Pills & Python

Pharmacy · Data · AI · Healthcare

BP504T

Pharmaceutical Dosage Forms II

Unit III — Emulsions

B.Pharm · Semester V · Theory notes

Syllabus coverage: UNIT III (6 hours).

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

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CHAPTER 4 — EMULSIONS: FORMULATION, MANUFACTURING, QC & ADVANCES

Chapter 4 · Emulsions: Formulation, Manufacturing, QC & Advances

Learning Objectives

1. Define emulsion and its types.
2. Explain theories of emulsification.
3. List additives and classify emulsifying agents.
4. Describe IPQC and QC tests for emulsions.
5. Explain instabilities of emulsions and their control.
6. Describe nano-emulsions, micro-emulsions and SMEDDS/SNEDDS.

Key definitions

- Emulsion: a biphasic liquid dosage form in which one liquid (dispersed/internal phase) is finely divided as droplets in another immiscible liquid (continuous/external phase).
- O/W emulsion: oil droplets in water (water is the continuous phase). Example: vanishing cream base, milk.
- W/O emulsion: water droplets in oil (oil is the continuous phase). Example: cold cream, butter.
- Emulsifying agent (emulsifier): an additive that reduces interfacial tension and forms a protective film around droplets, preventing them from joining together.
- HLB (Hydrophile–Lipophile Balance): a number scale indicating whether a surfactant prefers water or oil; guides emulsifier selection.

Terminology at a glance

Term	Simple meaning
Dispersed/internal phase	The droplets
Continuous/external phase	The surrounding liquid
Creaming	Droplets rising (o/w) or settling (w/o) — reversible
Coalescence	Droplets merging into bigger drops — irreversible, leads to breaking
Breaking/cracking	Complete separation into two layers
Phase inversion	O/W changing to W/O or vice versa
Micro-emulsion	Thermodynamically stable, transparent nano-droplet system
SMEDDS/SNEDDS	Self-micro/self-nano-emulsifying drug delivery systems — pre-concentrates that emulsify on contact with gut fluids

Explanations

4.4.1 Why emulsions?

To deliver oils/oily drugs in a palatable, water-miscible form (e.g., castor oil, cod-liver oil emulsions), to combine oil-soluble and water-soluble drugs, for topical creams/lotions, and to improve absorption of poorly soluble drugs.

4.4.2 Theories of emulsification (how emulsifiers work)

1. Surface tension theory: the emulsifier lowers the interfacial tension between oil and water, making it easier to break one liquid into droplets.
2. Oriented wedge theory: the emulsifier molecule is wedge-shaped; the wider end sits in the preferred phase, curving the film around droplets (wide end in water -> o/w).
3. Interfacial film theory: the emulsifier forms a tough, elastic film around each droplet, acting as a mechanical barrier against coalescence.
4. Electrical/double-layer theory: ionic emulsifiers give droplets the same charge, so they repel each other (like same poles of magnets).

4.4.3 Formulation additives

1. Emulsifying agents (primary stabilisers).
2. Viscosity builders: slow down creaming (Stokes' law applies to droplets too).
3. Preservatives: water phase needs protection.
4. Antioxidants: protect oxidisable oils.
5. Sweeteners, flavours, colours: for oral emulsions.
6. pH adjusters/buffers.

4.4.4 Classification of emulsifying agents

1. Natural: acacia, tragacanth, gelatin, egg yolk (lecithin).
2. Semisynthetic/synthetic surfactants: polysorbates (Tweens — o/w), sorbitan esters (Spans — w/o), sodium lauryl sulphate.
3. Finely divided solids: bentonite, magnesium hydroxide (form a film of solid particles around droplets).
4. Auxiliary emulsifiers: cetyl alcohol, glyceryl monostearate (thicken and support the film).

HLB guide (simple):

low HLB (3–6) -> w/o emulsifier; high HLB (8–18) -> o/w emulsifier. Choosing the right HLB is like choosing the right key for a lock.

4.4.5 Manufacturing

1. Heat oil phase and water phase separately (emulsifier dissolved in its preferred phase).
2. Add one phase to the other with vigorous stirring/homogenisation (hot-hot method).
3. Cool with continued stirring; add heat-sensitive ingredients (flavours, preservatives) after cooling.
4. IPQC; fill; label.

