory

Signature of Facilitator:

4. A 15 years old female with Pneumonia is prescribed Inj.Benzyl Penicillin. select the route, dilution and device required for administering TEST DOSE and **demonstrate** the steps with relevant communication.Facilitator's Observation of Demonstration (Tick in the appropriate box)

Date	Needs Improvisation (Plan remedial session)	Average	Satisfactory

Signature of Facilitator

5. A12 years old female child newly diagnosed as TYPE I Diabetes mellitus, select the route, device required & demonstrate administration of Regular Insulin with relevant communication .Facilitator's Observation of Demonstration (Tick in appropriate box)

Date	Needs Improvisation (Plan remedial session)	Average	Satisfactory

Signature of Facilitator

PH 4.1: ROUTES OF DRUG ADMINISTRATION
B. SPECIAL DRUG DELIVERY SYSTEMS

Specific Learning Objectives (SLO) At the end of the practical class the student shall be able to:

1. Select the appropriate dosage form for the clinical situation.
2. **Demonstrate the steps of the technique in using the drug delivery system**
3. Able to communicate the instructions to be given to patients on the proper usage of each dosage form. (Chew, powder, divide, place under tongue etc.,)

(NOTE: The facilitator to ensure that the learner is able to reproduce the steps in correct order with effective communication. NOT ENUMERATE)

A. INHALATIONAL DEVICES

Inhalation dosage forms contain drug particles or solutions administered by the respiratory route for local or systemic effect. Drugs so administered produce rapid action. Particle size is of major importance in the administration of this type of preparation. Optimum particle size for penetration into the pulmonary cavity is of the order of 0.5 to 7 µm. Inhalation therapy can be administered by:

- Pressurized aerosol systems (Metered dose inhaler)
- Dry powder systems (Rotahaler)
- Nebulier

Choice of device is based on age of the patient

Age	***Recommended device***
0-2yrs	Nebuliser, spacer with mask, aerochamber with mask
2-5yrs	Spacers, rotahaler
5-8yrs	Rotahaler, spacer
>8 yrs	Metered dose inhaler

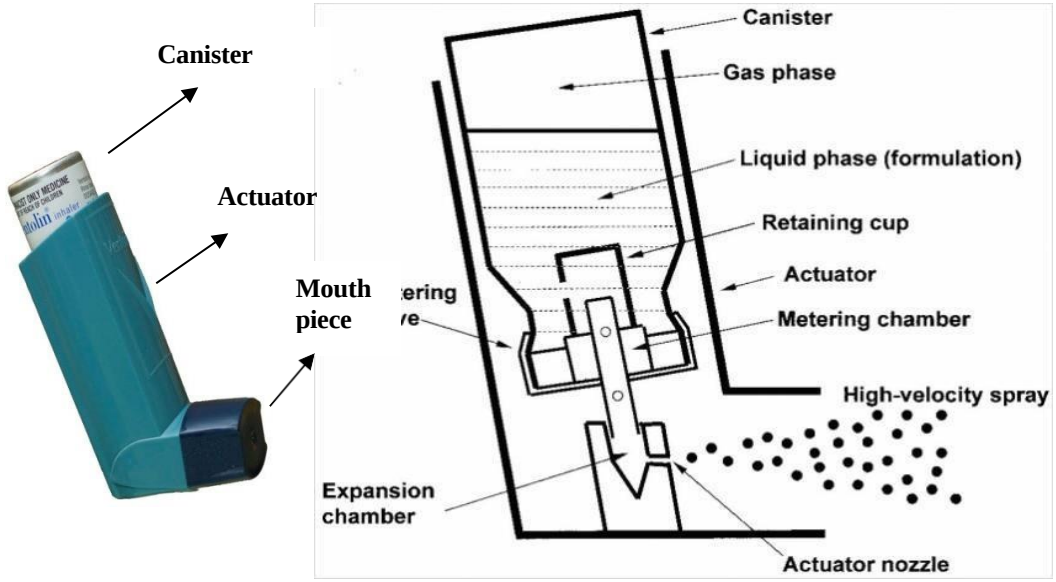
AEROSOL has been defined as colloidal system consisting of very finely subdivided liquid or solid particles suspended in a gas. Various chemical compounds have been used as aerosol propellants which include liquid gases (hydrofluoroalkanes) and compressed gases. The propellant generally is regarded as the heart of the aerosol package. In addition to supplying the necessary force to expel the product, it must also act as a solvent and diluent. Aerosol

valve regulates the flow of product from the container. Oral aerosol has been employed in the treatment of bronchial asthma while topical aerosol employed for various skin conditions.

Advantages of aerosol:

- Rapid onset of action.
- Circumvention of first pass effect.
- Lesser adverse effect as lower dose is given.
- Dose titration as per the need can be done.
- Preferred route for drugs which exhibit variable pharmacokinetics upon oral or parenteral administration
- A suitable route to avoid chemical or physical drug - drug interaction.

METERED DOSE INHALER:



Metered dose inhaler delivers a measured dose of drug per puff through a pressurized spray. Fine mists are produced by pressurized aerosols. Metered aerosol delivers more uniform dose. After withdrawing the inhaler, the patient should be instructed to hold the breath for at least 10 seconds.

STEPWISE DIRECTIONS FOR THE CORRECT METHOD OF USING INHALER

Step 1: Remove the dust cap from the mouthpiece and shake the inhaler vigorously.

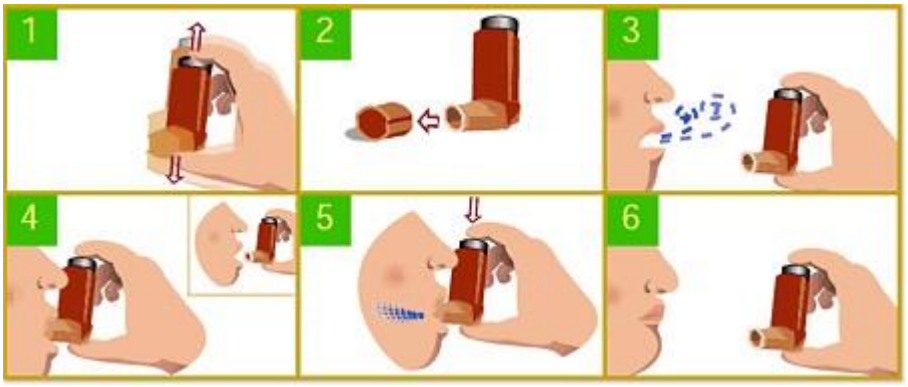
Step 2: Hold the inhaler vertically. Breath out slowly and gently until the lungs are comfortably empty, Tilt the head back. Close the lips tightly around the mouthpiece.

Step 3: Start breathing slowly and press the metal canister down firmly.

Step 4: Continue breathing in slowly and steadily until the lungs are full.

Step 5: Remove inhaler from mouth while holding the breath atleast 10 seconds..

Wait for at least one minute before puffing the next dose.



SPACER DEVICE: Infants and young children often have difficulty in co-ordinating the use of inhaler. A spacer is a device which can be attached to an inhaler. If necessary, a face mask can also be attached to the spacer.

LARGE-VOLUME SPACERS allow patients to inhale drugs from metered dose inhalers in their own time and can improve lung deposition in patients with poor technique.. Large-volume spacers also reduce oropharyngeal deposition of aerosol droplets, they are device of choice for administering high dose inhaled corticosteroids.

STEPWISE DIRECTIONS FOR CORRECT METHOD OF USING SPACER DEVICE

Step 1: Push the two halves of the spacer together firmly.

Step 2: Remove mouthpiece cap of the inhaler. Shake inhaler vigorously.

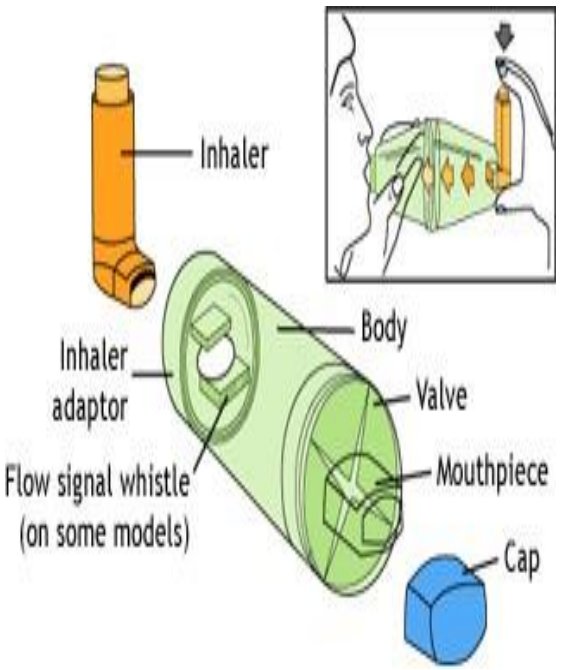
Step 3: Fix the inhaler into the narrow end of the spacer device.

Step 4: Place the mouthpiece cap over the other end of the spacer.

Step 5: Holding the Inhaler, press down on the canister to release a dose into the spacer

Step 6: Remove the mouthpiece cap. Close lips firmly around the mouthpiece to create a good seal. Inhale deeply through mouth from the spacer. Remove the spacer from the mouth and hold the breath for as long as comfortable. Breathe out slowly.

Note: If a second dose is required, wait for at least one minute before repeating steps 2 to 6.



