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BP504T

Pharmaceutical Dosage Forms II

Unit I — Monophasic Liquids & Pressurised Dosage Forms Foundations

B.Pharm · Semester V · Theory notes

Syllabus coverage: UNIT I (6 hours).

From-zero teaching standard: every technical term is defined before use.

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CHAPTER 1 — MONOPHASIC FOUNDATIONS: SOLUTIONS, SOLUBILITY & VEHICLES

Chapter 1 · Monophasic Foundations: Solutions, Solubility & Vehicles

Learning Objectives

By the end of this chapter you will be able to:

1. Define monophasic liquids and distinguish them from biphasic liquids.
2. List the need, advantages and limitations of liquid dosage forms.
3. Explain solubility-enhancement techniques used in pharmacy.
4. Name the types of pharmaceutical waters and describe how purified water and distilled water are made and quality-checked.
5. Classify solvents by toxicity as per the relevant classes.

Key definitions

- Monophasic liquid dosage form: a liquid medicine in which all the dissolved ingredients form ONE single phase — a true solution. Example: a sugar syrup with medicine dissolved in it. You cannot see any separate particles.
- Biphasic liquid dosage form: a liquid medicine in which two phases exist side by side — undissolved drug particles in liquid (suspension) or one liquid dispersed in another (emulsion). Example: an antacid suspension. You CAN see cloudiness or a separated layer.
- Solution: a homogeneous (completely uniform) mixture of a solute (the substance dissolved, e.g., a drug) and a solvent (the liquid it dissolves in, e.g., water).
- Solubility: the maximum amount of a solute that can dissolve in a given amount of solvent at a stated temperature, giving a clear solution. Usually expressed as g/100 mL.

Terminology at a glance

Term	Simple meaning
Solute	The "guest" that dissolves (the drug)
Solvent	The "host" liquid that does the dissolving
Vehicle	The liquid base that carries the drug to the patient
Homogeneous	Fully uniform — the same everywhere, like sugar dissolved in tea
Heterogeneous	Not uniform — parts can be seen separately, like sand in water
Syrup	A concentrated sugar (sucrose) solution used as a medicine base
Elixir	A clear, sweetened, usually alcoholic liquid medicine
Reconstitution	Adding water to a dry powder at the time of use to make a liquid
Solubilisation	Making a poorly soluble drug dissolve using special agents

Explanations

1.4.1 Why liquids? Need of liquid dosage forms

Some patients cannot swallow tablets or capsules — small children, elderly patients, and unconscious patients. Liquids are also needed when the dose must be adjusted very finely (e.g., a child's dose by body weight), when rapid absorption is required (a dissolved drug absorbs faster than a solid tablet that must first disintegrate), and when the drug itself is unstable as a solid or is given by routes like ear drops and nasal drops.

Think of it this way: a tablet is like a packed suitcase that must be opened before use. A solution is like already wearing the clothes — ready at once.

1.4.2 Advantages of liquid dosage forms

1. Easy to swallow — suitable for paediatric and geriatric patients.
2. Flexible dosing — the dose can be changed by changing the volume measured (with a measuring cup or dropper).
3. Faster absorption and quicker onset of action than solid dosage forms, because the drug is already dissolved.
4. Uniform distribution of the drug — every millilitre contains the same dose (in a true solution).
5. Pleasant taste and appearance can be given (flavoured syrups for children).
6. Suitable for patients with difficulty swallowing (dysphagia).

1.4.3 Limitations of liquid dosage forms

1. Bulky and heavy — transport and storage are costlier than tablets.
2. Less stable — dissolved drugs degrade faster (hydrolysis, oxidation, microbial growth).
3. Needs preservation — water-based liquids support bacteria and fungi, so preservatives are essential.

4. Accurate dosing depends on the measuring device — a household spoon is not accurate.
5. Taste must be masked — bitter drugs need flavouring/sweetening work.
6. Spillage and pouring problems; glass bottles can break.

