



IP 190: Cosmetic Product Development

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INTRODUCTION TO COSMETICS

Cosmetics

- articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body
- for cleansing, beautifying, promoting attractiveness, or altering the appearance (US FD & C Act)
- skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, shampoos, permanent waves, hair colors, toothpastes, and deodorants, as well as any material intended for use as a component of a cosmetic product

Cosmetic or Drug?

- Drugs
 - articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease
 - articles (other than food) intended to affect the structure or any function of the body of man or other animals (US FD&C Act)
- In the case of Cosmeceuticals
 - Borderline products

The Issue on Antibacterial Soap

- FDA issues final rule on safety and effectiveness of antibacterial soaps
- Rule removes triclosan and triclocarban from over-the-counter antibacterial hand and body washes
- See:
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm517478.htm>

- How can a product be both a cosmetic and a drug?

- Source:

<http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm#Definecosmetic>

Drug or Cosmetic

- Some products meet the definitions of both cosmetics and drugs.
- This may happen when a product has two intended uses.
- For example, a shampoo intended for antidandruff treatment is a drug because its intended use is to treat dandruff. Consequently, an antidandruff shampoo is both a cosmetic and a drug.
- Other cosmetic/drug combinations are toothpastes that contain fluoride, deodorants that are also antiperspirants, and moisturizers and makeup marketed with sun-protection claims. Such products must comply with the requirements for both cosmetics and drugs.

What about "cosmeceuticals"?

- The FD&C Act does not recognize any such category as "cosmeceuticals." A product can be a drug, a cosmetic, or a combination of both, but the term "cosmeceutical" has no meaning under the law.

How is the products intended use established?

- **Claims stated on the product labeling, in advertising, on the Internet, or in other promotional materials**
 - restore hair growth, reduce cellulite, treat varicose veins, or revitalize cells
- **Consumer perception as established through the product's reputation**
- **Ingredients that may cause a product to be considered a drug because of known therapeutic use**
 - fluoride in toothpaste
- **essential oils in fragrance products**
 - promoting attractiveness = cosmetic
 - aromatherapy claims = drug

Cosmetic Product Development

- Brainstorming
 - Trends
 - Capacity
 - Cost
- Identification of products for launch
- Launch plan
- Calendar of activities
- Facilitation and updates
- Launch

Cosmetic Product Development Team

- R&D
 - Formulation
 - Packaging
 - Regulatory
- Manufacturing
- Marketing
- Logistics
- Sales
- Finance

Cosmetic Formulation



Safety evaluation in humans

Selection of best formulation

Formulation screening

Feasibility checking and modification

Selection of appropriate excipients

Preformulation investigation

Objective and definition of target profile

Spectrum of cosmetic product development

- Cosmetic Ingredients
 - product should contain only ingredients that comply with the annexes of ASEAN Cosmetic Directive
- Water
 - water contamination
 - *inorganic ion concentration*
 - *presence of micro-organisms*
- Actives
- Fragrance
- Preservation
- Cosmetic Vehicle
- Packaging

Magic Formulation Triangle

Feasibility

Preparation of the active in the vehicle

Availability of required equipment and materials

Activity

Effectiveness after application

Stability

Physical
Chemical



Areas of Application for Cosmetics

Skin

Hair

Oral Cavity

Cosmetic Product Categories

- Skin Care Products
 - applied to the epidermis, lips and external genital organs
- Hair Care Products
 - applied to the hair system
- Oral Care Products
 - applied to the teeth and the mucous membranes of the oral cavity
- Decorative/Coloured Products
 - used to enhance appearance

Cosmetic Functions

- to clean
- to perfume
- to change appearance
- to correct body odours
- to protect
- to keep the target site in good condition

