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Dosage Forms Delivery Devices and Routes

Practical 01 / Skills laboratory simulation

Aim

Identify common dosage forms and demonstrate route and device checks on training materials.

Principle

Formulation and route influence release, absorption, suitability and instruction. Device technique determines whether a prescribed product is delivered as intended.

Materials and Requirements

- Empty medicine packages, inhaler trainer and model devices
- Route cards and authorisation checklist

Procedure

1. Read generic name, strength, formulation and route on each training label. Distinguish immediate, modified and enteric-release products.
2. Lay out the dummy products by route. Compare generic name, concentration per unit, physical form and release wording. Note instructions about opening, crushing, measuring or storage on each training label.
3. Match oral, sublingual, topical, inhaled, rectal or injectable forms to the authorised route written on the case card.
4. Check the dummy order against the assigned product and time. Explain a route or formulation mismatch to the supervising examiner and hold the demonstration until it is resolved.

Continue with step 5 on the next page.

Procedure Continued

Dosage Forms Delivery Devices and Routes

5. Demonstrate product-specific inhaler or measuring device use with its trainer. Compare the simulated injectable route checks with instructor demonstration on a task trainer.
6. For the assigned trainer inhaler point out its dose counter, preparation and breathing steps using the product instructions. For a liquid measure the checked dose with a suitably graduated oral device.
7. At injection-model stations identify the ordered site or route, appropriate safety device, aseptic setup and sharps disposal. Demonstrate only the instructor-approved sequence on the trainer.
8. Ask the simulated patient to repeat or demonstrate the important step and document any need for instruction or referral.
9. Ask for teach-back on preparation, dose measurement and storage. Record which step the patient repeated correctly and which needs reinforcement before closing the exercise.

Precautions

• Practise invasive administration on models with faculty guidance.

• Use exact product instructions. Do not substitute a generic inhalation method for the actual device.

Observations and Interpretation

Dosage Forms Delivery Devices and Routes

Observations and Record

Item	What to record	What it tells you
Package	Generic name, formulation and route	Avoids form and route errors
Device	Priming, use and care instructions as applicable	Supports correct device technique
Administration check	Order, identity, allergy and documentation	Confirms readiness in the simulation

Worked Example

A patient asks to crush a modified-release tablet. Verify product instructions and consult the team for a suitable alternative if crushing would alter the release.

Result and Interpretation

Present a matched form-and-route record and one patient-facing instruction anchored to the actual product.

Viva Questions and Answers

Why does release type matter?

It can change rate of delivery and exposure.

Does the same active ingredient imply the same route?

Check the exact product's design and label.

Adverse Drug Reaction Reporting

Practical 02 / Clinical or documentation case

Aim

Assess and document a fictional suspected adverse drug reaction for pharmacovigilance review.

Principle

A suspicion can be reported before causal certainty. Chronology, clinical description, other exposures and response after any authorised withdrawal support assessment.

Materials and Requirements

- Fictional medicine and event timelines
- Current official suspected-ADR form
- Local clinical escalation checklist

Procedure

1. Prioritise the clinical safety of the affected person and identify any need for urgent escalation in the scenario.
2. Identify the event and time, check vital observations on the scenario record and alert the supervisor for acute warning signs. Clinical care takes priority over completing the report.
3. List suspected and concomitant products, indication, formulation, start and stop dates, and time of onset.
4. Make a dated exposure table with generic and brand names, strength, route, indication and actual timing. Include nonprescription medicines, supplements and treatments given for the event.

Continue with step 5 on the next page.

Procedure Continued

Adverse Drug Reaction Reporting

5. Record the event, severity and seriousness separately. Include relevant examination and investigations, course and outcome.
6. Document the person's symptoms in their words, relevant objective findings and onset in relation to the medicine. Record any change after stopping under supervision and any previous documented exposure.
7. Check whether the case meets the reporting form's seriousness criteria such as hospitalisation or a life-threatening event. Record outcome and missing facts separately from the strength of suspicion.
8. Populate a clearly fictional reporting form and record follow-up information needed to judge competing causes.
9. Fill the mock form with reported patient, suspect medicine, event and reporter fields and identify the institutional reporting route. Add the follow-up plan without sending the fictional report.