1.4.4 Monophasic vs biphasic — master comparison

Feature	Monophasic liquids (solutions)	Biphasic liquids (suspensions, emulsions)
Number of phases	One — single homogeneous phase	Two — dispersed phase + continuous phase
Appearance	Clear and transparent	Cloudy/turbid
Drug state	Dissolved at molecular level	Undissolved particles or droplets
Need for shaking	No	Yes — "Shake well before use"
Dose uniformity	Automatic — every drop is identical	Depends on resuspending/redispersing
Examples	Simple syrup, elixirs, ear drops, mouthwash	Antacid suspension, milk of magnesia, emulsion laxatives

1.4.5 Solubility-enhancement techniques

A large number of useful drugs are poorly water-soluble. The formulation pharmacist has several tools:

1. Co-solvency: adding a water-miscible solvent (like alcohol, glycerin, propylene glycol, PEG) to water so the drug dissolves better. Example: elixirs use alcohol as a co-solvent.
2. Solubilisation with surfactants: surfactants form micelles (tiny ball-like clusters) that trap the poorly soluble drug inside and carry it in water. Like soap carrying grease in wash water.
3. pH adjustment (salt formation): many drugs are weak acids or weak bases. Converting them to their salt form (ionized form) greatly increases water solubility. Example: a weakly acidic drug dissolves better as its sodium salt.
4. Complexation: forming a reversible complex with an agent such as cyclodextrin — the drug sits inside the cyclodextrin cavity like a cup holding it, becoming soluble. Simple explanation: a cup (cyclodextrin) with a pocket that carries the drug into water.
5. Solid dispersion / eutectic mixtures: dispersing the drug in a water-soluble carrier at molecular level so it wets and dissolves faster.
6. Particle-size reduction (micronization/nanonization): smaller particles dissolve faster (larger surface area). Note: this increases the RATE of dissolution; for suspensions it also improves uniformity.
7. Use of hydrotropes: large amounts of certain salts (e.g., sodium benzoate) increase solubility of poorly soluble drugs.
8. Chemical modification (prodrug): attaching a water-soluble group to the drug molecule that is removed in the body. (More of a drug-design tool than a formulation tool.)

1.4.6 Pharmaceutical waters — types

Water is the most common vehicle. Not all water is equal:

1. Potable water: drinking water, used for initial washing/rinsing, not for final products.

2. Purified water (PW): water that has been treated (by distillation, deionisation, reverse osmosis) to remove impurities, suitable for preparing medicines that are not injected. Must meet pharmacopoeial tests (conductivity, microbial limits).
3. Water for Injection (WFI): highly purified, sterile, pyrogen-free water used for injectable products.
4. Distilled water: water obtained by distillation (boiling and condensing the vapour). Pharmacopoeial distilled water for medicine preparation is essentially purified water made by the distillation method.

1.4.7 Manufacturing and QC of purified/distilled water

Manufacturing steps: (1) Pre-treatment — filtration, softening to remove hardness; (2) Purification — reverse osmosis (RO), deionisation, or distillation; (3) Storage and distribution — in sanitised stainless-steel loops, kept circulating (usually above 70 °C in hot loops or with UV/ozone in cold loops) to prevent microbial growth.
Quality control tests (as the pharmacopoeia requires, in general terms): appearance (clear, colourless), conductivity, total organic carbon (TOC), microbial limits, and for WFI — sterility and bacterial endotoxin tests. Systems are validated and monitored continuously; alert and action limits are set and trended.
Key takeaway: water used in medicines is not tap water. It is manufactured through engineered systems and tested like any other medicine ingredient.

1.4.8 Classes of solvents as per toxicity

Organic solvents used in pharmaceuticals are grouped by their toxic potential (the pharmacopoeial guidance on residual solvents):

- Class 1 — solvents to be avoided: known or strongly suspected human carcinogens (e.g., benzene, carbon tetrachloride). Their use is avoided unless strongly justified, with very strict limits.
- Class 2 — solvents to be limited: non-genotoxic animal carcinogens or possible causative agents of other irreversible toxicity (e.g., chloroform, methanol, acetonitrile). Permitted with daily-exposure limits.
- Class 3 — solvents with low toxic potential: (e.g., ethanol, acetone, ethyl acetate). Considered safe at normal residual levels, with a general guideline limit.