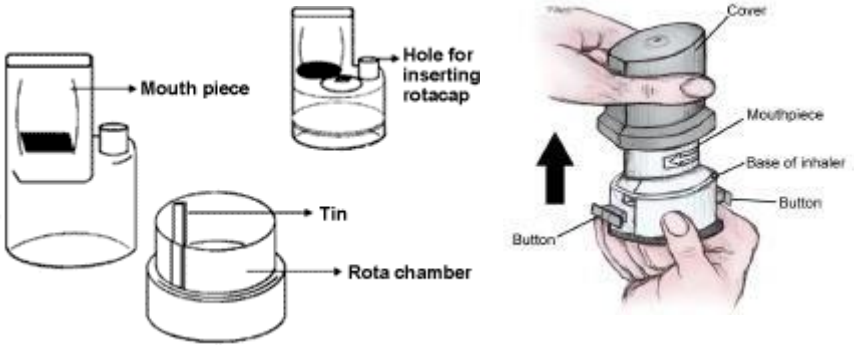
DRY POWDER INHALER (ROTAHALER):

Various dry powder devices do not require the patient to coordinate actuation with inhalation. They are suitable for many of the patients who have difficulty with metered dose inhalers including children

ROTAHALER is a device that delivers a measured dose of drug in a powdered form. The drug is used in the form of a capsule in this device. This technique does not require coordination of inspiration with drug delivery. Dry powder dosage forms are formulated by mixing micronized drug particles (2-5µm) with larger carrier particles to make it a free flowing powder for inhalation. During inhalation, the drug particles are liberated from the surface of the carrier particles by the energy of the inspired air flow and the turbulence created in dry powder inhaler. Thus, the small drug particles are deposited in the therapeutically significant regions of the lungs whereas the larger carrier particles tend to deposit on the oropharynx and are subsequently swallowed.

The rotahaler consists of two chambers – ***mouthpiece*** and the ***reservoir***. An integrated mesh separates the two chambers. To operate, the patient inserts the capsule into the raised square hole such that top end of the capsule is at level with the top of the hole. The base of the device is rotated at an angle of 360^0 during which a fin, present on the inner side of the base, knocks down the body of the capsule containing the drug powder into the reservoir. When the

patient inhales from the mouthpiece, air enters the reservoir through three small holes. As the patient continues to inhale, the separated capsule containing the drug rattles against the walls of the reservoir thereby effectively releasing the drug into a turbulent air stream.



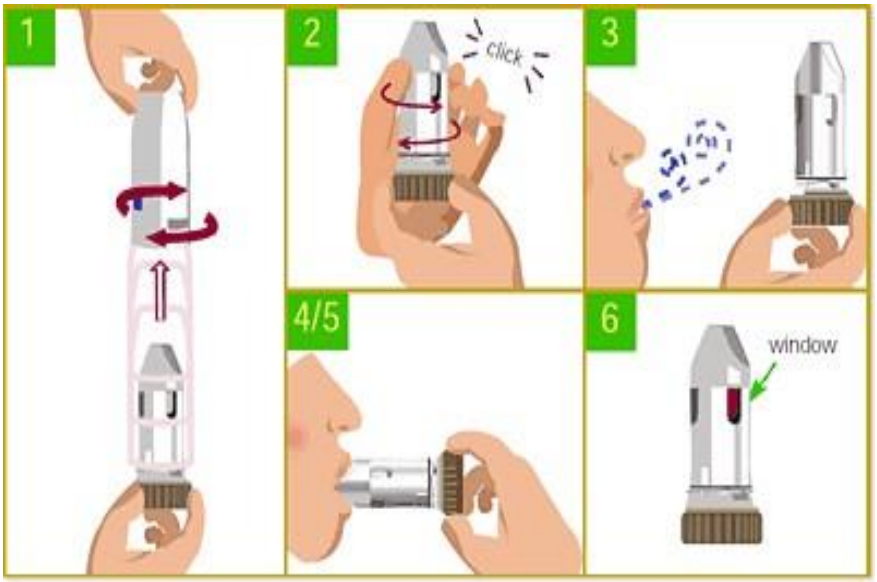
STEPS FOR CORRECT METHOD OF USING ROTAHALER

Step 1: Hold the rotahaler vertically and insert the rotacap (transparent end) first into the square hole of the rotahaler.

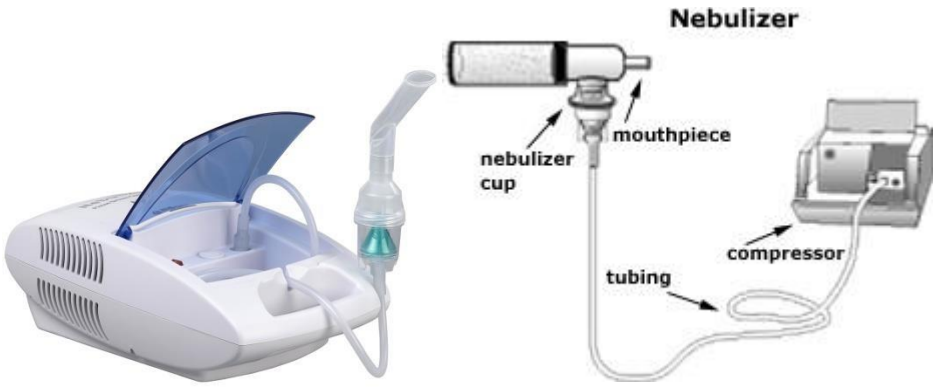
Step 2: Rotate the base of the Rotahaler in order to separate the two halves of the rotacap.

Step 3: Breathe in as deeply as possible. Hold the breath for 10 seconds. Breathe out slowly. If powder remains repeat the inhalation.

Note: If the breathing is correct, the soft rattling sound of the rotacap is heard. This confirms the proper method of using rotahaler.



NEBULIZER: Nebulizer is a suitable device for the inhalation of drug solutions. The droplets which are sufficiently fine and uniform in size reach the bronchioles. Nebulization is advocated for the management of severe attacks.



STEPWISE DIRECTIONS FOR USE OF NEBULIZER

Step 1: Assemble the nebulizer according to instructions given on the manual of the nebulizer. Connect the hose to an air compressor.

Step 2: Fill the medicine cup with the respirator solution prescribed according to the instructions.

Step 3: Attach the hose and mouthpiece to the medicine cup

Step 4: Place mouthpiece in the mouth. Breathe through mouth until all the medicine is used up (about 10-15 minutes). A nose clip to help breathing only through the mouth may be used.

Step 5: Wash the medicine cup and mouthpiece with water, and air-dry.

B. TRANSDERMAL DRUG DELIVERY SYSTEM (TDDS),

E.g. Transdermal patch (Skin patch) and Transdermal ointment

Transdermal drug delivery is a form that delivers the drug at a **constant rate to systemic circulation**. Transdermal drug delivery systems facilitate the passage of therapeutic quantities of drug substances through the skin and into the general circulation for their systemic effects. For transdermal drug delivery it is ideal if the drug penetrates through the skin to the underlying blood supply without drug being stored in the dermal layers. (in contrast to topical dosage forms where in drug residence in the skin is desired).

Liner – Protects the patch during storage. The liner should be removed before use.

Drug – Drug solution is in direct contact with the release liner

Adhesive – Holds the components of the patch together. It also helps keep the patch 'glued' to the skin

Membrane – Controls the release of the drug from the patch

Backing – Protects the overall patch during the application period

C. EYE/NASAL DROPS/SPRAY & EAR DROPS

1. EYE DROPS

- Wash your hands
- Do not touch the dropper opening.
- Ask patient to look upward.
- Pull the lower eyelid down to make a 'gutter'.
- Gently administer 1 drop into the 'gutter' without tip touching the eye
- Close the eyes
- Lightly press inner canthus of eye to prevent drainage of drug into nasolacrimal duct.
- Excess fluid can be removed with a tissue
- If more than one kind of eye drop is used, wait at least 5 min before applying the next drop

2. NASAL DROPS

- Blow the nose.
- Wash your hands thoroughly
- Sit down and tilt head backward or lie down with pillow under the shoulders.
- Avoid touching the dropper tip against the nose
- Apply the amount of drops prescribed.
- Bend the head forward towards the knees.
- Sit up after a few seconds, the drops will then drip into the pharynx.

- Repeat the procedure for the other nostril, if necessary.

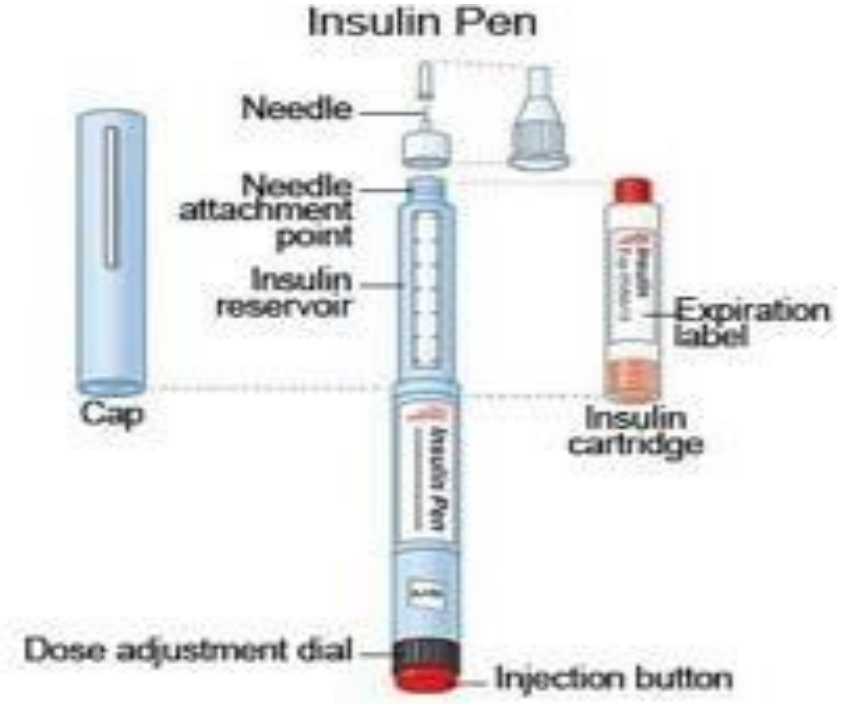
3. NASAL SPRAY:

- Blow the nose.
- Sit upright with head slightly tilted forward
- Insert the tip into the nostril while closing the other nostril
- Spray by squeezing the bottle and sniff slowly
- Remove the tip from nose and bend forward
- Repeat the procedure for the other nostril, if necessary.
- Clean the nozzle with alcohol swab

4. EAR DROPS:

- Wash your hands
- Ask the patient to lie on their side with affected ear facing up
- Gently pull the earlobe upwards and outwards to straighten the ear canal
- Make sure the ear canal is dry without any discharge
- Administer recommended number of drops
- Massage the tragus to allow the spread of medication into the ear canal
- Ask the patient to remain on the same side for 2-3 minutes
- Excess fluid can be removed with a tissue
- Clean the nozzle and replace the cap firmly after use.