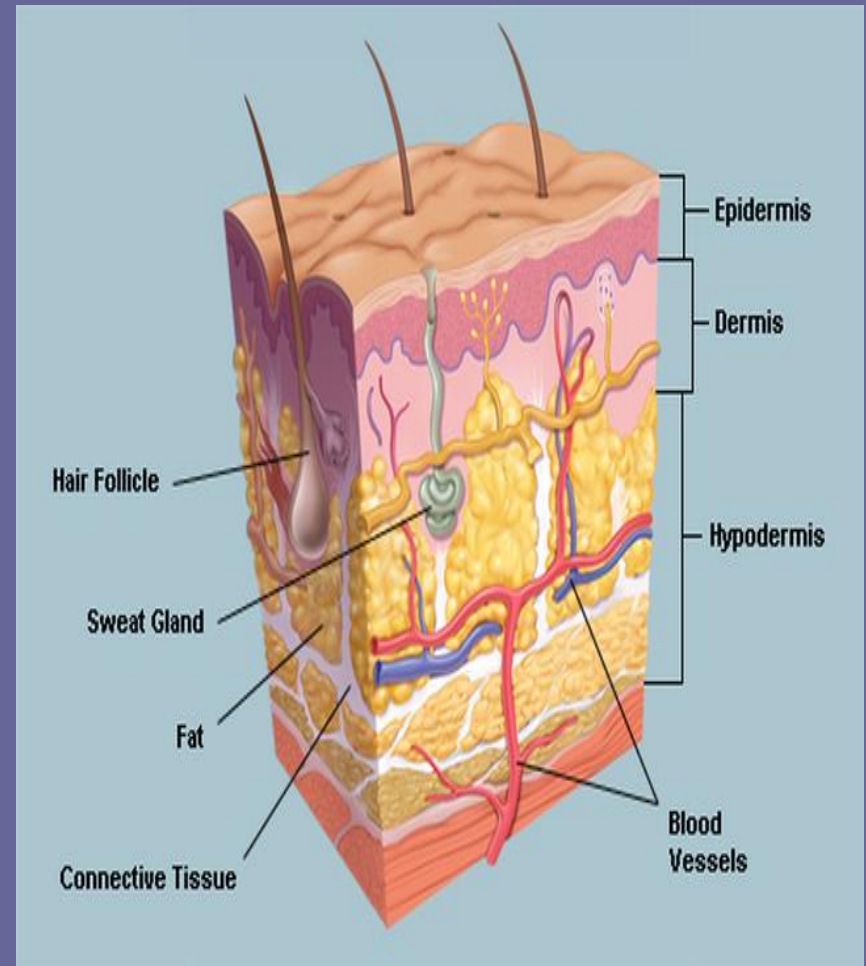
The Human Skin

- Largest organ in the body
 - 1.8 sqm, 8-12% of body weight
- Protective function: interface between body and the environment
- Metabolic, storage and regulatory functions

Structure of the Skin: Vascular and Nervous Systems

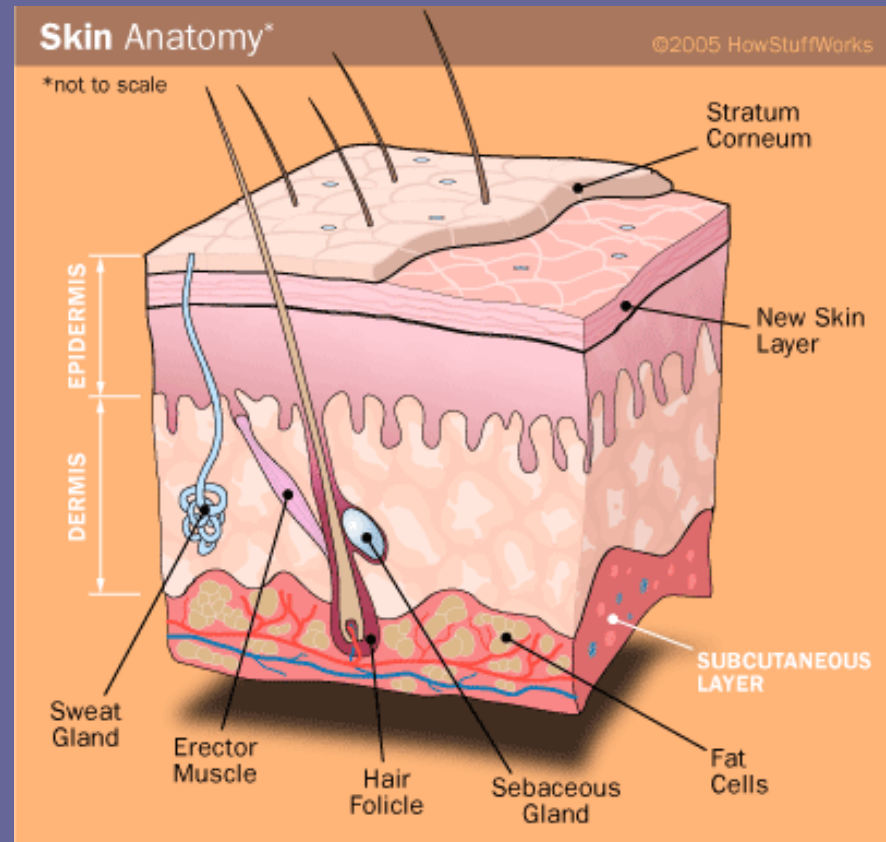
- Vascular System
 - Blood capillary networks
 - Lymphatic system
- Nervous System
 - Sensory: touch, pain, heat, cold
 - Autonomic: controls vascular system, skin appendages, smooth muscle (goose bumps, hair erection)

- The epidermis, the outermost layer of skin, provides a waterproof barrier and creates our skin tone.
- The dermis, beneath the epidermis, contains tough connective tissue, hair follicles, and sweat glands.
- The deeper subcutaneous tissue (hypodermis) is made of fat and connective tissue.