Simple analogy: Class 1 is the red zone (do not enter), Class 2 is the yellow zone (enter only with permission and limits), Class 3 is the green zone (safe under normal conditions).

Classifications

- Liquids by number of phases: monophasic (solutions) vs biphasic (suspensions, emulsions).
- Solutions by use: oral (syrups, elixirs, drops, mixtures), topical (lotions, liniments), otic (ear drops), nasal drops, mouthwashes/gargles.
- Solubility techniques: physical (micronization, solid dispersion), chemical (salt formation, pH adjustment, complexation, prodrug), formulation-based (co-solvency, surfactant solubilisation, hydrotropy).

Mechanism / how it works

- Dissolution mechanism: solvent molecules surround solute molecules and pull them apart (solvation/hydration); energy is needed to break solute–solute and solvent–solvent attractions, energy is released when solute–solvent attractions form. Net result decides solubility.
- Micellar solubilisation: surfactant molecules arrange with water-loving heads outward and water-hating tails inward, forming micelles; the poorly soluble drug dissolves in the oily core.

Diagram to draw

1. Solubility curve: x-axis temperature, y-axis solubility; a rising curve shows solubility increasing with temperature.
2. Purified-water system block diagram: raw water -> pre-treatment (filters/softener) -> RO/deioniser -> storage tank -> distribution loop (with sampling points) -> points of use.
3. Micelle diagram: circle of surfactant molecules, heads out, tails in, drug molecules trapped in the core.

Process flow

Purified water manufacturing:

Raw water -> Multimedia filtration -> Softening -> Activated carbon -> Reverse osmosis -> Electrodeionisation -> Storage -> Circulating distribution loop -> Use points (with online conductivity/TOC monitoring).

One-glance summary

One-glance summary

MONOPHASIC LIQUIDS — one glance

- [EXP] ONE phase · clear · dissolved drug · no shaking needed
- + Child/elderly friendly · flexible dose · fast absorption
- - Bulky · less stable · needs preservative · needs accurate measure
- [VEHICLE] Vehicles: purified water, distilled water, WFI · co-solvents (alcohol, glycerin, PG, PEG)
- [TRICK] Solubility tricks: co-solvency · micelles · salt formation · cyclodextrin · micronization
- [AVOID] Solvent classes: 1 = avoid · 2 = limit · 3 = low toxicity

Tables

Preparation	Typical vehicle/additives	Use
Simple syrup	Sucrose ~66.7% w/w in purified water	Sweet vehicle, demulcent

Preparation	Typical vehicle/additives	Use
Elixir	Alcohol + water + sweetener + flavour	Oral, clear
Drops	Water/glycerin	Concentrated small doses
Mouthwash/gargle	Water + flavour + antiseptic	Oral hygiene
Ear drops	Glycerin/propylene glycol	Otic

Examples

1. Paracetamol syrup for children: the drug is dissolved in a flavoured syrup base so a child who cannot swallow tablets gets an accurate weight-based dose.
2. Cough elixir: alcohol co-solvent keeps the active ingredients dissolved and the preparation clear.
3. Chloramphenicol ear drops: glycerin-based drops deliver drug to the ear canal where water would run out too fast.

Think of it this way

- A solution is like sugar fully dissolved in tea — you cannot see it, and every sip is the same.
- Micelles are like auto-rickshaws carrying passengers (drug molecules) through the rain (water) without getting wet.
- Cyclodextrin is like a cup with a pocket — it carries the drug into water.

Pharmacy relevance

Liquid dosage forms are the backbone of paediatric and geriatric therapy; the pharmacist must counsel on measuring devices (use the supplied cup/dropper, never a kitchen spoon), shaking instructions, storage, and expiry after opening.

India context

Most Indian households stock cough syrups, antacid suspensions and ORS; the pharmacist's role in explaining correct measuring and "shake well before use" is a daily reality in community pharmacy.