D. INSULIN PEN:



Steps for using an insulin pen:

- Wash your hands -Ensure your hands are clean to prevent infection.
- Prepare the insulin pen

  Remove the cap from the insulin pen.

  If using a new pen, remove the protective seal from a new needle.

  Attach the needle to the pen by screwing it on tightly.
- Prime the pen
  Dial up 2 units by turning the dosage knob.
  Hold the pen with the needle pointing upwards.
  Tap the insulin reservoir gently to move air bubbles to the top.
  Press the injection button fully to release insulin and expel any air bubbles. You should see a drop of insulin at the needle tip.
- Set the dose
  Turn the dosage knob to the number of units you need to inject. Select and clean the injection site
  Common injection sites include abdomen, thigh, buttocks, upper arm.
  Clean the area with an alcohol swab and let it dry.
- Inject the insulin
  Pinch the skin if necessary.
  Insert the needle at a 90-degree angle (or 45 degrees if you are thin).
  Press the injection button fully to deliver the dose.
  Hold the needle in place for 10 seconds to ensure all insulin is delivered.
- Remove the needle
  Pull the needle out gently.
  Press injection site with a cotton ball or swab for a few seconds; do not rub.
  Unscrew the needle from the pen and dispose of it in a sharps container.
- Store the insulin pen
  Replace the cap on the insulin pen.
  Store the pen according to the manufacturer's instructions (usually in a cool place).

MODEL EXERCISE:

1. Select an appropriate SDD for delivery of a drug for maintenance therapy of Bronchial Asthma in a 23 yrs male and Demonstrate the steps to use this device?

   Facilitator's Observation of Demonstration (Tick in the appropriate box)

Date	Needs Improvisation (Plan remedial session)	Average	Satisfactory

   Signature of Facilitator:

2. Select an appropriate SDD and Demonstrate the steps for Transdermal route for a patient planning to travel with history of motion sickness?

   Facilitator's Observation of Demonstration (Tick in the appropriate box)

Date	Needs Improvisation (Plan remedial session)	Average	Satisfactory

   Signature of Facilitator:

3. Select an appropriate SDD and Demonstrate in 2 years old child with Acute Bronchial Asthma.

   Facilitator's Observation of Demonstration (Tick in the appropriate box)

Date	Needs Improvisation (Plan remedial session)	Average	Satisfactory

   Signature of Facilitator:

4. Demonstrate the steps in use of eye drops in a patient who underwent Cataract surgery

   Facilitator's Observation of Demonstration (Tick in the appropriate box)

Date	Needs Improvisation (Plan remedial session)	Average	Satisfactory

   Signature of Facilitator:

5. Demonstrate the steps in use of Insulin pen to administer 8 Units of Lente Insulin.

   Facilitator's Observation of Demonstration (Tick in the appropriate box)

Date	Needs Improvisation (Plan remedial session)	Average	Satisfactory

   Signature of Facilitator:

INSTRUCTIONS FOR COMPLETING CERTIFIABLE COMPETENCIES TABLES*

1. **Attempt at activity by learner: Indicate if:**

- **F -**First attempt (or) only attempt
- **R -**Repeat of a previously done activity
- **Re -**Remedial

2. **Rating - Use one of three grades:**

- **B-** Below Expectation
- **M-** Meet Expectation
- **E -**Exceed Expectation

3. **Decision of faculty**

- ✓ **C:** activity is completed, therefore closed, and can be certified
- ✓ **R:** Repeat
- ✓ **Re:** activity needs remedial action

(Remedial is a planned activity at correcting deficits that prevent a learner from achieving an intended outcome. Remedial activity is done after repetition did not lead to satisfactory completion.)

* Ref: NMC module on Logbook Guidelines.

CERTIFIABLE COMPETENCY
PH.3.3 DRUG PROMOTIONAL LITERATURE

1	2	3	4	5	6	7	8
Exercise .No	**Drug Promotional literature**	**Date completed**	**Attempt at activity First or Only (F) Repeat (R) Remedial (Re)**	**Rating below (B) Expectations Meets (M) Expectations Exceeds (E) expectations OR Numerical Score**	**Decision of faculty Completed (C) Repeat (R) Remedial (Re)**	**Initial of faculty and date**	**Feedback Received Initial of learner**
PH.3.3 : Perform Critical Evaluation of the give Drug Promotional Literature							
1			**F**	**B**	**C**		
			R	**M**	**R**		
			Re	**E**	**Re**		
2							
3							
4							
5							

PH 3.3 DRUG PROMOTIONAL LITERATURE

Specific Learning Objectives: At the end of the practical group work the student shall be able to:
1. Critically analyze a drug advertisement.
2. Identify unethical marketing practices.
3. Realize the extent to which drug advertisements can influence prescribing behaviour.

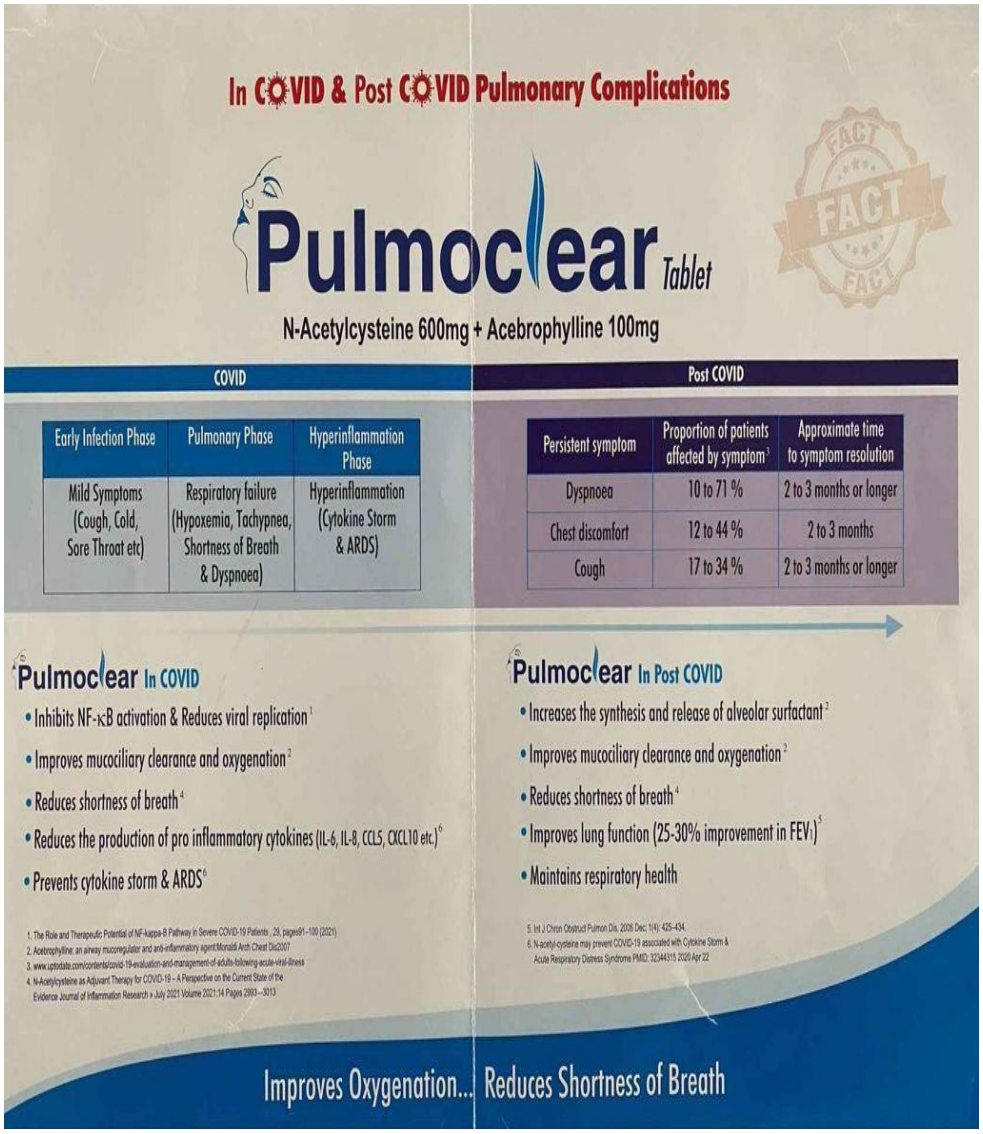
A brief introduction on drug promotion followed by Task:

EXERCISE: DRUG PROMOTIONAL LITERATURE

1. Critically review the Drug Promotional literature using WHO criteria, enter observation.
2. Will you recommend the drug quoted in the DPL based on your review?