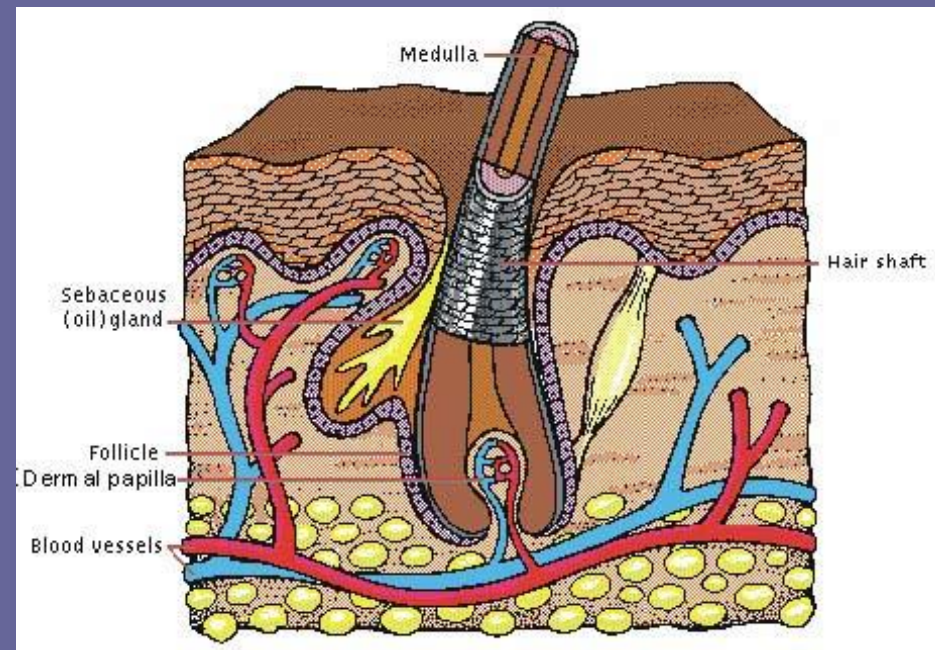
Structure of the Skin: Histological Layers

- Epidermis: protective covering
 - Stratum corneum
 - Stratum lucidum
 - Stratum granulosum
 - Stratum spinosum
 - Stratum basale
 - Basal membrane
- Corium: maintains the epidermis
 - Fibrous network of proteins
 - Collagen
 - Elastin
 - Reticulin
- Subcutis: connects the skin to the muscles, bones and other structures



Structure of the Skin: Skin Appendages

- Follicle Apparatus
 - Hair follicle, hair shaft, papilla, sebaceous gland, smooth muscle, other vascular and nervous systems
- Sweat Glands
 - Eccrine
 - Watery perspiration
 - Palms, soles, armpits, forehead
 - Apocrine
 - odors
 - Armpits, areola, genital region