Key points

1. Monophasic = one clear phase with dissolved drug; biphasic = two phases.
2. Liquids suit children/elderly, allow flexible dosing, absorb fast — but are bulky, less stable, need preservatives.
3. Poor solubility is handled by co-solvency, micelles, salt formation, complexation, micronization, hydrotropy.
4. Pharmaceutical waters: potable -> purified -> WFI; made by RO/deionisation/distillation with continuous QC.
5. Solvent toxicity classes: 1 avoid, 2 limit, 3 low toxicity.

Common confusions

- Syrup vs elixir: syrup is sugar-based and may or may not contain alcohol; elixir is a clear, sweetened, usually hydro-alcoholic preparation.
- Distilled water vs purified water: distillation is a manufacturing METHOD; purified water is a QUALITY grade achievable by distillation, RO or deionisation.
- Solubility vs dissolution rate: solubility is HOW MUCH can dissolve; dissolution rate is HOW FAST it dissolves.

Common mistakes

1. Using tap water in place of purified water for compounding.
2. Measuring liquid doses with household spoons instead of calibrated devices.
3. Forgetting that solutions do NOT need shaking (that instruction is for suspensions).

Mnemonics

- "1 Avoid, 2 Limit, 3 Low" — solvent toxicity classes.
- CoSoMiSaCyHy: Co-solvency, Solubilisation (micelles), Salt formation, Cyclodextrin, Hydrotropy — solubility techniques.

Exam summary

Monophasic liquids are single-phase clear solutions. Their advantages (easy swallowing, flexible dosing, fast action) are balanced by bulk, stability and preservation needs. Solubility enhancement uses co-solvency, micellar solubilisation, salt formation, complexation, micronization and hydrotropy. Pharmaceutical waters are graded (potable, purified, WFI, distilled) and manufactured by RO/deionisation/distillation with pharmacopoeial QC. Solvents are classified by toxicity (Class 1 avoid, Class 2 limit, Class 3 low toxicity).

One-minute revision

One phase = solution. Children/elderly + flexible dose + fast action. Solubility: co-solvent, micelle, salt, cyclodextrin, micronize. Waters: purified/RO, WFI pyrogen-free. Solvent classes 1-avoid, 2-limit, 3-low.

Exam questions

Short answers:

1. Define monophasic liquid dosage form with two examples.
2. List four advantages and four limitations of liquid dosage forms.
3. Differentiate monophasic and biphasic liquids.
4. What are the types of pharmaceutical waters?
5. Name the three solvent toxicity classes with one example each.

Long answers:

1. Discuss the various solubility-enhancement techniques used in pharmaceutical formulation with examples.
2. Describe the manufacture and quality control of purified water for pharmaceutical use.

MCQs:

1. Which of the following is a monophasic liquid? (a) Suspension (b) Emulsion (c) Syrup (d) Lotion — Answer: (c)
2. Micelles are formed by: (a) Sugars (b) Surfactants (c) Polymers (d) Salts — Answer: (b)
3. Class 1 solvents are: (a) Low toxicity (b) To be avoided (c) To be limited (d) Freely used — Answer: (b)
4. Water for Injection must be: (a) Only clear (b) Sterile and pyrogen-free (c) Flavoured (d) Coloured — Answer: (b)
5. Cyclodextrin improves solubility by: (a) Heating (b) Complexation (c) Filtration (d) Dilution — Answer: (b)

Viva:

1. Why do suspensions carry "shake well before use" but solutions do not?
2. Give one example each of a co-solvent and a hydrotrope.

Application-based:

1. A bitter, poorly water-soluble drug is to be given to a 4-year-old. Suggest a suitable liquid dosage form and justify your choice of solubility technique.

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CHAPTER 2 — FORMULATION, MANUFACTURING, QC & PACKAGING OF MONOPHASIC LIQUIDS

Chapter 2 · Formulation, Manufacturing, QC & Packaging of Monophasic Liquids

Learning Objectives

1. List raw-material considerations and common additives used in liquid formulations.
2. Describe the processing steps for manufacturing solutions, syrups and elixirs.
3. Explain the QC tests performed on solutions, syrups and elixirs.
4. Describe powders for reconstitution as solutions.
5. Explain measuring, filling and packaging techniques, container–closure integrity, and automation in liquid manufacturing.