Checklist for Critical evaluation of Drug Promotional Literature		
S.No	Checkpoints	Yes/No
1	International Non- Proprietary Name (INN) of each substance	
2	Pharmacological Data: Brief description of pharmacological effects and mechanism of action	
3	Clinical information	
3a	Indications (based on diagnostic criteria)	
3b	• Dosage regime and relevant pharmacokinetic data • Average and range for adults and children • Dosing interval • Average duration of treatment • Special situations, e.g. renal, hepatic, cardiac or nutritional insufficient that require either increased or reduced dosage	
3c	Contra indications	
3d	Precautions and warnings (reference to pregnancy, lactation, etc).	
3e	Adverse effects,	
3f	Drug interactions	
3g	Overdosage: Brief clinical description of symptoms, Non-drug treatment and supportive therapy, Specific Antidotes	
4	Pharmaceutical information	
4a	Dosage form	
4b	Strength of dosage form	
4c	Excipients	
4d	Storage condition and shelf life	
4e	Pack sizes,	
4f	Description of Product and package	
4g	Legal category: Narcotic or controlled drug,Prescription / non-prescription	
4h	Name and address of manufacturers and importers	
4i	References	
Impression to Recommend /Reject a drug based on the Drug advertisement		

MODEL EXERCISE:1



DPL EXERCISE 2:

DPL EXERCISE 3:

DPL EXERCISE 4:

DPL EXERCISE 5:

Reflections of the Learner

PH 2.2 ORAL REHYDRATION SOLUTION

Specific Learning Objectives**:** at the end of the session the learner should be able to

1. Know the composition and rationale of the composition.
2. Demonstrate the preparation of ORS from POWDER.
3. Able to Communicate the technique of ORS preparation.
4. Able to communicate effectively on the details of storing and administering the prepared solution

Steps in Preparation of Oral Rehydration Solution from ORS Powder

- Boil and cool one Litre of water
- Open ORS sachet and add whole content in one litre water.
- Shake well for few minutes to dissolve it completely.
- ORS is ready for use and it should be used within 24 hours.

How To Use (Instruction to Child's Parents or Attendants)

1. It is used to prevent or overcome dehydration due to fluid loss in diarrhoea.
2. It should be prepared fresh for a day.
3. Give small amount of ORS after every episode of diarrhoea or vomiting as follows:
   - Children < 2 years - 50-100 mL of ORS
   - Children 2-10 years - 100-200 mL of ORS
   - Children > 10 years and adults - 200-250 mL of ORS
4. Repeat the above dose to administer as much as possible.
5. Discard the remaining amount at the end of day.
6. If child or adult has vomiting or cannot take orally or frequent diarrhoea then consult the doctor immediately for further treatment (suitable IV. fluid).

MODEL EXERCISE

Exercise. No: 1

1. What is meant by O.R.S?
2. Composition and Rationale of ORS SALT?
3. What is Super ORS?

Exercise. No: 2:

A 5 years old child with complaints of watery stool for past 24 Hrs. On Examination child shows signs of Moderate(8%) Dehydration, but able to consume liquids orally.in the above scenario:

1. Communicate and demonstrate the steps to prepare ORS solution?
2. Observe if the Child's mother is able to reproduce the steps?
3. Effective communication of the need and importance to take O.R.S ?

Facilitator's Observation of Demonstration (Tick in the appropriate box)

Date	Needs Improvisation (Plan remedial session)	Average	Satisfactory

Signature of Facilitator:

PH 4.2 COMPUTER ASSISTED LEARNING (CAL)

Specific Learning Objectives: at the end of the session the learner should be able to

1. Choose the appropriate animal experiment to study the effect of drugs.
2. Able to interpret the graph obtained on application of various drugs using CAL .
3. Able to explain the rationale of therapeutic use based on the observation in the graph displayed in CAL

Briefing on experimental animals : Students are taken to Department animal house /learning through alternative to Animal experiments i.e, Computer Assisted Learning(CAL)

CAL: Simulation of responses to various drugs in vivo/ isolated animal tissues like Rabbit-Eye, Dog-BP, Frog- Heart through computer software An instructor will then outline how to operate the software and you are allowed to work on your own..At the click of the computer mouse drugs are selected, injected and response displayed in the monitor are interpreted and justified by the learner .

Exercise :1 ACTION OF DRUGS ON THE RABBIT'S EYE

Animals: Rabbit in CAL

Apparatus: Droppers, measuring scale, torch, cotton wool (in the CAL system)

Drugs & solutions:

1. Saline
2. Pilocarpine
3. Atropine sulphate
4. Lignocaine
5. Ephedrine

PROCEDURE: In CAL Software ,Select animal, Rabbit Measure diameter of both the pupils with the help of a scale. Observe the condition of the conjunctiva (congested or not) and elicit the corneal and light reflexes. Record your findings. In the left eye put one drop of saline and in the right eye one drop of Test drug. Exercise done for all the test drugs individually.

1. Diameter of the pupil
2. Light reflex
3. Corneal reflex

Questions

1. Interpret the observation in the monitor and justify your findings?

DRUG	DIAMETER OF PUPIL IN mm	LIGHT REFLEX	CORNEAL REFLEX

2. Clinical application of the test drugs?

3. Write 5 Example of drugs administered as Eye drops ?

Exercise :2 EFFECT OF DRUGS ON PERFUSED FROG'S HEART

Animal: Frog -Heart in CAL
Drugs and Solutions:

Adrenaline HCl	Acetyl choline
Noradrenaline	Potassium chloride
Isoprenaline	Atropine sulphate
Calcium chloride	Frog Ringer
Propranolol HCl	

PROCEDURE : select the test drug , observe and interpret response , select the appropriate drug to demonstrate stimulant and depressant effect and add to show the response and draw your tracings in your record .

Diagram -Tracing of effects of drugs on Heart

QUESTIONS

1. Interpret the observation in the monitor and explain your findings?
2. Clinical application of the test drugs?

Exercise :5 EFFECT OF DRUGS ON DOG'S BLOOD PRESSURE

Animal: Dog in CAL
PROCEDURE : select the test drug , observe and interpret response , select the appropriate drug to demonstrate vasopressor & vasodepressor effect and add to show the response and draw your tracings in your record
Drugs and solutions :
Normal Saline
Adrenaline HCl
Noradrenaline
Isoprenaline
Ephedrine
Propranolol HCl
Acetyl choline
Atropine sulphate
Alpha blocker- clonidine
Histamine, Tyramine

Diagram -Tracing of effects of drugs on Dog BP

Diagram -Tracing of effects of drugs on Dog BP continued…

QUESTIONS

1. Interpret the observation in the monitor and explain your findings?
2. Clinical application of the test drugs ?

PH 3.1 PRESCRIPTION WRITING

Specific Learning Objectives: At the end of the session a learner should be able to:

1. Identify the parts of a prescription and realize the importance of each.
2. Write a prescription in the correct format.
3. Understand the medico-legal aspects of a prescription.

Principles of Prescription Writing: A prescription is a written order or communication from a registered medical practitioner or other licensed practitioner to a pharmacist embodying salient instructions regarding the dispensing of prescribed medication for a particular patient..

Parts of a Prescription:

1 Physician (Prescriber) Information: Name , Designation, MCI Reg.No, Address with phone number and e-mail. Date of issue of prescription.

2 Patient Information: The name, address, age and sex of the patient

3 Superscription: consists of the heading where the symbolRx an abbreviation for recipe, the Latin for 'take thou' or 'you take' is found.

4 Inscription: The inscription (**body of prescription**) comprises an important part ofprescription containing:

- Name(s) of drug(s) and their strength, quantities, route, frequency, timing, course.
- Instruction regarding dosage form like tablet, capsule, suspension, mixture, etc ,

5 Subscription: gives specific directions for the pharmacist on how to compound the medication.

6 Transcription or Signatura : Gives instructions to the patient Dose ,Duration ,Before Food Or After Food, Course , Refill: The number of times a prescription is to be repeated is written by thephysician under renewal instructions.

7 Signature: Finally the prescription must bear the signature of the prescriber to impart it the legal validity

Drug regulatory act and schedules: The Government of India has promulgated Drugs and Cosmetics Act long before to regulate the import, manufacture, distribution and sale of drugs. However, subsequent amendments for this act have been passed from time to time as per the requirements. The following drug schedules are important for physicians which are prescription elated schedules.

1. **Schedule H (prescription drugs):** Drugs included in this schedule are sold by retailers only on production of valid prescription given by a registered medical practitioner.

2. **Schedule W:** This includes only few drugs that shall be marketed under generic names only. For example: aspirin, chlorpromazine, ferrous sulphate and piperazine.

3. **Schedule X:** Drugs having dependence liability are included in this schedule. Strict directions are given regarding labelling, prescription, storage and sale of these drugs. These drugs must be stored under lock and key in a safe so that only responsible persons will have access. Importantly, the supply of these drugs has to be maintained and recorded in a register.

4. **Schedule G:** This provides list of drug preparations with a label that states "Caution: It is dangerous to use this preparation except under medical supervision".

5. **Schedule J:** This is an informative schedule which gives the list of ailments for which no drug should claim prevention or cure. For example HIV and atherosclerosis.

6. **Schedule K:** This defines the conditions under which certain circumstances registered medical practitioners and hospitals are exempted from provisions as given in Chapter IV of Drugs and Cosmetics Act 1940 of India.

7. **Schedule C:** This appraises the clinical values of biologicals and other special products. For example vaccines, sera, insulin and antibodies.

8. **Schedule F:** This depicts specifications for standard ophthalmic preparations.

INFORMATION IN DRUG LABEL

Tablets, Capsules	**Injection**
a) Trade name, generic name b) Formulation c) Number of tablets, strength of each tablet d) Storage instruction e) Name of manufacturer f) Date of manufacture, date of expiry g) Batch number h) Price	a) Trade name, generic name b) Formulation c) Concentration of the drug d) Total volume of solution e) Instruction for reconstitution f) Name of manufacturer g) Date of manufacture, date of expiry h) Batch number i) Storage conditions j) Approved routes of administration

Latin phrases: Although present prescriptions are written in English, at times, Latin phrases and terms creep in. The following terms are frequently seen in modern day prescriptions.