Precautions

- Do not enter personal identifiers in the training report.
- Avoid deliberate re-exposure as a teaching test.

Observations and Interpretation

Adverse Drug Reaction Reporting

Observations and Record

Item	What to record	What it tells you
Chronology	Exposure and event dates	Tests temporal plausibility
Event	Features, outcome and seriousness	Supports safety review
Assessment	Alternatives and follow-up	Preserves uncertainty and next steps

Worked Example

A fictional patient reports a rash after starting a new medicine while unwell with an infection. Record both possible contributors and check for systemic or mucosal features that warrant urgent review.

Result and Interpretation

Complete the training report and explain what information is missing. Use the local pathway for a real case.

Viva Questions and Answers

How do severity and seriousness differ?

Severity concerns intensity. Seriousness concerns outcomes such as life threat or hospitalisation.

Must a reaction be proved before reporting?

A suspected reaction can be reported.

Drug Interaction and Medication Reconciliation

Practical 03 / Clinical or documentation case

Aim

Reconcile medicines and assess a plausible interaction or duplication in a fictional chart.

Principle

Interaction risk depends on exact products, formulation, timing, indication and patient factors. A computer alert needs a clinical assessment.

Materials and Requirements

- Fictional patient chart with prescribed and nonprescribed items
- Approved product information and drug interaction references

Procedure

1. Collect prescribed, over-the-counter and supplement products with strength, route and actual use.
2. Use two available sources such as an interview and medicine list. Record generic name, formulation, dose, timing, route, actual use and allergy or adverse reaction history.
3. Compare medication history and orders and flag missing drugs, duplications and possible interaction pairs.
4. Align each home medicine with the current order in a two-column list. Mark intentional changes, omitted entries, possible duplications and additions whose purpose needs confirmation.

Continue with step 5 on the next page.

Procedure Continued

Drug Interaction and Medication Reconciliation

5. Check whether the interaction affects concentration, effect or both and review the evidence strength and patient factors.
6. Use the approved interaction reference or relevant product information for each candidate pair. Identify the evidence, direction of the expected effect, timing and relevant organ function or symptom.
7. Prioritise issues by likely harm in the case and flag the one requiring immediate review. Check whether the selected advice applies to the actual route, dose and coexisting treatment.
8. Prepare a focused query and propose authorised alternatives or monitoring for supervising-team discussion.
9. Present the discrepancy or interaction, the supporting details and a proposed plan for clinician confirmation. Record who will review it and what must be monitored.

Precautions

- Identify brand and active ingredient separately.
- Escalate high-risk discrepancies before any administration.

Observations and Interpretation

Drug Interaction and Medication Reconciliation

Observations and Record

Item	What to record	What it tells you
Medication list	Actual use and discrepancies	Defines the inputs
Interaction	Mechanism, plausibility and relevance	Prioritises review
Action	Clarification, monitoring and owner	Enables follow-up without self-authorising a change

Worked Example

Two fictional product names conceal the same active ingredient. Verify both ingredients and cumulative exposure and seek clarification before the simulated order proceeds.

Result and Interpretation

Document an updated list and one justified priority intervention.

Viva Questions and Answers

What is a pharmacodynamic interaction?

One medicine changes the effect of another without necessarily changing its concentration.

Why ask about supplements?

They can affect response, metabolism or safety.

P Drug Selection and Rational Prescription Writing

Practical 04 / Clinical or documentation case

Aim

Choose and justify a personal drug option for a defined teaching problem and write a clear mock prescription.

Principle

A standard preferred option is a starting point. The individual's diagnosis, treatment objective, benefit, risks, preferences and access determine suitability.

