

Monophasic Dosage forms

Introduction Of Monophasic Dosage Forms

Definition:

- Monophasic dosage forms are pharmaceutical preparations consisting of a **single-phase system**, in which the active pharmaceutical ingredient (API) is either **molecularly dispersed** (true solution) or **uniformly distributed** throughout a homogenous liquid base.

Key Characteristics:

- Uniform throughout (no phase separation)
- No undissolved solid or immiscible liquid present
- Generally clear (exceptions include emulsified systems)

Classification Of Monophasic Dosage Forms

A. Internal Use

Formulation	Description	Example
Oral solutions	Drug completely dissolved in water or co-solvent	Paracetamol syrup, Iron drops
Elixirs	Clear, sweetened hydroalcoholic solutions	Phenobarbital elixir
Syrups	Highly concentrated aqueous solutions of sugar (sucrose/sorbitol) with or without drug	Cough syrup
Aromatic waters	Saturated solutions of volatile oils in water	Peppermint water
Tinctures	Alcoholic extract of crude drugs	Tincture of iodine
Drops	Small-volume solutions for oral/nasal administration	Multivitamin drops

B. External Use

Formulation	Description	Example
Nasal solutions	Isotonic, buffered aqueous solutions for nasal delivery	Xylometazoline nasal spray

Ophthalmic solutions	Sterile, isotonic solutions for the eye	Timolol eye drops
Otic solutions	Ear drops (may be aqueous or oil-based)	Ciprofloxacin ear drops
Topical solutions	For application on skin	Hydrogen peroxide solution
Injections	Sterile, pyrogen-free aqueous or oily solutions	Insulin injection

Theoretical Aspects Of Formulation

- Formulating monophasic dosage forms involves **balancing solubility, stability, and patient acceptability**.

The key formulation principles include:

1. Solubility Enhancement

- Ensure the drug is fully dissolved.
- Use of pH adjustment, co-solvents, surfactants, or complexing agents.

2. Stability

- Protection from hydrolysis, oxidation, light, temperature.
- Use of buffers, antioxidants, and chelating agents.

3. Palatability & Acceptability

- Especially for oral solutions and pediatric preparations.
- Use of sweeteners, flavours, colorants, and viscosity agents.

4. Preservation

- Prevent microbial contamination in aqueous systems.
- Use of preservatives like parabens, benzoates, sorbates.

5. pH Control

- Maintain chemical stability of API.
- Adjust for physiological compatibility (e.g., eye, nasal solutions).

6. Osmolarity Adjustment

- Especially critical in ophthalmic, nasal, and parenteral solutions.
- Use of NaCl, dextrose, or sorbitol for isotonicity.

Adjuvants Used in Formulation

- Adjuvants are **inactive ingredients** added to improve:
 - Stability
 - Aesthetic appeal
 - Palatability
 - Safety

A. Stabilizers

These include antioxidants, chelating agents, and buffers.

1. Antioxidants

- Prevent oxidation of drugs (especially vitamins, phenolics).
- Types:
 - Aqueous systems: Sodium metabisulfite, Sodium bisulfite, Ascorbic acid
 - Oily systems: Butylated hydroxytoluene (BHT), Butylated hydroxyanisole (BHA), α -Tocopherol (Vitamin E)

Example	Use Level
Sodium metabisulfite	0.1–0.2%
Ascorbic acid	0.05–0.2%
BHT	0.01–0.02%

2. Chelating Agents

- Bind trace metals that catalyze oxidation.
- Example: Disodium EDTA (0.01–0.05%)

3. Buffers

- Maintain pH to ensure stability and solubility.
- Common Buffers: Citrate buffer, Acetate buffer, Phosphate buffer

API	Preferred pH	Buffer
Ascorbic acid	3.0–4.0	Citric acid/sodium citrate
Eye drops	6.5–7.4	Phosphate buffer

B. Colorants

Purpose:

- Provide aesthetic appeal, flavour correlation, and dosage form identification.

Classification:

- Synthetic dyes: FD&C dyes (e.g., Tartrazine, Sunset yellow)
- Natural dyes: Caramel, Chlorophyll, Curcumin

Use Levels:

- Very small concentrations: 0.001–0.05%

Selection Criteria:

- Must be approved for pharmaceutical use.
- Compatible with API and other excipients.
- Stable to light, pH, and temperature.

Flavour	Color
Orange	Sunset yellow
Strawberry	Erythrosine
Mint	Brilliant green

C. Flavours**Purpose:**

- Mask unpleasant taste (bitterness, metallic, sour).
- Improve palatability, especially in pediatric and geriatric use.

Types:

- Natural: Fruit extracts, essential oils
- Artificial: Synthesized aromatic compounds

Common Flavour Agents:

Flavour	Typical Use
Orange	Vitamin drops
Peppermint	Antacids, cough syrups
Vanilla	Multivitamin syrups
Strawberry	Pediatric syrups

Considerations:

- It should be non-toxic and stable.
- pH compatibility is important.
- May be used in combination with sweeteners (e.g., sucralose, sorbitol)

Flavouring Oils (Oil-in-Water Emulsions):

- Examples: Lemon oil, Anise oil, Peppermint oil
- Added using emulsifiers like Polysorbate 80



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