Latin phrase	**Abbreviations**	**Pharmacy**
Semel in die, Semel die	o.d.	Once a day
Bis in die, bis die	b.i.d., b.d.	Twice a day
Ter in die, ter die	t.i.d., t. d.	Three times a day
Quarter in die, quarter die	q.i.d.	Four times a day
Quaque die	q.d.	Every day
Omni mane	o.m.	Every morning
Omni nocte	o.n.	Every night
Hora somnis	h.s.	At bed time
Ante cibos	a.c.	Before food
Post cibos	p.c.	After food
Si opus sit	s.o.s.	As and when required
Per os	p.o.	By mouth
Statim	stat.	Immediately
Misce fiatmistura	m.ft.m.	Mix to make a mixture
Ad Libitum	ad.lib.	As much as you please
Quantum sufficiat	q.s.	As much as is sufficient

Commonly used Weights and Measures:

Weights	**Measures:**	**Approximate equivalents of Domestic measures:**
1 kilogram (kg) = 1000 g 1 gram (g) = 1000 mg 1 milligram (mg) = 1000 μg 1 microgram (μg) = 1000 ng	1 litre (L) = 1000 ml 1 millilitre (ml) = 1000 microlitres 1 international unit (IU) =1000 milli IU	1 teaspoon = 5 ml 1 tablespoon =15 ml 1 drop = 0.05ml 16 drops = 1 ml

INSTRUCTIONS FOR FACILITATOR ON
COMPLETING CERTIFIABLE COMPETENCIES TABLE

1. **Attempt at activity by learner: Indicate if:**

- **F -**First attempt (or) only attempt
- **R -**Repeat of a previously done activity
- **Re -**Remedial

2. **Rating - Use one of three grades:**

- **B-** Below Expectation
- **M-** Meet Expectation
- **E -**Exceed Expectation

3. **Decision of faculty**

- ✓ **C:** activity is completed, therefore closed, and can be certified
- ✓ **R:** Repeat
- ✓ **Re:** activity needs remedial action

(Remedial is a planned activity at correcting deficits that prevent a learner from achieving an intended outcome. Remedial activity is done after repetition did not lead to satisfactory completion.)

* Ref: NMC module on Logbook Guidelines.

CERTIFIABLE COMPETENCIES

PH.3.1 PRESCRIPTION WRITING

1	2	3	4	5	6	7	8
Exercise .No	Diagnosis	Date completed	Attempt at activity First or Only (F) Repeat (R) Remedial (Re)	Rating below (B) Expectations Meets (M) Expectations Exceeds (E) expectations OR Numerical Score	Decision of faculty Completed (C) Repeat (R) Remedial (Re)	Initial of faculty and date	Feedback Received Initial of learner
PH 3.1 Write a rational, correct and legible generic prescription for a given condition and communicate the same to the patient							
1	Essential Hypertension		F	B	C		
			R	M	R		
			Re	E	Re		
2							
3							
4							
5							

1	2	3	4	5	6	7	8
Exercise .No	Diagnosis	Date completed	Attempt at activity First or Only (F) Repeat (R) Remedial (Re)	Rating below (B) Expectations Meets (M) Expectations Exceeds (E) expectations OR Numerical Score	Decision of faculty Completed (C) Repeat (R) Remedial (Re)	Initial of faculty and date	Feedback Received Initial of learner
PH 3.1 Write a rational, correct and legible generic prescription for a given condition and communicate the same to the patient							
6							
7							
8							
9							
10							

MODEL EXERCISE
PRESCRIPTION WRITING FORMAT

1. **Clinical History:**

   Mr. Ravikumar, 52 years old sedentary lifestyle male worker came with chief complaints of frequent headaches and dizziness over past 2 months with no other significant medical history. O/E BP is 160/90 mmHg measured twice in upper arm. He was diagnosed with Essential Hypertension. Write the Prescription for this patient.

Doctors Name: XYZ Registration number:12345 Address: Phone:	Patient Name: Ravikumar Age: 52 years Sex: M Address:	Date:

Diagnosis: ESSENTIAL HYPERTENSION

Rx:

TAB. TELMISARTAN 40 MG ONCE DAILY AFTER FOOD FOR 1 MONTH
TAB CILINIDIPINE 10 MG ONCE DAILY FOR 1 MONTH

Advice:

1. SALT RESTRICTION
2. LOW FAT DIET
3. AVOID SMOKING AND ALCOHOL
4. AIM TO MAINTAIN IDEAL BODY WEIGHT
5. REGULAR PHYSICAL EXERCISE.
6. TO REVIEW AFTER 1 MONTH

Doctor's Signature

Reflection of the Learner

EXPECTED MINIMUM STANDARD PRESCRIPTIONS

Section A- Systems – Separate Assessment

1. **Anaphylactic shock**

Doctor's Signature		
Reflections of Learner		

2. **Type 2 Diabetes Mellitus**

Doctor's Signature		
Reflections of Learner		

3. **Acute Angina**

Doctor's Signature		
Reflections of Learner		

4. A**cute Convulsions**

Doctor's Signature		
Reflections of Learner		

5. **Acute Severe Bronchial Asthma**

Doctor's Signature		
Reflections of Learner		

6. **Urinary tract infection in Pregnant female**

Doctor's Signature		
Reflections of Learner		

7. **Pulmonary Tuberculosis- (Drug Sensitive)**

Doctor's Signature		
Reflections of Learner		

8. **Treatment of Vivax/ Falciparum malaria**

Doctor's Signature		
Reflections of Learner		

Section B- Toxicology

Justification for the exercise : Poisoning cases are commonly encountered by medical graduates in real practice, case based learning will help in application oriented learning.

Management of Poisoning - Paper Case sheets – Separate Assessment

A. Organophosphorous compound poisoning

MODEL EXERCISE:

A Farmer with a history of handling insecticides is brought to the hospital with convulsions, sweating & laboured breathing. On examination pupils were constricted, profuse salivation, lacrimation, pulse 50 / min, respiration rapid, rales & rhonchi all over the lungs.

1. Identify the cause of illness?

The symptoms of convulsions, sweating & laboured breathing with signs of constricted pupil, profuse salivation, lacrimation, bradycardia, and crepitations in lung fields suggest OPC Poisoning

2. How will you manage above poisoning?

- Remove stained clothes
- Wash skin and mucous membrane with water
- Gastric lavage
- Maintenance of airway and circulation.
- Atropine suphate 2mg IV stat and repeated every 10-15 min till full atropinisation occurs which is assessed by degree of dilatation of pupil, increase in heart rate, disappearance of crepitations.
- Pralidoxime (2-PAM) 1-2 g given as slow I.V infusion over 30 minutes after dilution(5% solution in 10 ml Normal Saline) .It must be given before ageing of the enzyme occurs.

B. Atropine poisoning

C. **Methyl alcohol poisoning**

D. **Paracetamol overdose.**

E. **Iron poisoning**

CERTIFIABLE COMPETENCY

PH 3.2 PRESCRIPTION AUDIT

1	2	3	4	5	6	7	8
Exercise .No	Diagnosis	Date completed	Attempt at activity First or Only (F) Repeat (R) Remedial (Re)	Rating below (B) Expectations Meets (M) Expectations Exceeds (E) expectations OR Numerical Score	Decision of faculty Completed (C) Repeat (R) Remedial (Re)	Initial of faculty and date	Feedback Received Initial of learner
PH 3.2 : CRITICISE CORRECT AND REWRITE A GIVEN PRESCRIPTION							
1	Chronic Intestinal Amoebiasis		F	B	C		
			R	M	R		
			Re	E	Re		
2							
3							
4							
5							

PH 3.2 PRESCRIPTION AUDIT

Specific Learning Objectives**:** At the end of session the learner should be able to

- To identify the errors in the format of Prescription
- Detection of prescribing errors with their reasons.
- To reduce the irrational usage of antibiotics, syrups, injections, etc.
- Develop the good practice of writing complete, legible and rational prescriptions.

MODEL EXERCISE

1. A 35 year old male who is a habitual drinker came with symptoms of chronic intestinal amoebiasis was given T.Metronidazole 15 in number Criticize, Correct & Rewrite.

Criticism:

- Not in correct Format, Drug name in upper case only
- Dose and duration of metronidazole are not given.
- Metronidazole produces disulfiram like reaction with alcohol.
- In Patients with alcoholic history must be prescribed alternate drug like Satranidazole which does not produce disulfiram like reaction.
- Diloxanide furoate which eliminate luminal cysts must be prescribed as the patient is suffering from chronic intestinal amoebiasis.

Corrected prescription:

Doctors Name: Registration number: Address: Phone:	Patient Name: Age: Sex: Address:	Date:
Diagnosis: Chronic Intestinal Amoebiasis.		
Rx: Tablet. SATRANIDAZOLE 300mg orally twice daily x 5 days. Tablet. DILOXANIDE FUROATE 500mg orally thrice daily x 10 days.		
Advice: Avoid raw & uncooked vegetables Ensure Safety of drinking water.		
Doctor's Signature		

2. 60 years old female was taking tab chlorpromazine and she developed drug induced parkinsonism. She was prescribed

Tab.Levodopa 100mg BD
Tab.Carbidopa 10mg BD
Tab.Thioridazine 1 gram
Criticise , Correct & Rewrite The Prescription

		Doctor's Signature

3. 50 year old male with acute anginal pain was prescribed

Inj. Pentazocine	50mg
Glyceryl Trinitrate	2 mg
Propranolol	200mg

Criticise , Correct & Rewrite The Prescription

		Doctor's Signature

4. A primi gravida, has taken with T.Aceclofenac 100mg as self medication for body pain . She developed gastritis for which she was prescribed
   Cap. Misoprostol 200 µg qid
   Antacid gel 2 tsp tid
   Criticise , Correct & Rewrite The Prescription

Doctor's Signature		

5. A 60 year old postmenopausal woman with osteoporosis with h / o ischemic heart disease was prescribed

   T.Raloxifene 60mg od for 15 days

   Criticise , Correct & Rewrite The Prescription.