Materials and Requirements

- Fictional cases and current institutional treatment guide
- Mock prescription form and review checklist

Procedure

1. Define the problem, relevant measurements and measurable therapeutic objective.
2. Write the patient-specific problem and a measurable outcome on the case sheet. Check allergies, concurrent medicines, feasibility and baseline information needed to judge benefit.
3. Compare options by effectiveness, safety, suitability and cost. Verify the selected option against the fictional patient constraints.
4. Construct a comparison with a row for each candidate drug or non-drug option. Compare expected benefit, important harms, restrictions and access using the supplied source.

Continue with step 5 on the next page.

Procedure Continued

P Drug Selection and Rational Prescription Writing

5. Select the agreed teaching option and check contraindications, route, organ context and patient preferences with the supervisor. Document why the choice fits the stated objective.
6. Copy the clinician-provided teaching regimen onto a mock prescription with generic name, strength, form, route, frequency, duration and clear units.
7. Enter the fictional patient identifiers, date, prescriber fields and the exact authorised regimen. Use an unambiguous frequency, route, dose unit and duration or review date and write any special administration instruction.
8. Add monitoring, counselling and review instructions and ask a peer to read the simulated order back for ambiguity.
9. Ask another learner to read back the order and explain one monitoring point and one safety instruction. Correct omissions and note how response would be reviewed before continuing or stopping.

Precautions

- Label every order as a teaching exercise.
- Avoid unsafe abbreviations and ambiguous decimals. Include a leading zero for quantities below one.

Observations and Interpretation

P Drug Selection and Rational Prescription Writing

Observations and Record

Item	What to record	What it tells you
Treatment choice	Goal and justified option comparison	Supports rational selection
Order fields	Drug, units, instructions and identity fields	Reduces ambiguity
Follow-up	Benefit, adverse effects and review	Makes the decision revisitable

Worked Example

A fictional order says “one tablet daily” with no strength and two marketed strengths. Mark the order incomplete and seek clarification before the simulated dispensing.

Result and Interpretation

Prepare a fictional prescription and choice rationale anchored to the stated current guidance and patient factors.

Viva Questions and Answers

Does a P drug fit every patient?

Suitability still needs to be checked individually.

What makes a prescription legible in practice?

Complete fields, clear language and unambiguous units.

Dose and Volume Calculations in Special Populations

Practical 05 / Report and data interpretation

Aim

Check a supplied training dose, convert units and identify safety checks for a special-population scenario.

Principle

Units must cancel to the intended output. Clinical suitability depends on indication, age, organ function, product, body-size basis and the approved dosing source.

Materials and Requirements

- Fictional pre-authorised order and labelled training stock
- Current product-specific references
- Calculator and independent-check worksheet

Procedure

1. Identify the stated quantity and units, body weight or other dose basis and the required clinical constraints.
2. Mark the case weight and its units, then underline whether the mock order is per dose or per day. Check for the latest measured weight and any specified dose cap.
3. Check order limits and organ or pregnancy context using the appropriate supplied product information.

Continue with step 4 on the next page.

Procedure Continued

Dose and Volume Calculations in Special Populations

4. Use the provided reference to identify any renal or hepatic adjustment, paediatric limit, pregnancy consideration or required independent check. Hold an incomplete order for clarification.
5. Perform dimensional analysis with matching units. For a labelled liquid divide the authorised mass by the concentration to get volume.
6. Convert the units on paper so the dose basis cancels. Multiply the authorised dose per kilogram by weight and apply the stated frequency or division of a daily amount.
7. Check liquid strength as mass per mL, then divide the checked mass by that concentration. Record the calculated amount and the practical rounded volume according to the supplied guide.
8. Read the result back with units and verify feasibility, rounding rules and any discrepancy with the authorised reviewer.
9. Repeat the calculation independently or request a second check. Read back route, timing, final units and administration volume and record any limit or reason to query the order.

Precautions

- Use measured weight and product-specific evidence where relevant.
- Do not generalise adult dosing to children or use an isolated renal number as a dosing decision.