Functions of the Skin

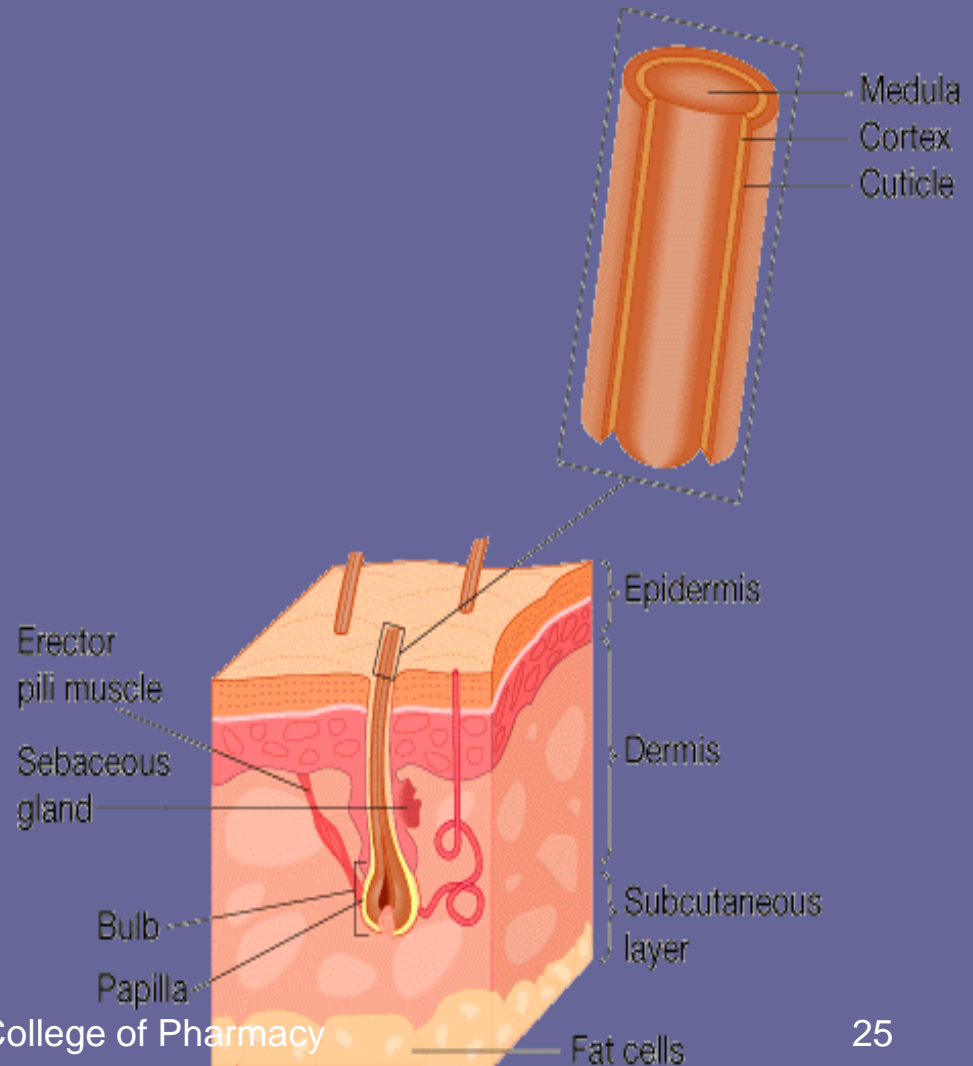
- Protection against the environment
- Heat regulation
- Metabolism of the skin
 - Oxygen, carbon dioxide
 - Protein, vitamin D
- Fat storage
 - Dormant fat, fat-soluble vitamins A and E
- Sensory
 - Stimuli and information, touch
- Social
 - aesthetic

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- Oral Care Products
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The Human Hair

- Insulator, protective covering, orientation and tactile functions
- Parts:
 - Shaft (protruding above the skin)
 - Root (anchored in the skin)



COSMETIC PRODUCTS



Cosmetic Products

- Cosmetic Product Categories
 - ACD List
- Formulating Cosmetic Products
 - Raw Materials
 - Cosmetic Vehicles
 - Preserving Cosmetics

ACD Illustrative List by Category of Cosmetic Products

- Creams, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc.).
- Face masks (with the exception of chemical peeling products¹).
- Tinted bases (liquids, pastes, powders).
- Make-up powders, after-bath powders, hygienic powders etc.
- Toilet soaps, deodorant soaps, etc.
- Perfumes, toilet waters and eau de Cologne.
- Bath and shower preparations (salts, foams, oils, gels, etc.).
- Skin wash products.
- Anti-cellulite products
- Anti-acne products
- Depilatories.
- Deodorants and antiperspirants.

http://www.fda.gov.ph/attachments/category/197/Annexe%20I_Illustrative%20List.pdf

ACD Illustrative List by Category of Cosmetic Products

- Hair care products
 - hair tints and bleaches
 - for waving, straightening and fixing
 - setting products
 - Cleansing (lotions, powders, shampoos)
 - anti-dandruff
 - conditioning (lotions, creams, oils)
 - anti hair-loss
 - Hairdressing (lotions, lacquers, brilliantines)
- Shaving products
 - Creams
 - Foams
 - lotions
- make-up and make-up removal
- Products for application to the lips

ACD Illustrative List by Category of Cosmetic Products

- Products for care of the teeth and the mouth
 - Mouth wash
 - Anti-caries toothpaste
 - Breath fresheners (liquid or spray)
- Products for nail care and make-up
- Products for external intimate hygiene
- Sunbathing products and sunscreen products
- Products for tanning without sun
- Skin-whitening products
- Anti-wrinkle products
- Anti-bacterial products
- Bust contouring products

Skin Care Preparations

- Emulsions, multiple emulsions, microemulsions, oils, gels (oleogels, hydrogels, oil/water gels)
- Natural balance/functioning of the skin
- External skin care is indispensable due to aging of the skin
Resulting to loss of elasticity
leading to reduced ability to absorb water.