Doctor's Signature		

PH 3.5 SELECTION OF P – DRUG

Specific Learning Objectives**:** At the end of the teaching session the learner should be able to

- Apply the concept of essential medicine in deriving the list
- Adopt the steps and criteria in selecting most appropriate drug for the given clinical scenario

Aim of Essential Drug Concept **:**To satisfy the priority health care needs of the population by ensuring Availability ,Accessibility ,Affordability ,Safety, Efficacy of most wanted drugs.

SELECTION OF 'P' DRUG The concept of P drug is **to** promote the practice of rational therapeutics with **the objective to** promote use of cost effective, safe and suitable medicines.

The criteria are efficacy, safety, suitability and cost effectiveness.

Efficacy: The first selection criterion for any group of drugs is efficacy. Efficacy **is** not based on pharmacodynamics alone. The therapeutic objective is that the drug should work as soon as possible. Pharmacokinetics are therefore important as well. Thus groups that contain drugs or dosage forms with a rapid effect are more beneficial in acute asthma

Safety: All drug groups have side effects, most of which are a direct consequence of the working mechanism of the drug

Suitability: It is referred to dosage schedule, dosage form, contraindication and precaution

Steps in Selecting a P-DRUG

1. Define the diagnosis
2. Specify the therapeutic objective
3. Make an inventory of effective groups
4. Choose an effective group according to criteria
5. Active substance, dosage form, Standard dosage schedule and Standard duration.

CERTIFIABLE COMPETENCY

PH. 3.5 SELECTION OF P-DRUG

1	2	3	4	5	6	7	8
Exercise .No	Diagnosis	Date completed	Attempt at activity First or Only (F) Repeat (R) Remedial (Re)	Rating below (B) Expectations Meets (M) Expectations Exceeds (E) expectations OR Numerical Score	Decision of faculty Completed (C) Repeat (R) Remedial (Re)	Initial of faculty and date	Feedback Received Initial of learner
PH 3.5 : Prepare And Explain a List of P- Drugs For the Given Condition							
1	Urinary tract infection		F	B	C		
			R	M	R		
			Re	E	Re		
2							
3							
4							
5							

MODEL EXERCISE:

1. A 28 year old primi gravida in the first trimester of pregnancy, with c/o burning micturition and increased frequency. Urine sample was sent for Culture & Sensitivity : C/S Report: E.Coli grown in culture. Resistant : Ampicilllin , Cotrimoxazole. Sensitive : Cephalexin, Norfloxacin, Amikacin

   - Clearly define the diagnosis- Urinary tract infection in Pregnancy
   - Specify the therapeutic objectives: Relief of symptoms. : Treat the cause - Antibiotic
   - List of effective group of drugs

DRUG	MERITS	DEMERITS
Norfloxacin	Bactericidal	Contraindicated in pregnancy expensive
Cephalexin 250mg q.i.d PO	Highly effective, Oral route	Expensive
Cotrimoxazole	Economical	Contraindicated in pregnancy Resistance has emerged
Ampicillin	Access group	Development of resistance
Amikacin	Bactericidal	Parenteral route expensive Contraindicated in Pregnancy

Effective Group: cephalosporins

P-Drug -Antibiotic: Cephalexin 250mg q.i.d oral for 5 days

Reflection of Learner

2. Select a P-drug for hypertension in a young male 28 yrs.

Reflection of Learner

3. Select a P-Drug for the treatment of new onset type 2 diabetes Mellitus.

Reflection of Learner

4. Select a P-Drug for a 29 yrs old poor patient diagnosed as enteric fever?

Reflection of Learner

5. Select a P-Drug for a 58 yrs old male with diagnosed as Acute Gout?

Reflection of Learner

PH 3.4 ADVERSE DRUG REACTION REPORTING

Specific Learning Objectives:At the end of the session student should be able to

- Identify the type of reporting as Adverse reaction to drug , vaccines, blood transfusion, device based on the information provided.
- Able to fill the adverse drug reaction reporting form

Pharmacovigilance is a science relating to detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. Recently, its concerns have widened to include herbals, traditional complementary medicines, blood products, biologicals, medical devices and vaccines. The Dept of Pharmacology functions as Adverse reaction Monitoring Centre of PvPI.

Importance of ADR reporting in India:

- Adverse Drug Reactions occurs in 0.3 per cent to 7 per cent of all hospital admissions. The incidence of serious ADRs is 6.7 per cent
- There is a rapid increase in the number of new drugs entering the market from the last few decades
- Indian population is known for vast ethnic variability, different disease prevalence patterns, practice of different systems of medicines, socioeconomic status, a standardized and robust pharmacovigilance and drug safety monitoring programme is a must.
- The purpose of the Pharmacovigilance Program of India is to collect, collate and analyze data to arrive at an inference to recommend regulatory interventions, besides communicating risks to healthcare professionals and the public.
- Doctors including Dentists, Nurses, and Pharmacists and Public/patient may report suspected adverse drug events.

MODEL PROBLEMS ON ADVERSE DRUG REACTIONS.

1. A40 yr old chronic alcoholic developed amoebic liver abscess prescribed Metronidazole. After few days he developed flushing, headache, tightness in chest and mental confusion.
2. A 23yr old lady was on treatment for grándmal epilepsy. After few days she developed gum hypertrophy and hirsutism.
3. A 50 yr old Hypertensive patient Prescribed Tab.ENALPRIL . At night he could not sleep well because of irritating dry cough.
4. A 16 year old suffering from pulmonary tuberculosis was prescribed isoniazid + rifampicin + pyrazinamide+ethambutol for two months. After one month the young girl complained of diminished vision
5. A 12 years old child presented to emergency department with torticollis and rigidity of neck muscels few hours after she received Inj.Metocolperamide for vomiting .

CERTIFIABLE COMPETENCY
PH 3.4 ADVERSE DRUG REACTION REPORTING

1	2	3	4	5	6	7	8
Exercise .No	**Case scenario of adverse drug reaction**	**Date completed**	**Attempt at activity First or Only (F) Repeat (R) Remedial (Re)**	**Rating below (B) Expectations Meets (M) Expectations Exceeds (E) expectations OR Numerical Score**	**Decision of faculty Completed (C) Repeat (R) Remedial (Re)**	**Initial of faculty and date**	**Feedback Received Initial of learner**
PH.3.4 : Recognize and Report An Adverse Drug Reaction							
1			**F**	**B**	**C**		
			R	**M**	**R**		
			Re	**E**	**Re**		
2							
3							
4							
5							

Reflection of Learner:

Version 1.4

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For **VOLUNTARY** reporting of ADRs 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

PvPI Helpline (Toll Free) :1800-180-3024 (9:00 AM to 5:30 PM, Monday-Friday)

Initial Case ❑ Follow-up Case ❑

FOR AMC / NCC USE ONLY

Reg. No. / IPD No. / OPD No. / CR No. :

AMC Report No. :

Worldwide Unique No. :

A. PATIENT INFORMATION *

1. Patient Initials:

2. Age or date of birth:

3. Gender: M ☐ F ☐ Other ☐

4. Weight (in Kg.)

B. SUSPECTED ADVERSE REACTION *

5. Event / Reaction start date (dd/mm/yyyy)

6. Event / Reaction stop date (dd/mm/yyyy)

7. Describe Event/Reaction management with details , if any

12. Relevant investigations with dates :

13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.)

14. Seriousness of the reaction : No ☐ if Yes ☐ (*please tick anyone*)

☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Disability
☐ Hospitalization-Initial/Prolonged ☐ Other Medically important

15. Outcome:

☐ Recovered ☐ Recovering ☐ Not Recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S) *

S. No.	8. Name (Brand/ Generic)	Manufacturer (if known)	Batch No. / Lot No.	Expiry Date (if known)	Dose	Route	Frequency	Therapy Dates		Indication	Causality Assessment
								Date Started	Date Stopped		
i											
ii											
iii											
iv#											

9. Action taken after reaction (*please tick*)

S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown
i						
ii						
iii						
iv						

10. Reaction reappeared after reintroduction of suspected medication (*please tick*)

Yes	No	Effect unknown	Dose (if re-introduced)

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Dates		Indication
					Date Started	Date Stopped	
i							
ii							
iii#							

Additional Information :

D. REPORTER DETAILS *

16. Name & Address : _____

_____

Pin : _____ Email : _____

Contact No- : _____

Occupation : _____ Signature : _____

17. Date of this report (dd/mm/yyyy) :

Signature and Name of Receiving Personnel :

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

* Mandatory Fields for suspected ADR Reporting Form

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☐ Life threatening ☐ Disability
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15. Outcome:

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☐ Fatal ☐ Recovered with sequelae ☐ Unknown

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								Date Started	Date Stopped		
i											
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9. Action taken after reaction (*please tick*)

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ii						
iii						
iv						

10. Reaction reappeared after reintroduction of suspected medication (*please tick*)

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					Date Started	Date Stopped	
i							
ii							
iii#							

Additional Information :

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4. Weight (in Kg.)

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5. Event / Reaction start date (dd/mm/yyyy)

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7. Describe Event/Reaction management with details , if any

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14. Seriousness of the reaction : No ☐ if Yes ☐ (*please tick anyone*)

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☐ Life threatening ☐ Disability
☐ Hospitalization-Initial/Prolonged ☐ Other Medically important

15. Outcome:

☐ Recovered ☐ Recovering ☐ Not Recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

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S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown
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iv						

10. Reaction reappeared after reintroduction of suspected medication (*please tick*)

Yes	No	Effect unknown	Dose (if re-introduced)

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Dates		Indication
					Date Started	Date Stopped	
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Additional Information :

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Contact No- : _____

Occupation : _____ Signature : _____

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Worldwide Unique No. :

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1. Patient Initials:

2. Age or date of birth:

3. Gender: M ☐ F ☐ Other ☐

4. Weight (in Kg.)

B. SUSPECTED ADVERSE REACTION *

5. Event / Reaction start date (dd/mm/yyyy)

6. Event / Reaction stop date (dd/mm/yyyy)

7. Describe Event/Reaction management with details , if any

12. Relevant investigations with dates :

13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.)