Observations and Interpretation

Dose and Volume Calculations in Special Populations

Observations and Record

Item	What to record	What it tells you
Input	Specified order, weight or relevant organ function	Verify appropriateness in context
Calculation	Unit conversion and output	Check algebra and decimal location
Independent check	Confirmed or escalated discrepancy	Prevents a calculation from becoming an unsafe order

Worked Example

Fictional order requires 40 mg from training stock labelled 20 mg/mL. The arithmetic result is 2.0 mL. Check the product, route and authorisation separately.

Result and Interpretation

Record both the numeric result and the professional judgement or authorisation still required.

Viva Questions and Answers

Why show units at every step?

Dimensional checks catch common mistakes.

Does correct arithmetic prove clinical appropriateness?

The indication, product, patient and route also require verification.

Drug Information Package Insert and Claims Appraisal

Practical 06 / Report and data interpretation

Aim

Answer a drug information query and distinguish an approved claim from promotional presentation.

Principle

Sources serve different purposes. Product information gives authorised information for the applicable market. Original studies and guidelines can answer comparative questions when critically appraised.

Materials and Requirements

- Fictional query and promotional card
- Current package insert and an approved guideline or original trial report

Procedure

1. Define the question, population, comparator, outcome and urgency.
2. Write an answerable question that specifies who is being treated, what choice is compared and which outcome matters. Identify whether the answer is time critical in the simulated discussion.
3. Locate the relevant current package sections such as indication, contraindication and warning. Record product and version.
4. Match the product, formulation, population and label revision to the question. Extract the relevant indication, warning and approval conditions into the worksheet.

Continue with step 5 on the next page.

Procedure Continued

Drug Information Package Insert and Claims Appraisal

5. Compare the promo claim with the underlying comparator, absolute outcomes, follow-up and study exclusions.
6. Identify study design, follow-up and who was excluded. Calculate an absolute difference from the reported event counts where possible and compare it with the relative headline.
7. Check whether the comparator, dose and outcome apply to the case. Look for a credible source for claims of safety and flag wording based on an uncertain or surrogate outcome.
8. Role-play a factual request to a representative or media contact in class. Document the source and remaining uncertainties without real outreach.
9. Draft a short response listing the supported claim, the missing data and the next source to check. Rehearse it as a role-play with no external sending.

Precautions

- Verify date, regulator and product details.
- Separate safety signals, relative effects and absolute outcomes.

Observations and Interpretation

Drug Information Package Insert and Claims Appraisal

Observations and Record

Item	What to record	What it tells you
Query	Defined clinical decision and audience	Directs selection of sources
Claim	Outcome, comparator and evidence strength	Distinguishes claim from support
Answer	Concise conclusion and uncertainty	Enables an informed decision

Worked Example

A training headline says a risk is cut by 50%. Trial risks of 4% and 2% also imply an absolute difference of 2 percentage points. Assess study population and follow-up before applying the claim.

Result and Interpretation

Write a patient- or clinician-appropriate response with the decision-relevant evidence and its limits.

Viva Questions and Answers

What is the absolute reduction from 4% to 2%?

Two percentage points.

Why check the comparator?

Relative benefit depends on what the intervention was compared with.

Medication Adherence and Patient Counselling

Practical 07 / Communication role-play

Aim

Identify a specific barrier and practise teach-back for an authorised medicine plan.

Principle

Adherence can be affected by concerns, side effects, literacy, access and practical constraints. Counselling starts by understanding what happened in everyday use.

Materials and Requirements

- Standardised patient and approved label
- Device trainer where relevant
- Action and review worksheet

Procedure

1. Ask what the person takes, what they believe it helps with and what gets in the way.
2. Ask the person to describe yesterday's actual medication routine and compare it with the verified plan. Explore missed doses, cost, understanding and concerns without assigning blame.
3. Select one priority barrier and review access, schedule, adverse effects or inhaler technique as indicated.

Continue with step 4 on the next page.