Bath Preparations

- Mainly for cleansing
- Refreshing, relaxing, recuperating, stimulation, care, pleasure, luxury
- (Other than soap) bath salts, bath tablets, bath oils, bubble bath



Hair Care Preparations

- Hair care preparations in the hair and hair care preparations that are rinsed out.
- Shampoo
- Conditioner
- Hair shaping (perming, straightening)
- Hair shaping (spray, gel, mousse)
- Hair colorant

Oral Care Preparations

- Cavities and alveolar disease most common human ailment.
- Cavities at young age and inflammatory disease of the tooth socket at age 35 and above.
- Toothpaste
- Mouthwash
- Gargle
- Denture cleanser
- Denture adhesive

Decorative / Make-Up Preparations

- All decorative body care preparations contain coloring agents which change the hue of the face, eye region, lips, or nail. In addition to ingredients that promote skin care and protection.
- Facial make-up
- Eye care preparation
- Lip care preparation
- Nail care preparation

Decorative Body Care Preparations

- Facial make up should impart natural appearance to the skin, freshen pale skin and smooth over irregularities. The color pigments used for this are incorporated into an emulsion, powder loose or compressed.
- Eye cosmetics applied to the eyebrows, eyelids and eye lashes

Decorative Body Care Preparations

- Lip care preparations primary purpose to prevent drying and cracking of the lips.
- Lip preparations with coloring agents impart color to pale lips, alter shape of the lip, or match lip color to color of hair or clothes.
- Nail care preparations intended to cleanse and maintain as well as shape and color fingers and nails.

Feminine Hygiene Preparation

- Quality of the preparation is judge in terms of quality and compatibility. Use should not lead to irritations and side effects such as an imbalance in the indigenous microorganisms of the genital area.
- Feminine wash
- Douche

Foot Care Preparation

- A variety of preparations concerned with specific influences on the foot, such as foot stress and load, circulation, the skin structure of the sole of the feet and footwear. Not including products with intended medicinal effect (e.g. for corns and calluses)
- Foot wash
- Foot deodorant
- Foot powder
- Foot lotion

Perfumes, Scents, and Fragrances

- Perfume
- Eau de parfum
- Eau de toilette
- Cologne
- Splash

Considerations in Cosmetic Production

- Manufacturing Facilities
- Materials
- Methods
- Machines
- Manpower

ASEAN Guidelines for Cosmetic Good Manufacturing Practice

Manufacturing Facilities

- FDA-licensed
- GMP-Compliant with 13 Cosmetic Modules
 - Quality Management System
 - Premises
 - Personnel
 - Production
 - Quality Control
 - Equipment
 - Sanitation and Hygiene
 - Documentation
 - Internal Audit
 - Storage
 - Contract Manufacturing
 - Complaints and Product Recalls

Materials

Raw Materials

- Availability of stocks/ delivery leadtime
- Minimum packing
- Storage conditions
- Handling requirements

Packaging Materials

product should be packed in non-reactive containers which still project an attractive cosmetic product

- no incompatibilities with the contents and containers
- HDPE, PETG (PETE) and PP
- Labels should comply with ACD labelling requirements
 - product name and function
 - directions for use
 - full ingredient list
 - distributor's details
 - net weight of products