Key definitions

- Additive (excipient): a non-drug ingredient added to improve stability, taste, appearance or preservation of the medicine.
- IPQC (In-Process Quality Control): checks done DURING manufacturing to catch problems early.
- Container–closure integrity: proof that the sealed container keeps the product safe from leakage, contamination and moisture throughout its shelf life.
- Reconstitution: adding a specified amount of purified water to a dry powder at dispensing time to make the liquid medicine fresh.

Terminology at a glance

Term	Simple meaning
Preservative	Chemical that stops bacteria/fungi growing in the liquid
Sweetener	Makes the medicine taste acceptable
Flavour	Covers unpleasant taste/smell
Colour	Makes the product attractive and identifiable
Viscosity builder	Thickener that improves mouth-feel and pourability
Buffer	Keeps the pH steady so the drug stays stable and soluble
Antioxidant	Stops the drug being damaged by air (oxidation)
Chelating agent	Traps metal ions that would catalyse degradation

Explanations

2.4.1 Raw-material considerations

- Drug: purity, particle size, solubility profile, stability in solution.
- Vehicle: purified water quality (checked before every batch), co-solvents of pharmacopoeial grade.
- Additives: each must be compatible with the drug and with each other; preservative efficacy must be proven.
- Simple rule: garbage in, garbage out — a solution can never be better than its starting materials.

2.4.2 Common additives and their roles

1. Vehicles/solvents: purified water, alcohol, glycerin, propylene glycol, sorbitol.
2. Sweeteners: sucrose, sorbitol, saccharin, aspartame (for sugar-free/diabetic products).
3. Flavours: fruit flavours to mask bitterness (cherry, orange, mint).
4. Colours: to make the product attractive and distinguishable (never to hide defects).
5. Preservatives: benzoic acid/sodium benzoate, methyl/propyl parabens, sorbic acid — chosen as per pH and product type.

6. Buffers: citrate, phosphate buffers to hold pH.
7. Antioxidants: sodium metabisulphite, ascorbic acid, BHT.
8. Chelating agents: EDTA (disodium edetate) to lock up trace metals.
9. Viscosity builders: methylcellulose, xanthan gum, to improve pourability and mouth-feel.

2.4.3 Processing (manufacturing steps)

1. Check and weigh all raw materials; verify purified water quality.
2. Dissolve the drug in the vehicle (with co-solvents if needed) with stirring.
3. Add sweeteners, flavours, colours, buffers, preservatives in sequence, dissolving each fully.
4. Make up to final volume with purified water; mix well.
5. Filter (clarification) to remove any undissolved particles or fibres.
6. IPQC: check appearance, pH, specific gravity, assay of a sample.
7. Fill into clean containers, seal, label; finished-product QC; pack.

For syrups, sucrose may be dissolved by heat (with care — overheating causes caramelisation/inversion) or by agitation at room temperature.

2.4.4 QC of solutions, syrups and elixirs

- Appearance/clarity: clear, free from particles (visual inspection).
- Colour, odour, taste: conform to specification.
- pH: within the specified range.
- Specific gravity/density: confirms correct concentration.
- Viscosity (for syrups): within limits.
- Assay: drug content per labelled volume (e.g., 95–105% of label claim — exact limits per the pharmacopoeial monograph).
- Microbial limits: total counts and absence of specified pathogens.
- Preservative content: within effective range.
- Weight/volume of fill: each container holds the labelled amount.
- Alcohol content (for elixirs): within the declared range.

2.4.5 Powders for reconstitution as solutions

Some drugs are unstable in water (e.g., certain antibiotics). They are supplied as dry powders/granules; the pharmacist or patient adds a measured amount of purified water at the time of dispensing, shakes to dissolve, and the resulting solution is used within a short period (e.g., 7–14 days, with "discard after" dating and refrigeration if directed). Advantages: long shelf life of the dry powder + convenience of a liquid at use time. The label must state the exact volume of water to add and the beyond-use date.