Procedure Continued

Medication Adherence and Patient Counselling

4. Clarify which barrier the person wants to address and why it occurs. Consider access, timing, side effects, language and technique before proposing one practical change.
5. Use plain language to explain the authorised dose instructions and when to seek advice. Demonstrate the device if appropriate.
6. Use a dummy device or medicine label to demonstrate the exact agreed instruction. Ask the person to show how they would take or prepare it and correct one step at a time.
7. Explain through the supplied guidance who to contact for side effects, supply problems or a missed dose. Check the person has a realistic way to reach that contact.
8. Ask for teach-back and agree a feasible reminder, referral or follow-up time with the person.
9. Document the agreed support, preferred reminder and time for review. Use teach-back to confirm the plan and arrange clinician review of any medicine concern.

Precautions

- Avoid blame and preserve privacy.
- Do not create a new dosing schedule during the role-play.

Observations and Interpretation

Medication Adherence and Patient Counselling

Observations and Record

Item	What to record	What it tells you
Barrier	Specific behaviour and patient perspective	Supports a practical response
Counselling	Correct product use and follow-up	Checks what matters to the patient
Teach-back	Patient explanation or demonstration	Shows what needs further clarification

Worked Example

A fictional learner discovers a person misses morning doses on night shifts. Explore a clinician-approved plan or reminder that aligns with their schedule and check understanding.

Result and Interpretation

Present the agreed step, the teach-back result and how the team will reassess.

Viva Questions and Answers

What is teach-back?

The person explains the agreed action in their own words or demonstrates it.

Why ask about actual use?

An order may differ from what the person can or does take.

Dose Response and Pharmacokinetics from Teaching Data

Practical 08 / Report and data interpretation

Aim

Compare dose-response and concentration-time curves in a computer or worksheet exercise.

Principle

Potency concerns the amount needed for a defined response. Efficacy concerns the attainable response. Clearance, volume and bioavailability affect exposure.

Materials and Requirements

- Supplied concentration-response curves and concentration-time data
- Calculator or plotting worksheet

Procedure

1. Plot effect versus log concentration using the supplied data and identify the baseline and plateau.
2. Label axes with units and place the supplied concentrations on the intended log scale. Retain the original points and note any missing baseline or plateau.
3. Compare EC50 and maximum response for the provided curves and note any uncertainty or missing plateau.
4. Estimate the maximum effect and find the concentration giving half that effect for each curve. Compare potency and maximal effect separately and report where interpolation is uncertain.

Continue with step 5 on the next page.

Procedure Continued

Dose Response and Pharmacokinetics from Teaching Data

5. Plot time versus concentration and estimate an illustrative half-life only in a supported terminal phase.
6. For the time-concentration data first inspect the profile and identify points representing the terminal phase under the teaching assumptions. Plot logged concentration against linear time for that portion.
7. Check for a roughly linear decline before estimating half-life from the fitted slope or comparable concentration points. Record the method and relevant units and show uncertainty from sparse sampling.
8. Connect the observed curve with an appropriate mechanism hypothesis and explain why experimental potency cannot alone decide a patient dose.
9. Summarise which curve shifted and what changed in magnitude. Contrast the descriptive result against the mechanistic hypothesis by identifying a further experiment or result to check it.

Precautions

- Use supplied simulation data rather than animal exposure.
- Do not estimate a terminal slope from the absorption interval.

Observations and Interpretation

Dose Response and Pharmacokinetics from Teaching Data

Observations and Record

Item	What to record	What it tells you
Concentration-response	EC50 and maximal effect	Separates operational potency and efficacy
Exposure curve	Sampling times and reliable terminal points	Supports an estimated half-life
Interpretation	Model, assumptions and comparison	Limits the conclusion to the data

Worked Example

A simulated terminal concentration declines from 8 to 4 to 2 mg/L at 2-hour intervals. The illustrative half-life over that interval is 2 hours.

Result and Interpretation

Report graph, observations and model limits. Keep clinical treatment decisions separate from the data exercise.

Viva Questions and Answers

What does EC50 mean?

The concentration producing half of the fitted maximal effect for the defined system.

Can different potency imply different maximum response?

The two properties are assessed separately.

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