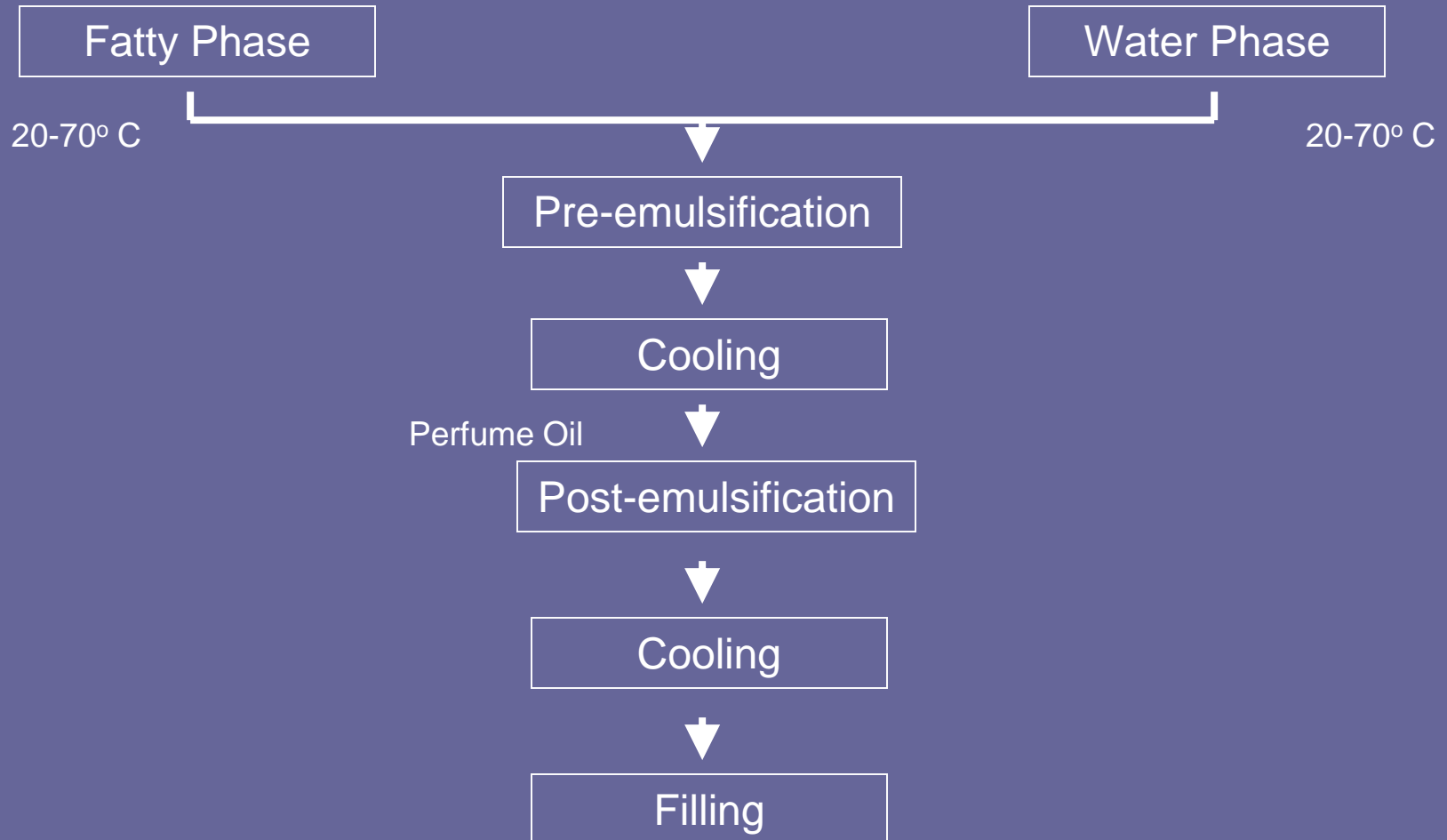
Methods

- Mixing
- Homogenization
- Dispersion
- Emulsification
- Suspension
- Size-reduction

Methods

- Influence product quality
- Well-defined and known conditions of preparation methods during early development phase
 - transition to scaling-up
 - reproducibility

Emulsification



Machine

- **designed to suit the product to be compounded**
- **Consider**
 - **ease of use**
 - **Efficiency**
 - **Cleaning**
 - **non-reactive contact materials (stainless steel)**

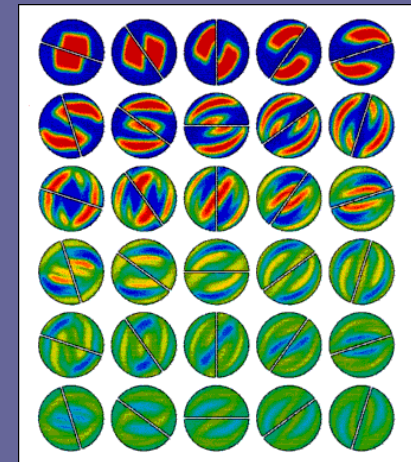
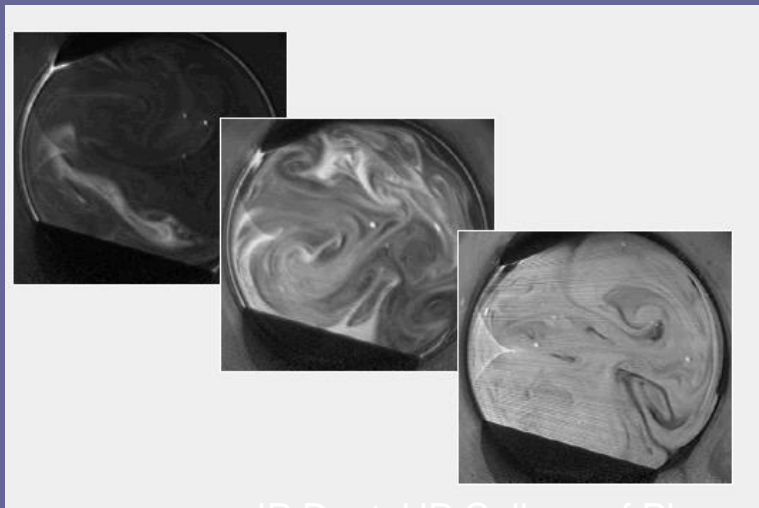
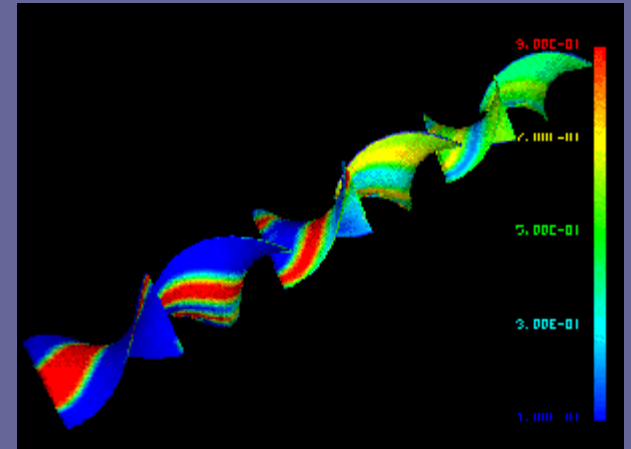
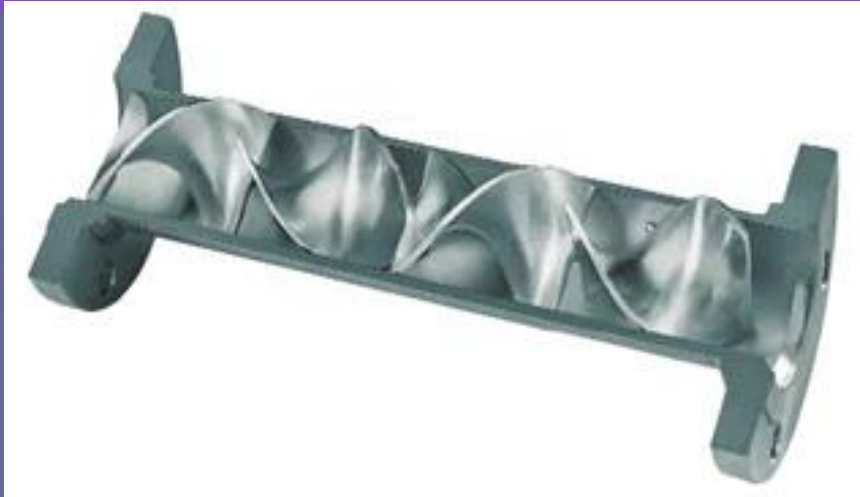
Mixing and Homogenization Systems