2.4.6 Measuring, filling & packaging techniques

- Measuring: graduated cylinders, volumetric flasks (laboratory); piston fillers and peristaltic pumps (industry) for accurate volume filling.
- Filling: gravity filling, vacuum filling, pressure/piston filling; liquids are filled by volume, with in-process weight/volume checks.
- Packaging: amber glass or PET bottles with child-resistant or tamper-evident closures; measuring cups/droppers/syringes supplied with the pack.

2.4.7 Container–closure integrity

The sealed pack must: prevent leakage, block microbial entry, protect from light and moisture, and not interact with the product (no leaching of plastic components, no sorption of preservative into the closure). Integrity is verified by tests such as dye-ingress, vacuum-decay or microbial-challenge tests during development and validation.

2.4.8 Automation in liquid manufacturing

Modern plants use automated: water-system monitoring, PLC-controlled mixing vessels, CIP (clean-in-place) systems, automatic filling–capping–labelling lines, and vision inspection for fill level and particles. Benefits: consistency, fewer human errors, better documentation, higher output.

Worked calculation — every step

Question:

A paracetamol syrup contains 120 mg per 5 mL. What volume should a child weighing 20 kg receive if the prescribed dose is 10 mg/kg? Solution (every step shown):

- Step 1: Required dose = 10 mg/kg × 20 kg = 200 mg.
- Step 2: Syrup strength = 120 mg per 5 mL, i.e., 24 mg per 1 mL.
- Step 3: Volume = required dose ÷ strength = 200 mg ÷ 24 mg/mL = 8.33 mL ~ 8.3 mL.
- Answer: measure 8.3 mL (about 8.5 mL with the supplied cup).

Classifications

- Additives by function: vehicles, sweeteners, flavours, colours, preservatives, buffers, antioxidants, chelators, thickeners.
- Filling methods: gravity, vacuum, piston/pressure.
- Container–closure integrity tests: dye ingress, vacuum decay, microbial challenge.

Mechanism / how it works

- Preservative action: preservatives disrupt microbial cell membranes or enzymes; most work best in their unionised form, hence pH control matters.
- Antioxidant action: sacrificial oxidation — the antioxidant gets oxidised first, sparing the drug; chelators remove metal catalysts of oxidation.

Diagram to draw

1. Liquid manufacturing line: weighing -> mixing vessel -> filtration -> storage tank -> filling machine -> capping -> labelling -> packing.
2. Bottle cross-section: labelled parts — closure, tamper-evident band, shoulder, body, measuring marks.

Process flow

Batch manufacture of a syrup:

Verify raw materials & water quality -> dissolve sucrose in purified water -> add drug (pre-dissolved if needed) -> add flavours, colours, preservatives -> make up to volume -> mix -> filter -> IPQC (appearance, pH, specific gravity, assay) -> fill -> seal -> label -> finished-product QC -> pack and dispatch.

One-glance summary

One-glance summary

MONOPHASIC MANUFACTURE — one glance

- [SALT] Raw materials: drug + purified water + additives (sweetener, flavour, preservative, buffer, antioxidant, EDTA)
- [STEP] Process: dissolve -> add excipients -> make up volume -> filter -> IPQC -> fill -> seal -> label
- [QC] QC: clarity · pH · specific gravity · assay · microbial limits · fill volume
- [PACK] Unstable drugs -> dry powder for reconstitution (add water at dispensing)
- Pack: amber bottle + tamper-evident closure + measuring device
- [AUTO] Automation: PLC mixing · CIP · auto fill-cap-label · vision inspection

Tables

Additive class	Examples	Purpose
Preservative	Sodium benzoate, parabens	Prevent microbial growth
Antioxidant	Sodium metabisulphite, ascorbic acid	Prevent oxidation
Chelating agent	Disodium EDTA	Trap metal ions
Buffer	Citrate, phosphate	Hold pH steady
Sweetener	Sucrose, sorbitol, saccharin	Taste masking
Thickener	Methylcellulose, xanthan gum	Mouth-feel, pourability

Examples

1. ORS powder: a powder for reconstitution as a solution — dissolved in a litre of clean water at home.
2. Antibiotic dry syrup: supplied dry because the antibiotic degrades in water; reconstituted at the pharmacy.
3. Iron tonic: a solution with flavour, sweetener and antioxidant to keep the iron stable and palatable.

