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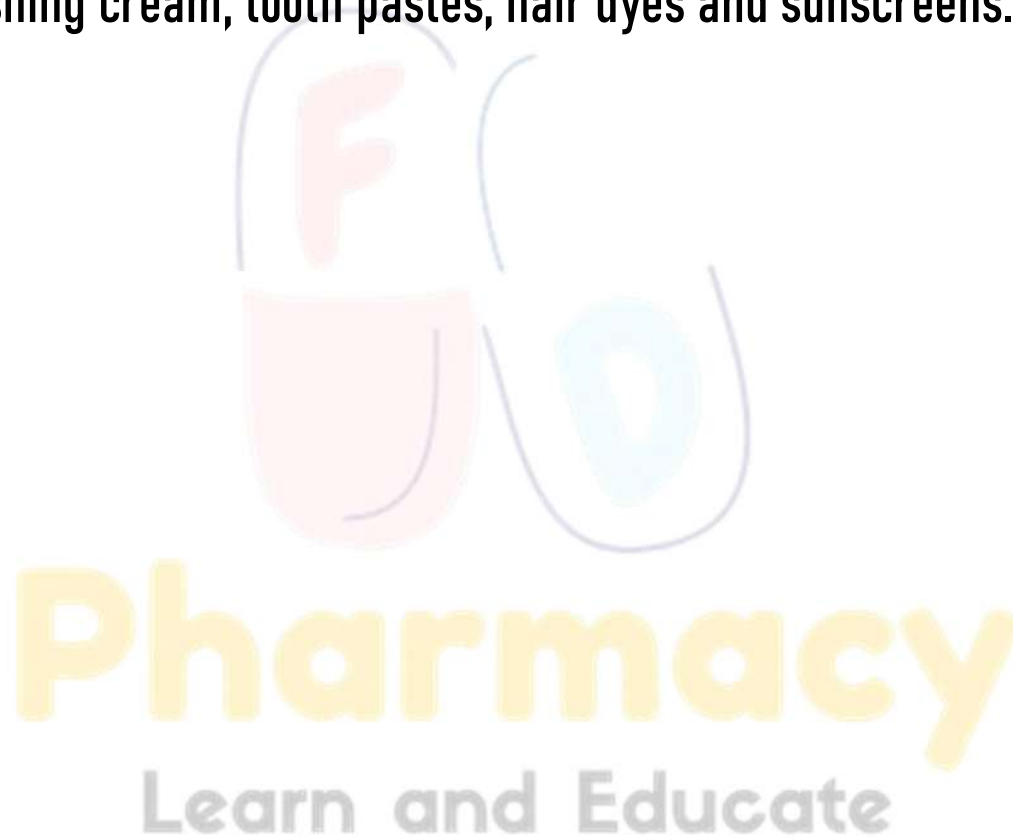
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INDUSTRIAL PHARMACY - I

UNIT 5

TOPIC :

- **Cosmetics** : Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens.



Cosmetics

- Cosmetics are topical preparations applied to skin, hair, lips, nails, or teeth to cleanse, beautify, protect, or alter appearance without affecting the body's physiological functions.
- They are distinct from pharmaceuticals because their primary purpose is cosmetic, not therapeutic, although some may contain active ingredients for protection (e.g., sunscreen, fluoride in toothpaste).



Scope and Importance

1. Aesthetic Improvement
 - Enhance appearance, color, and texture of skin, lips, and hair.
 - Examples: Lipsticks, face creams, hair dyes.
2. Protection
 - Protect skin and hair from environmental damage, UV radiation, dryness, and pollution.
 - Examples: Sunscreens, cold creams.
3. Hygiene and Cleansing
 - Maintain cleanliness of skin, hair, and oral cavity.
 - Examples: Shampoos, toothpastes, soaps.
4. Moisturization and Conditioning
 - Maintain skin elasticity and hair softness.
 - Examples: Vanishing creams, hair conditioners.
5. Psychological Benefits
 - Enhance self-confidence and personal appearance.

Characteristics of Cosmetics

- Non-toxic and non-irritant to skin, eyes, or mucous membranes.
- Chemically and physically stable during shelf-life.
- Pleasant color, odor, and texture for consumer acceptability.
- Easy to apply and remove.