- Considerations
 - Type
 - Size
 - Mixing speed
 - Mixing time

Type of Mixers

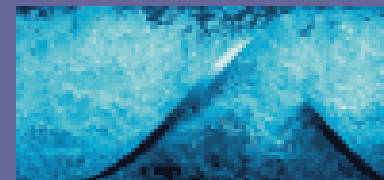
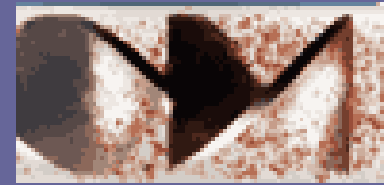
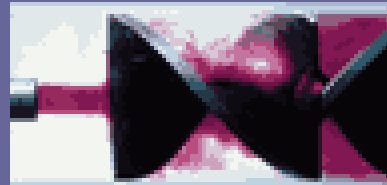
- Static and Dynamic Mixers
 - For combining soluble /insoluble components
 - Agitators for dynamic mixing (rotor & stator)
 - Pipeline mixing: pipe length is at least 100x the diameter
 - Static mixers: for low-viscosity mixing
 - Kenics mixer
 - Sulzer mixer

Kenics Mixer



Kenics Mixer: Applications

- **Turbulent Blending**
 - rapid mixing by inducing circular patterns that reverse direction at each element intersection
- **Laminar Blending**
 - alternating helical elements continually divide, stretch and reorient the flow stream to produce complete mixing with minimum pressure drop
- **Liquid/Liquid Dispersion**
 - uniform turbulent shear field quickly disperses immiscible liquids and produces a narrow drop size distribution
- **Gas Liquid Dispersion**
 - gases can be incorporated into turbulent liquids with enhanced mass transfer rates to maximize absorption or reaction.
- **Extrusion**
 - Thermogenizers to blend thermal gradients as well as supplemental color and additive blending



Sulzer Mixer



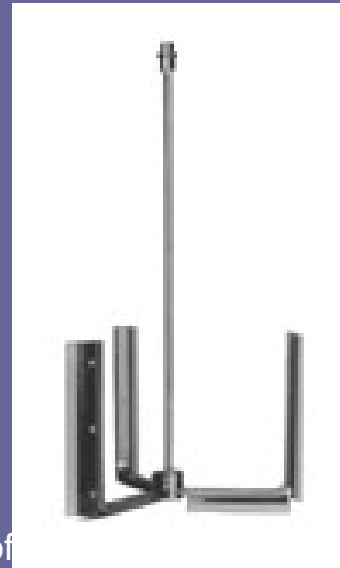
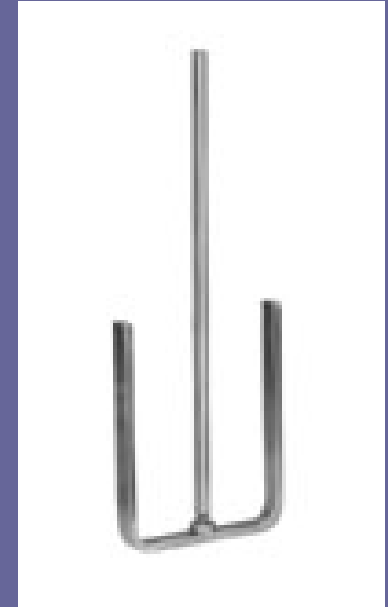
Turbine Type Impellers