Think of it this way

- Additives are like the supporting actors in a film — the drug is the hero, but without them the show fails.
- IPQC is like tasting the curry while cooking, not only after serving.

Pharmacy relevance

The pharmacist reconstitutes dry syrups, counsels on storage ("use within 14 days, keep refrigerated"), and supplies the correct measuring device.

India context

Dry antibiotic syrups and ORS sachets are among the most dispensed items in Indian pharmacies; correct reconstitution counselling directly affects treatment success.

Key points

1. Raw-material quality decides product quality.
2. Standard processing: dissolve -> excipients -> volume -> filter -> IPQC -> fill -> seal.
3. QC covers clarity, pH, specific gravity, assay, microbes, fill volume.
4. Unstable drugs are supplied as powders for reconstitution.
5. Container–closure integrity protects against leakage, microbes, light and interaction.
6. Automation improves consistency and documentation.

Common confusions

- IPQC vs finished-product QC: IPQC happens during manufacture; finished-product QC happens on the packed product before release.
- Preservative vs antioxidant: preservative fights microbes; antioxidant fights chemical degradation by air.

Common mistakes

1. Adding the full volume of water before dissolving the drug (dissolve first, then make up to volume).
2. Skipping filtration, leaving fibres/particles in a "clear" solution.
3. Not labelling reconstituted products with the discard date.

Mnemonics

- "D-E-V-F-I-F": Dissolve, Excipients, Volume, Filter, IPQC, Fill — manufacturing order.
- C-P-S-A-M-F: Clarity, pH, Specific gravity, Assay, Microbes, Fill volume — QC tests.

Exam summary

Monophasic liquids are made by dissolving the drug and additives in a suitable vehicle, making up to volume, filtering, and filling under IPQC. QC includes clarity, pH, specific gravity, assay, microbial limits and fill volume. Water-unstable drugs are supplied as powders for reconstitution. Packaging

uses amber bottles with tamper-evident closures and measuring devices; container–closure integrity is validated; automation ensures consistency.

One-minute revision

Dissolve -> excipients -> volume -> filter -> IPQC -> fill. QC: clarity, pH, gravity, assay, microbes, fill. Dry powder + water at dispensing = reconstitution. Amber bottle, tamper-evident cap, measuring cup. Automation = consistency.

Exam questions

Short answers:

1. List six additives used in oral liquids with one example each.
2. What is IPQC? Give three IPQC tests for syrups.
3. Why are some antibiotics supplied as dry powders for reconstitution?
4. What is container–closure integrity? Name two integrity tests.
5. List two advantages of automation in liquid manufacturing.

Long answers:

1. Describe the formulation and manufacturing of a syrup, including raw-material considerations and processing steps.
2. Discuss the quality control tests for solutions, syrups and elixirs.

MCQs:

1. Which additive prevents microbial growth? (a) Antioxidant (b) Preservative (c) Buffer (d) Chelator — Answer: (b)
2. EDTA is used as a: (a) Sweetener (b) Chelating agent (c) Flavour (d) Colour — Answer: (b)
3. Powders for reconstitution are used when the drug is: (a) Too sweet (b) Unstable in water (c) Too cheap (d) Coloured — Answer: (b)
4. IPQC is performed: (a) After packing only (b) During manufacturing (c) Never (d) By the patient — Answer: (b)
5. Amber bottles protect from: (a) Heat (b) Light (c) Sound (d) Pressure — Answer: (b)

Viva:

1. Why is the drug dissolved before making up to final volume?
2. What beyond-use information must be on a reconstituted antibiotic syrup label?

Application-based:

1. Calculate the volume of a 250 mg/5 mL suspension-style syrup needed for a 15 kg child prescribed 15 mg/kg. (Steps: dose = 225 mg; strength = 50 mg/mL; volume = 4.5 mL.)

References