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Sprowel's American Pharmacy.	

محتوى المحاضرة

Emulsion Stability

A kinetically stable emulsion is one in which the dispersed droplets retain their initial character and remain uniformly dispersed throughout the continuous phase.

In pharmaceutical emulsions, stability has a much wider definition as it is generally equated with a long shelf life. Thus in addition to kinetic stability, the emulsion must retain its original appearance, odor and consistency, and exhibit no microbial contamination.

Emulsion Stability

An emulsion without an emulsifier will quickly return to the original state of separate oil and water layers; that is, the emulsion will break or crack.

In the presence of an emulsifier, this state is approached via five distinct processes:

- Flocculation
- Creaming

- Coalescence
 - Cracking
 - Phase separation
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Flocculation

This process refers to aggregation or joining droplets together (without any change in primary droplet size) to form large units or clumps (flocules) which rise or settle in the emulsion depending on their densities.

Creaming or Sedimentation

- Aggregates of globules of the internal phase have a greater tendency than individual particles to rise to the top of the emulsion or fall to the bottom.
 - Such a preparation of the globules is termed the *creaming* of the emulsion.
 - It is a reversible process.
 - Creamed emulsion can be restored to its original state by gentle agitation.
 - If insufficient shaking is employed before each dose, improper dosage of the internal phase substance may result.
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Creaming or Sedimentation (Stokes equation)

According to the Stokes equation, the rate of separation of the dispersed phase of an emulsion may be related to such factors:

1. Particle size of the dispersed phase
2. Difference in density between the phases
3. Viscosity of the external phase

- Larger particle size, greater density difference, and lower viscosity increase the rate of creaming.
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Upward vs. Downward Creaming

- Upward creaming: occurs in unstable o/w or w/o emulsions where the internal phase has a lesser density than the external phase.
 - Downward creaming: occurs when the internal phase is denser than the external phase.
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Strategies to Enhance Stability

1. Reduce globule/particle size as fine as possible.
 2. Minimize density difference between internal and external phases.
 3. Ensure viscosity of the external phase is reasonably high.
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Coalescence and Breaking (Cracking)

- When one droplet contacts another, coalescence occurs producing a single droplet of greater diameter.
 - The surface area of the new droplet is less than that of the two initial droplets.
 - This process continues until complete phase separation (two liquid layers).
 - Separation of the internal phase from the emulsion is called breaking (cracking).
 - This is irreversible because the protective sheath around globules no longer exists.
 - A cracked emulsion cannot be recovered by shaking.
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Phase Inversion

- Process of exchange between dispersed phase and medium.
 - Example: an o/w emulsion may invert to a w/o emulsion with time or condition changes.
 - Occurs when dispersed phase exceeds a theoretical maximum of ~74% of total volume.
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Environmental Considerations

- Protect emulsions against extremes of cold and heat.
 - Freezing and thawing coarsen an emulsion or break it.
 - Excessive heat has the same effect.
 - Light, air, and contaminating microorganisms can adversely affect stability.
 - Proper formulation and packaging are used to minimize hazards.
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Storage Conditions

- Light-sensitive emulsions → light-resistant containers.
 - Emulsions prone to oxidative decomposition → antioxidants included, tight container closure with label warnings.
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Preservation of Emulsions

- Molds, yeasts, and bacteria can decompose the emulsifier.
 - Fungi (molds & yeasts) are more likely contaminants than bacteria.
 - Fungistatic preservatives (methylparaben + propylparaben) are generally included in aqueous phase of o/w emulsions.
 - Alcohol (12–15% of external phase volume) often added to oral o/w emulsions for preservation.
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Therapeutic Examples

Oral Emulsions

- Mineral Oil Emulsion:
 - o/w type prepared with mineral oil, acacia, syrup, vanillin, alcohol, purified water.
 - Prepared by dry gum method (4:2:1).
 - Used as lubricating cathartic with better palatability.
 - Variations may include additional cathartic agents.
 - Castor Oil Emulsion:
 - Indication: laxative for constipation, colon preparation.
 - Simethicone Emulsion:
 - Indication: defoaming agent for gastrointestinal gas relief.
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Topical Emulsions

- Lotions:
 - Many hand/body lotions for dry skin are o/w emulsions.
 - Some deliver drugs systemically (e.g., *Estrasorb* with estradiol for menopausal symptoms).
- Shampoos:
 - Solutions, emulsions, or suspensions used for hair/scalp cleansing.
- Liniments:
 - Alcoholic/oleaginous solutions or emulsions of medicinal substances rubbed on skin.
 - Vehicle depends on desired action (rubefacient, counterirritant, massage) & solubility of components.
 - Must be labeled “For external use only.”

- Liniments containing emulsions/insoluble matter must be shaken before use and labeled “Shake well.”
- Prepared in the same manner as solutions, emulsions, or suspensions