- excellent mixing action over the range of stirring speeds
- 4- blade and 6-blade styles
 - 4-blade impellers for reactors nlt 300 mL; positioned anywhere on the stirring shaft, one impeller near the bottom of the vessel to keep solids in suspension and a second impeller near the base of the vortex to pull reactant gases down into the liquid phase
 - for systems with effective viscosities up to 25,000 centipoise with a 16 in-lb magnetic drive or up to 50,000 cP with 60 in-lb magnetic drive



Anchor Stirrers

- for moderate to high viscosity materials
- usually works best in vessels with an inside depth to diameter ratio of 1.5 to 1 or less
- intended to operate at relatively slow speeds and generally require a heavy duty drive system capable of generating and delivering sufficient torque to the agitator
 - Footless magnetic drives
- basic types:
 1. A U-shaped, flat bar anchor.
 2. A flat blade, paddle type anchor.
 3. A two-arm or three-arm, self centering anchor with PTFE wiper blades



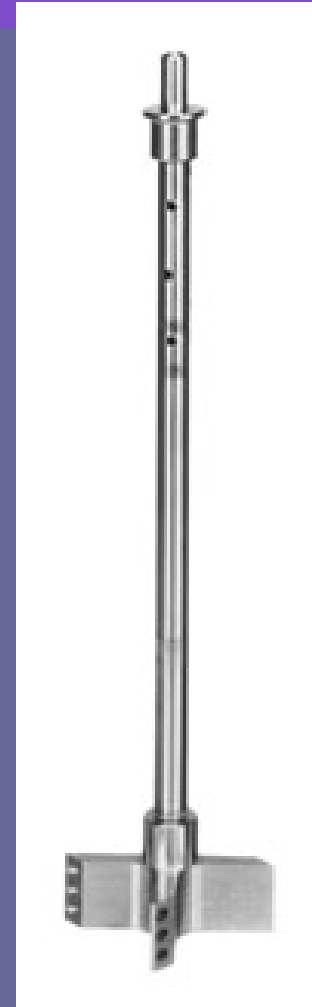
Spiral Stirrers

- produce a positive down thrust or upward thrust action when working with viscous polymers or other high viscosity mixtures
- work best in floor stand reactors with adjustable speed, heavy duty drive systems
 - left-hand (down thrust) or right hand (upward thrust) spirals
 - down thrust spiral is generally preferred for heavy suspensions



Gas Entrainment Impellers

- maximum gas dispersion into a liquid system
- impeller attached to a hollow stirring shaft through which gases are continuously recirculated from the head space above the liquid thru the impeller into the liquid phase
 - speed of the stirrer creates a vacuum at the tip of the impeller
 - Gas enters openings near the top of the shaft and is pulled through dispersion ports located at the tips of the impellers
 - the higher the stirring speed – the higher the vacuum – and the higher the driving force



Paddle Type



Propeller Stirrer



Baffles

- impede the rotation of the liquid with the impeller to enhance the operation of these gas entrainment impellers
- natural baffling is provided by the internal thermowell, dip tube and cooling coils
- removable baffles

High-Pressure Homogenization

- Preparation is forced through a narrow aperture under pressure of 10^7 - 10^8 Pa and then collides against an impact ring
- High stability
- Smooth appearance
- Particle size:
 - Liquid/liquid dispersion: nanometer
 - Solid/fluid dispersion: micrometer
- Batch or continuous

High Pressure Homogenizer



Production Techniques

Continuous Facilities

- Little product change
 - Large production
- Formulations have slight variations
- Emulsification/dispersion combined with continuous heat-exchangers (coolers)
- Production run with continuous filling and packaging
- Computer-driven production
- Uniform quality with minimal fluctuations

Discontinuous Facilities

- Frequent product changes
 - Many preparations produced in small amounts
- Formulations with many components
- Components measured gravimetrically
- Heating or cooling requirements
- Equipment run manually or semi-automatically
- Supplementary or additional processing required after lab analysis

Manpower

- The Pharmacist is responsible for the company's compliance w/ FDA regulations
- Key personnel should be oriented w/ ACD Cosmetic GMP Modules and qualified on their assigned tasks thru related trainings

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