14. Seriousness of the reaction : No ☐ if Yes ☐ (*please tick anyone*)

☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly

☐ Life threatening ☐ Disability

☐ Hospitalization-Initial/Prolonged ☐ Other Medically important

15. Outcome:

☐ Recovered ☐ Recovering ☐ Not Recovered

☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S) *

S. No.	8. Name (Brand/ Generic)	Manufacturer (if known)	Batch No. / Lot No.	Expiry Date (if known)	Dose	Route	Frequency	Therapy Dates		Indication	Causality Assessment
								Date Started	Date Stopped		
i											
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9. Action taken after reaction (*please tick*)

S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown
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10. Reaction reappeared after reintroduction of suspected medication (*please tick*)

Yes	No	Effect unknown	Dose (if re-introduced)

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Dates		Indication
					Date Started	Date Stopped	
i							
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Additional Information :

D. REPORTER DETAILS *

16. Name & Address : _____

_____

Pin : _____ Email : _____

Contact No- : _____

Occupation : _____ Signature : _____

17. Date of this report (dd/mm/yyyy) :

Signature and Name of Receiving Personnel :

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Use separate page for more information

* Mandatory Fields for suspected ADR Reporting Form

ADVICE ABOUT REPORTING

A. What to report?

All adverse events should be reported

Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines & Herbal Products.

Report every serious adverse drug reactions. A reaction is serious when the patient outcome is :

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability (significant, persistent or permanent)
- Congenital anomaly
- Report intervention to prevent permanent impairment or damage

NOTE : Serious/Adverse Event following immunization can also be reported in Serious AEFI case Notification Form available on http://www.ipc.gov.in

B. Who can report?

All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurse etc.) can report adverse drug reactions

C. Where to report?

Duly filled in Suspected Adverse Drug Reaction Reporting Form can be sent to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC) for PvPI.

Call on Helpline (Toll Free) 1800 180 3024 to report ADRs or directly mail this filled form to pvpi.ipc@gov.in

A list of nationwide AMCs is available at : http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D.What happens to the submitted information?

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC-PvPI through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The Signal Review Panel of PvPI reviews the data and suggests any interventions that may be required.

E. Mandatory fields for suspected ADR Reporting Form (*)

Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) & reporter information.

For Adverse Drug Reaction Reporting Tools

- **E-mail : pvpi.ipc@gov.in**
- **PvPI Helpline (Toll Free) : 1800 180 3024** (9:00 AM to 5:30 PM, Monday-Friday)
- **ADR Mobile App : "ADRPvPI"**

WHO -UMC CAUSALTY ASSESSMENT CATEGORIES

Causality Term	Assessment criteria*
Certain	• Event or laboratory test abnormality, with plausible time relationshipto drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probable / Likely	• Event or laboratory test abnormality, with reasonable time relationshipto drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional / Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable / Unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified

PH 5.1 to 5.7 ATTITUDE ETHICS AND COMUNICATION

The "Indian Medical Graduate" (IMG) shall possess requisite knowledge, skills, attitudes, value and responsiveness, so that he or she may function appropriately and effectively *as a doctor of first contactof the community* while being globally relevant.

Specific Learning Objectives : at the end of the session learner should be able to

1. Communicate effectively to patient with empathy and ethics on all aspects of drug use.(2.1&2.8 Module)
2. Communicate to patient regarding optimal use of a) drug therapy b)devices c)storage of medicines.
3. Motivate patients with chronic diseases on medication compliance & cost of treatment.
4. Demonstrate an understanding of the caution in prescribing drugs likely to produce dependence and recommend the line of management.

NOTE: The facilitator to ensure that the learner is able to demonstrate all the appropriate points to be communicated for the given scenario- NOT ENUMERATE

Basic principles in Check list :

- Greet
- Explain the disease, importance of life long treatment to prevent complications
- Insist the completion of course of antibiotic to prevent resistance.
- Prevent spread of infectious disease to family and society by Prophylaxis and behavior respectively
- Report in case of experiencing adverse effects on taking the medications
- Precautions in intake and storage.

AETCOM- MODEL EXERCISE

1. Demonstrate effective communication to a mother on reconstitution and administration of Cefpodoxime suspension (available as powder for 30 ml suspension) prescribed for her 2 years old child with LRI- 5 ml twice a day for 5 days
    - Greet
    - Tell the need to buy 2 bottles as the course is 5 days.
    - Insist the completion of course of antibiotic to prevent resistance
    - Demonstrate the steps in reconstitution- warm water 30 ml/bottle
    - Shake the bottle in every use
    - Use within 5 days of reconstitution.
    - Use the measuring cup provided.

Facilitator's Observation of Demonstration (Tick in the appropriate box)

Date	Needs Improvisation (Plan remedial session)	Satisfactory

Signature of Facilitator:
Reflection of Learner:

2. Demonstrate effective communication of compliance in a newly diagnosed patient with Essential Hypertension

   Check list: as relevant:

Facilitator's Observation of Demonstration (Tick in the appropriate box)

Date	Needs Improvisation (Plan remedial session)	Satisfactory

Signature of Facilitator:
Reflection of Learner:

3. Demonstrate effective communication to a son of an elderly patient to get consent for IV Cannulation.

   Check list: as relevant:

Facilitator's Observation of Demonstration (Tick in the appropriate box)

Date	Needs Improvisation (Plan remedial session)	Satisfactory

Signature of Facilitator:

Reflection of Learner:

4. Demonstrate effective communication on compliance in a newly diagnosed Pulmonary Tuberculosis?

   Check list: as relevant:

Facilitator's Observation of Demonstration (Tick in the appropriate box)

Date	Needs Improvisation (Plan remedial session)	Satisfactory

Signature of Facilitator:

Reflection of Learner:

5. Demonstrate effective communication on insisting compliance diet and lifestyle to a parent and 10 yrs old child newly diagnosed as Type I Diabetes Mellitus .

   Check list: as relevant:

Facilitator's Observation of Demonstration (Tick in the appropriate box)

Date	Needs Improvisation (Plan remedial session)	Satisfactory

Signature of Facilitator:

Reflection of Learner:

PH 3.7 ESSENTIAL MEDICINE

Specific Learning objectives: at the end of the session the learner should be able to

1. Describe the selection criteria for a drug to be included in the essential drug list .
2. Apply the concept and derive the essential list using the National formulary.

According to WHO essential drugs are "List of drugs that satisfy the health care needs of the majority of the population; they should therefore, be available at all times in adequate amount and in appropriate dosage forms".

Aim of formulating this list to ensure availability of most of the drugs in appropriate dosage forms in adequate quantity to majority of the population at affordable price and this is applicable in developing countries.

WHO provides a Model List Of Essential Medicines (MLEM)and frames guidelines for various member countries to prepare the list of essential drugs/ medicines suitable for the need of their country i.e. based on the diseases prevalent in a particular country and requirements. WHO model list will be regularly updated every two years with additions and deletions based on the disease and drug developments.

Based on the WHO model list of Essential Medicines, every member country prepares a National List of Essential Medicines (NLEM) as per their country requirement with relevance to the prevalent diseases and financial resources.

In India, "National List of Essential Medicines (NLEM) provided in National Formulary. The therapeutic categories and their use in level of health care are mentioned as P-Primary, S-Secondary, T- Tertiary. The current revision NLEM 2022 can be accessed from CDSCO website. List of Medicines selected is based on WHO Model List and National List of Essential Medicines (NLEM), Standard Treatment Guidelines.

Exercise 1: Prepare a list of General Anaesthetics referring NLEM 2022 for the healthcare facilities given below. A. Primary Health Care/Centre; B. District Hospital;

Exercise.1:

A. Primary Health Care/Centre (PHC): Include all the General Anaesthetics in level of healthcare P. as per the list in NLEM 2022 ,the list derived is .

1. Ketamine, injection 10 mg/mL and 50 mg/mL
2. Nitrous oxide
3. Oxygen
4. Propofol, injection 10 mg/mL
5. Thiopentone, Powder for injection 0.5g and 1 g

B. Secondary Health Care (District Hospital): Include all General Anaesthetics under level of healthcare S, as per the list in NLEM 2022 the list derived is:

1. Halothane
2. Isoflurane
3. Ketamine, injection 10 mg/mL and 50 mg/mL
4. Nitrous oxide
5. Oxygen
6. Propofol, injection 10 mg/mL
7. Thiopentone, Powder for injection 0.5g and 1 g
8. Sevoflurane

Exercise 2: Prepare a list of Anti Diabetic Drugs referring NLEM 2022 for the healthcare facilities given below. A. District Hospital ;B. Medical college Hospital

Exercise 3: Prepare a list of Antipsychotic Drugs referring NLEM 2022 for the healthcare facilities given below. A. Primary Health Centre; B. District Hospital.

PH 8.2. ANTIMICROBIAL STEWARDSHIP

Specific Learning objectives: at the end of the session the learner should be able to

1. Familiarise with WHO classification of antibiotics & Antibiogram.
2. Apply the principles of Antimicrobial stewardship in antimicrobial therapy.

Antimicrobial stewardship is defined as "Coordinated intervention designed to improve and measure the appropriate use of antimicrobial agents, by promoting the selection of optimal antimicrobial drug regimen including dosing, duration of therapy and route of administration"

WHO classified antibiotics as "AWARE" – Access, WAtch, RE serve, based on susceptibility and resistance potential.

1. **Access**: group of narrow spectrum antibiotics effective for common susceptible organisms, with low resistance potential, Example: Amikacin, Ampicillin, Co-trimoxazole.
2. **Watch** : group of broad spectrum antibiotics, recommended as first choice for more severe clinical presentation & critical infections , but with high resistance potential, use needs strict monitoring. Example: Ceftriaxone, Ciprofloxacin.
3. **Reserve:** Last choice antibiotics for treating multi drug resistant infection. Example: Linezolid,Polymyxin.