4.4.6 IPQC & QC tests

- Appearance: uniform, no separation.
- Type test: dilution test (o/w dilutes with water), dye test, conductivity.
- Globule/droplet size: microscopic measurement; smaller is more stable.
- Viscosity, pH.

- Creaming rate: volume of separated layer on standing.
- Centrifugation test: accelerated stability check.
- Assay, microbial limits, fill volume.

4.4.7 Instabilities and control

1. Creaming: reversible rising/settling; controlled by small droplets, matched densities, higher viscosity; redisperses on shaking.
2. Flocculation: droplets clustering without merging; controlled by proper emulsifier.
3. Coalescence: irreversible merging; controlled by strong interfacial film, adequate emulsifier.
4. Breaking (cracking): complete separation; prevented by correct emulsifier type/concentration, avoiding temperature extremes.
5. Phase inversion: prevented by correct phase-volume ratio and emulsifier HLB.
6. Microbial growth: controlled by preservatives (water phase is vulnerable).

4.4.8 Packaging

Well-closed amber containers; creams in tubes/jars; oral emulsions in bottles with measuring devices; "shake well" where creaming occurs.

4.4.9 Advances

1. Nano-emulsions: droplets in the nanometre range; kinetically stable, improved drug absorption.
2. Micro-emulsions: thermodynamically stable, transparent systems; form spontaneously with the right surfactant/co-surfactant mix.
3. SMEDDS/SNEDDS: anhydrous pre-concentrates (oil + surfactant + co-solvent + drug) filled in soft gelatin capsules; on reaching gut fluids they spontaneously form micro/nano-emulsions, greatly improving absorption of poorly soluble drugs. Overview: formulation is simple (mix and fill); applications include drugs with poor oral bioavailability. Simple analogy: a dry sponge (pre-concentrate) that blooms into a fine emulsion the moment it touches water.

Worked calculation — every step

Question:

A cod-liver oil emulsion contains 50% v/v oil. How much oil does a 10 mL dose deliver? Steps: 50% v/v means 50 mL oil per 100 mL emulsion -> per 10 mL: (50/100) × 10 = 5 mL of oil. Answer: 5 mL.

Classifications

- By phase: o/w vs w/o (and multiple emulsions o/w/o, w/o/w).
- Emulsifiers: natural, synthetic surfactants, finely divided solids, auxiliary.
- Instabilities: reversible (creaming, flocculation) vs irreversible (coalescence, breaking).

Mechanism / how it works

- Emulsification: mechanical energy breaks the dispersed phase into droplets; the emulsifier instantly adsorbs at the new interface, lowering tension and forming a protective film.
- SMEDDS self-emulsification: on dilution in gut fluids, the surfactant system spontaneously generates fine droplets with minimal energy input.

Diagram to draw

1. O/W vs W/O: circles of oil droplets in water and vice versa, with emulsifier film drawn around droplets.
2. Instability ladder: creaming -> flocculation -> coalescence -> breaking, with reversibility marked.
3. SMEDDS capsule to emulsion: capsule -> gut fluid -> fine droplets diagram.

Process flow

Emulsion manufacture:

Weigh phases -> heat oil phase & water phase separately -> dissolve emulsifier in preferred phase -> add internal phase to external phase with homogenisation -> cool with stirring -> add flavours/preservatives -> IPQC (type test, droplet size, viscosity, pH) -> fill -> label -> QC -> pack.

One-glance summary

One-glance summary

EMULSIONS — one glance

- [EXP] Liquid droplets in liquid · TWO phases · o/w or w/o
- [SALT] Emulsifiers: acacia · Tweens (o/w) · Spans (w/o) · bentonite
- [INFO] HLB: low (3–6) -> w/o · high (8–18) -> o/w
- [!] Enemies: creaming (reversible) · coalescence (irreversible) · breaking · phase inversion
- [QC] QC: type test · droplet size · creaming rate · centrifugation · assay
- Advances: nano-emulsions · micro-emulsions · SMEDDS/SNEDDS (self-emulsifying capsules)

Tables

Emulsifier	HLB tendency	Emulsion type
Spans (sorbitan esters)	Low (3–6)	W/O
Tweens (polysorbates)	High (8–18)	O/W
Acacia	—	O/W (natural)
Bentonite	—	O/W (solid film)