Classification of Cosmetics

Category	Examples / Form	Primary Function
Lip Products	Lipsticks, Lip balms	Color, moisture, protection
Hair Preparations	Shampoos, Hair dyes, Hair oils	Cleansing, coloring, conditioning
Skin Preparations	Cold cream, Vanishing cream, Lotions	Moisturization, protection
Oral Care	Toothpaste, Mouthwash	Cleaning, whitening, breath freshness
Sun Protection	Sunscreens	UV protection
Other	Powders, Deodorants	Absorption of sweat, fragrance

Objectives of Cosmetic Formulation

1. Safety: Non-toxic, hypoallergenic, non-irritant.
2. Stability: Resistant to oxidation, rancidity, or microbial contamination.
3. Efficacy: Performs intended function (cleansing, coloring, moisturizing, or UV protection).
4. Aesthetics: Pleasant color, odor, texture, and ease of application.
5. Compliance: Easy to use, convenient, and packaged appropriately.

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Lipsticks

- Lipsticks are cosmetic preparations applied to the lips to impart color, protection, and sometimes fragrance or medicinal effects.
- They consist of pigments, waxes, oils, and other additives to achieve a smooth texture, proper melting point, and adherence to lips.
- Lipsticks may be plain (cosmetic) or medicated (e.g., with sunscreens, vitamins, or antifungal agents).



Objectives of Lipstick Formulation

1. Impart desirable color to the lips.
2. Provide smooth, glossy, and uniform application.
3. Maintain stability under storage conditions (melting, color fading).
4. Provide adhesion and spreadability on lips.
5. Include protective agents (emollients, sunscreens) if required.

Composition of Lipstick

Component	Function	Typical Range
Waxes (hard waxes)	Provide hardness, shape, melting point	20–30%
Oils (emollients)	Smooth application, moisturizing	20–40%
Pigments / Dyes	Provide color	5–20%
Butters (optional)	Improve spreadability and texture	2–5%
Antioxidants / preservatives	Prevent oxidation of oils	0.1–0.5%
Fragrance / flavoring	Improve sensory appeal	0.1–0.5%

Functions of Components

1. Waxes

- Provide rigidity and help maintain shape.
- Examples: Beeswax, Carnauba wax, Candelilla wax, Paraffin wax.
- Determines melting point of lipstick (typically 50–60°C).

2. Oils / Emollients

- Facilitate easy spread on lips.
- Examples: Castor oil, Mineral oil, Lanolin, Cocoa butter.
- High oil content → glossy, soft lipstick.
- Low oil content → firm, long-lasting lipstick.

3. Pigments

- Provide color and opacity.
- Examples: Red lakes (CI 15850), Iron oxides (CI 77491, 77492, 77499), Titanium dioxide (opacifier/whitener).

4. Antioxidants

- Prevent rancidity of oils.
- Examples: BHT (Butylated hydroxytoluene), Tocopherol (Vitamin E).

5. Fragrance / Flavor

- Mask unpleasant odor of waxes or oils.
- Example: Vanilla, peppermint oil, essential oils.

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Method of Preparation (Fusion Method)

Step 1: Melting of Waxes and Butters

- Weigh all waxes and butters.
- Melt in a water bath or fusion kettle at 70–80°C until uniform.

Step 2: Addition of Oils

- Slowly add oils/emollients to the melted wax.
- Mix thoroughly to ensure uniform dispersion.

Step 3: Incorporation of Pigments

- Pigments are pre-ground into a fine dispersion using oils (called pigment dispersion).
- Add pigment paste gradually to wax-oil mixture while stirring.

Step 4: Addition of Antioxidants and Fragrances

- Mix antioxidants and fragrance when the mixture is slightly cooled (~50°C).
- Ensures prevention of evaporation and degradation of sensitive components.

Step 5: Pouring into Molds

- Pour the uniform mixture into lipstick molds while still molten.
- Allow to cool slowly to solidify.
- Demold lipsticks and polish the surface if required.

Step 6: Packaging

- Fill lipsticks into tubular or twist-up containers.
- Label with shade, ingredients, manufacturer, and expiry date.

Quality Control / Evaluation Tests

Test	Purpose
Appearance / color uniformity	Ensure smooth, bright, and uniform color
Melting point	Determines storage stability and safety
Hardness	Ensure lipstick does not break or crumble
Spreadability	Evaluates smooth application
Adhesion / longevity test	Duration of color retention on lips
Odor / fragrance test	Sensory evaluation
Microbial load	Should comply with cosmetic microbial limits

Factors Affecting Lipstick Formulation

1. Wax type and proportion → Controls hardness and melting point.
2. Oil content → Affects shine, spreadability, and moisturizing effect.
3. Pigment type → Influences color intensity, opacity, and stability.
4. Additives → Antioxidants prevent rancidity; fragrance enhances appeal.
5. Processing conditions → Uniform mixing, correct temperature, and slow cooling prevent air entrapment and surface defects.