Antibiogram: is pathogen-specific susceptibility data, updated at least annually, to optimize expert-based recommendations for empirical therapy.

Antimicrobial stewardship focuses on the **five 'D's** of Antimicrobial therapy

1. **Diagnosis:** Correct diagnosis and source of infection
2. **Drug:** Correct choice of antimicrobial agent
3. **Dose optimization:** of antimicrobial dosing based on Patient characteristics (e.g., weight, renal/liver function), Causative organism, Site of infection (e.g., central nervous system, blood), pharmacokinetic and pharmacodynamic characteristics of the drug (e.g., concentration or time dependent activity) Example, Modifying Meropenem to 500 mg q24h when the patient is on hemodialysis.
4. **De-escalation**:(Antibiotic De-Escalation) is defined as the discontinuation of one or more components of combination empirical therapy and/or the change from a broad-spectrum to a narrower spectrum antimicrobial, as per the available culture or genotypic reports commonly recommended in the intensive care unit (ICU) patient who is treated with broad-spectrum antibiotics as a strategy to prevent antimicrobial resistance.

   Example1. a patient with a suspected urinary tract infection on empirical meropenem grows extended-spectrum beta-lactamase-producing E. coli. Meropenem is changed to Ertapenem and is considered de-escalation as ertapenem has no coverage for Pseudomonas spp.
5. **Discontinuation** : Stopping antimicrobials after completing the duration of therapy as per evidence-based guidelines or when infection is not confirmed, or diagnosis of non-infectious condition.

Terminologies in Antimicrobial stewardship:

- Empirical antibiotic therapy is Initial broad-spectrum antibiotic treatment targeted the most probable causative microorganism. The recommendations should be based on local susceptibility data, scientific data of evidence or expert opinion when evidence is lacking.

- Definitive antibiotic therapy is Targeted narrow-spectrum antibiotic treatment for the causative microorganism as per the report of culture & susceptibility or genotyping testing by polymerase chain reaction/next generation sequencing analysis or serological testing
- **Redundant therapy** is treatment with overlapping antibiotic spectra for two or more consecutive days, a potentially remediable source of antibiotic overuse. Example: For covering anaerobic organisms, metronidazole is administered along with piperacillin tazobactam, though both drugs have adequate anaerobic coverage.
- **IV to PO switch:** In Suspected severe infections treat with antimicrobials is initially started with intravenous medications. The short intravenous course of therapy for 2–3 days, followed by oral medications for the remainder of the course. Early switch over from IV to Oral therapy Reduces risk of cannula-related infections and risk of thrombophlebitis, Reduction in the hidden costs and earlier discharge from the hospital.

The three types of IV to PO conversions:

1. Sequential therapy: Refers to the act of replacing a parenteral version of a medication with its oral counterpart of the same compound. Example: conversion of inj. linezolid 600 mg q12h to tab linezolid 600 mg q12h
2. Switch therapy: Describes the conversion of an IV medication to a PO equivalent; within the same class and has the same level of potency but of a different compound. Example: switch over from Inj. Ceftriaxone 1 g q12h to Tab Cefixime 200 mg q12h.
3. Step-down therapy refers to conversion from an injectable to an oral agent in another class or to a different medication within the same class wherein the frequency, dose, and spectrum of activity may not be exactly the same. Example: conversion of Inj. Cefotaxime 1 g to Tab Ciprofloxacin 500 mg.

   Patient selection criteria for IV to oral switch over therapy are: Patient tolerates oral feeds, Signs of resolving an infection, PK of oral formulation are almost comparable to that of the parenteral form.

- **Antibiotic Timeout :** An antibiotic time-out (ATO) at 48–72 hours is a critical component of antimicrobial stewardship programs to improve judicious antibiotic use. It is a strategy to prompt clinicians to re-evaluate antibiotic appropriateness, including the need for de-escalation and discontinuation.
- **Antibiotic cycling** refers to the scheduled rotation of antibiotics with similar spectrums of activity, with a return to the original antibiotic after a defined period and re-initiation of the rotation. The basic principle of this intervention is that during periods when an antibiotic is out of rotation, resistance to that agent declines because of reduced selective pressure on that antibiotic class.
- **Bug-drug mismatch** is the antimicrobial(s) a patient is receiving do(es) not provide adequate therapy (e.g., is resistant) for the microbiologically identified organism presumed to be causing the clinical infection.

  Example 1: culture and susceptibility results of drainage from an intra-abdominal abscess may isolate Klebsiella sp. resistant to piperacillin/tazobactam in a patient empirically started on piperacillin/tazobactam for intraabdominal infection.

  Example 2: Or a patient may be receiving intravenous levofloxacin for pyelonephritis, with Escherichia coli resistant to levofloxacin cultured from the blood and urine.
- Therapeutic drug monitoring is the clinical practice of measuring specific drugs at designated intervals to maintain a constant concentration in a patient's bloodstream, thereby optimizing individual dosage regimens. Example: TDM needed for voriconazole, posaconazole, vancomycin etc.

MODEL HOSPITAL ANTIBIOGRAM

Organism	Isolate	Susceptibility %				
		Amoxycillin (A)	Ceftriaxone (WA)	Levofloxacin (WA)	Linezolid (Re)	Daptomycin (Re)
MRSA	6630	0	0	25	100	80
E.Coli	12006	50	94	65	0	-
H.Influenzae	500	100	95	-	-	-

Exercise 1: Using the hospital antibiogram given above, select appropriate antimicrobial therapy with dose and route for patient diagnosed with Septicaemia, organism isolated is Methicillin Resistant Staph.Aureus, susceptible to Linezolid for a 65 years old Diabetic male, with hypotension.

Linezolid IV 600 mg q12h for 3 days, switch to PO for 5 days based on clinical status.

Justification: Reserve group is recommended in MRSA, earlier IV to PO switch of same antibiotic.

Exercise 2: Using the hospital antibiogram given above, select appropriate empirical antimicrobial therapy with dose and route for patient diagnosed with Acute Suppurative Otitis Media for a 25 years old male. Justify your answer.

Cap**.** Amoxycillin 500 mg q8h PO for 3 days.

Justification: simple infection, antibiogram shows susceptibility, drug in Access group

Exercise 3: Using the hospital antibiogram given above, select appropriate empirical antimicrobial therapy with dose and route, for patient diagnosed with Urinary tract infection, for a 35 years old female.Justify.

Exercise 4: Using the hospital antibiogram given above, select appropriate empirical therapy with dose and route, for patient diagnosed with Upper Respiratory Tract infection for 2 Days in a 30 years old healthy male. Justify.

RECORD OF RESEARCH

The learner to undertake a scholastic project of 1-2 months in the form of research project., present a concept paper, attend CME on research

- These are based on the preferences of individual institution.
- The projects are included for internal assessment.

SYNOPSIS OF RESEARCH/PAPER/CME

SIGNATURE OF FACILITATOR

RECORD OF JOURNAL ACTIVITY

S.No1	BRIEF NOTE OF ACTIVITY
1	Publication/Presentation of Poster / Paper conference in Pharmacology
2	Presenting Synopsis of Review Article from any Journal- Topic of choice
3	Presenting a case series/case report in SGD

SIGNATURE OF FACILITATOR

RECORD OF HOME ASSIGNMENTS

Title of Assignment WITH Details
Pharmacogenetics/Drugs and Pregnancy /Drug Interactions Laboratory Animals/Recent advances in therapeutics – disease of choice Any one of the examples given above.

SIGNATURE OF FACILITATOR

RECORD OF SELF DIRECTED LEARNING

No	TITLE /SYNOPSIS OF ACTIVITY	
1	SEMINAR	
2	MUSEUM STUDY (student groups will be given project to create model/charts)	
3	LIBRARY ASSIGNMENTS • Treatment Protocol - Reference from Standard Text Books • E- library access- FDA approved new drug	

SIGNATURE OF FACILITATOR

No	SELF DIRECTED LEARNING LEARNER'S REFLECTIONS	
1	SEMINAR	
2	MUSEUM STUDY (student groups will be given project to create model/charts)	
3	LIBRARY ASSIGNMENTS • Treatment Protocol - Reference from Standard Text Books • E- library access- FDA approved new drug	

SIGNATURE OF STUDENT

PANDEMIC MODULE*EXERCISE

Specific Learning Objectives -Practical exercise:At the end of the session learner should be able to :

a. Identify the phase of clinical trial from the given scenario
b. Able to explain the ethics deviation in a given scenario
c. Accelerated approval
d. Able to identify on label & off label use of given drug

<table>
<tr><th>Activity</th><th>Answers</th><th>Reflection of learner</th></tr>
<tr><td>1. A clinical trial was performed in 5000 population across the globe to compare safety and efficacy of the Investigational new drug.Identify the phase of clinical trial?</td><td></td><td></td></tr>
<tr><td>2. A clinical trial involved paediatric patients consent was not obtained.What is the ethics deviation in the above trial?</td><td></td><td></td></tr>
<tr><td>3. A vaccine developed for a pandemic with no standard treatment was approved in a shorter time give one example</td><td></td><td></td></tr>
<tr><td>4. Students are provided with name of drugs and conditions , exercise is to match the shuffled on label and off-label uses of the drugs.</td><td>
<table>
<tr><th>Drug</th><th>On label</th><th>Off label</th></tr>
<tr><td>Montelukast</td><td>Asthma</td><td>Hypertensive heart disease</td></tr>
<tr><td>Duloxetine</td><td>Depression</td><td>Depression</td></tr>
<tr><td>Warfarin</td><td>Atrial fibrillation</td><td>Anxiety</td></tr>
<tr><td>Olanzapine</td><td>schizophrenia</td><td>Anemia of chronic disease</td></tr>
<tr><td>Epoietin alfa</td><td>Chronic renal failure</td><td>COPD</td></tr>
</table>
</td><td></td></tr>
</table>

**Ref: Pandemic module 2.5- NMC*

Signature of Facilitator