Instability	Reversible?	Control
Creaming	Yes (shake)	Small droplets, viscosity
Flocculation	Yes	Proper emulsifier
Coalescence	No	Strong film, enough emulsifier
Breaking	No	Correct HLB, avoid heat/cold shock
Phase inversion	No	Correct phase ratio

Examples

1. Cod-liver oil emulsion: makes the oil palatable and miscible for children.
2. Cold cream (w/o): leaves a protective oily film on skin.
3. Vanishing cream (o/w): disappears into skin, non-greasy.
4. SMEDDS capsule: improves absorption of a poorly soluble drug.

Think of it this way

- An emulsifier is like a peacemaker holding two quarrelling groups (oil and water) apart.
- Coalescence is like small rain puddles joining into one big puddle.

Pharmacy relevance

Pharmacists compound simple emulsions, counsel on shaking oral emulsions, and advise on storage (avoid freezing/heat which crack emulsions).

India context

Emulsion-type creams and lotions dominate the Indian topical market; pharmacists routinely explain the difference between greasy (w/o) and non-greasy (o/w) products.

Key points

1. Emulsion = liquid droplets in another liquid; o/w or w/o.
2. Emulsifiers work by lowering interfacial tension and forming protective films (4 theories).
3. HLB guides selection: low -> w/o, high -> o/w.
4. Instabilities: creaming (reversible), coalescence/breaking (irreversible).
5. QC: type test, droplet size, creaming rate, centrifugation, assay.
6. Advances: nano/micro-emulsions, SMEDDS/SNEDDS.

Common confusions

- Creaming vs breaking: creaming is reversible separation into layers (shake to fix); breaking is permanent separation that shaking cannot fix.
- Micro-emulsion vs nano-emulsion: micro-emulsions are thermodynamically stable and transparent; nano-emulsions are kinetically stable and usually translucent.

Common mistakes

1. Adding the phases at very different temperatures (causes cracking).
2. Using an o/w emulsifier for a w/o product (wrong HLB -> phase inversion).
3. Freezing an emulsion during storage.

Mnemonics

- "Low W/O, High O/W" — HLB rule.
- Instabilities: "Cre-Floc-Coal-Break" — creaming, flocculation, coalescence, breaking (increasing severity).

Exam summary

Emulsions are biphasic liquids of oil and water stabilised by emulsifiers, of o/w or w/o type. Four theories explain emulsifier action; HLB guides selection. Formulation needs emulsifiers, thickeners, preservatives and antioxidants. Instabilities range from reversible creaming to irreversible breaking. QC includes type tests, droplet size and centrifugation. Advances include nano-emulsions, micro-emulsions and SMEDDS/SNEDDS.

One-minute revision

Two liquids, one as droplets. O/W or W/O. Emulsifier = film + low tension. HLB low->W/O, high->O/W. Creaming reversible, breaking not. Advances: nano, micro, SMEDDS.

Exam questions

Short answers:

1. Define emulsion with two examples each of o/w and w/o.
2. List the four theories of emulsification.
3. Classify emulsifying agents with examples.
4. Differentiate creaming and cracking.
5. Write a short note on SMEDDS.

Long answers:

1. Describe the formulation and manufacturing of emulsions.
2. Discuss the instabilities of emulsions and their evaluation.

MCQs:

1. Milk is an example of: (a) W/O (b) O/W (c) Solution (d) Suspension — Answer: (b)
2. Low HLB surfactants favour: (a) O/W (b) W/O (c) Solutions (d) Gels — Answer: (b)
3. Which instability is irreversible? (a) Creaming (b) Flocculation (c) Coalescence (d) None — Answer: (c)
4. Cold cream is: (a) O/W (b) W/O (c) Gel (d) Paste — Answer: (b)
5. SMEDDS forms emulsion on contact with: (a) Air (b) Gut fluids (c) Skin (d) Light — Answer: (b)

Viva:

1. How do you identify whether an emulsion is o/w or w/o?
2. Why must emulsions not be frozen?

Application-based:

1. An o/w cream shows oil separation after a hot summer in storage. Diagnose and suggest corrective actions.

References