Shampoos

- Shampoos are cosmetic formulations for cleansing the hair and scalp.
- They are aqueous solutions or gels containing detergents (surfactants), conditioning agents, thickeners, and additives.
- Shampoos aim to remove dirt, sebum, dead skin cells, and styling products while maintaining hair shine, smoothness, and scalp health.
- They may also have medicated properties for dandruff, lice, or hair loss.



Objectives of Shampoo Formulation

1. Clean hair and scalp effectively.
2. Maintain hair natural moisture and luster.
3. Be non-irritating to scalp and eyes.
4. Ensure pleasant appearance, fragrance, and foam stability.
5. Be stable during storage and easy to rinse.

Composition of Shampoo

Component	Function	Typical Examples / Range
Surfactants / Detergents	Cleansing and foam formation	Sodium lauryl sulfate (SLS), Sodium laureth sulfate, Cocamidopropyl betaine (10–15%)
Co-surfactants / Mild surfactants	Reduce irritation	Lauryl glucoside, Decyl glucoside
Conditioners / Cationic agents	Softness, detangling, manageability	Polyquaternium, Cetrimonium chloride (0.2–0.5%)
Thickeners / Viscosity enhancers	Desired consistency and pourability	Hydroxyethyl cellulose, Xanthan gum, Carbomer (0.2–1%)
pH adjusters / Buffers	Maintain scalp/hair pH (5.5–6.5)	Citric acid, Sodium citrate
Preservatives	Prevent microbial growth	Methylparaben, Propylparaben, Phenoxyethanol
Fragrances / Colorants	Improve aesthetic appeal	Perfume oils, approved dyes
Active ingredients (optional)	Medicated or cosmetic effect	Ketoconazole (anti-dandruff), Minoxidil (hair growth), Herbal extracts

Functions of Key Components

1. Surfactants / Detergents
 - Remove oil, dirt, and sebum from hair and scalp.
 - Anionic surfactants (SLS) → strong cleansing but can irritate.
 - Amphoteric / non-ionic surfactants → milder, less irritating.
2. Conditioning Agents
 - Reduce static electricity, improve combability, and make hair soft and shiny.
3. Thickeners
 - Provide desirable viscosity, prevent product from being too runny.
 - Ensure uniform distribution during application.
4. pH Adjusters
 - Hair surface is slightly acidic (~5.5).
 - Maintaining acidic pH → prevents cuticle damage and frizz.
5. Preservatives
 - Prevent microbial growth in aqueous formulations.
 - Important for multi-use bottles.

Method of Preparation (General Procedure)

Step 1: Preparation of Aqueous Phase

- Dissolve water-soluble ingredients (water, thickeners, pH adjusters, preservatives) in water.
- Hydrate polymers or gums to form uniform solution.

Step 2: Incorporation of Surfactants

- Slowly add primary surfactants (SLS, SLES) to the aqueous phase with stirring.
- Maintain temperature 25–40°C to avoid foam loss.

Step 3: Addition of Conditioning Agents and Additives

- Add cationic conditioners, herbal extracts, colors, and fragrances.
- Mix gently to prevent foam formation during processing.

Step 4: pH Adjustment

- Measure pH (5–6.5) and adjust using citric acid or sodium citrate.

Step 5: Filtration and Homogenization

- Filter if necessary to remove particulate matter.
- Homogenize to obtain uniform viscosity and appearance.

Step 6: Filling and Packaging

- Fill into sterilized bottles under clean conditions.
- Seal and label with product name, usage instructions, storage conditions, and expiry date.

Quality Control / Evaluation Tests

Test	Purpose
Appearance / color / clarity	Visual inspection for uniformity
pH	Ensure scalp compatibility (5–6.5)
Viscosity	Uniform pourability and consumer acceptability
Foam height / stability	Evaluate cleansing efficiency and aesthetic appeal
Spreadability	Ease of application on hair
Surface tension	Determines cleaning ability
Microbial load	Ensure preservative efficacy
Stability	Storage test for color, fragrance, and phase separation

Factors Affecting Shampoo Formulation

1. Type of surfactant → Cleansing efficiency, foam quality, irritation potential.
2. pH → Hair and scalp compatibility.
3. Viscosity → Consumer acceptability and uniform application.
4. Conditioning agents → Hair softness and shine.
5. Additives / actives → Medicated vs cosmetic shampoo.

Packaging and Labeling

- Containers: Plastic or glass bottles with caps.
- Labeling: Product name, ingredients, directions, batch no., manufacturing date, expiry date.
- Storage: Cool, dry place, away from sunlight.

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Cold Cream

- Cold cream is a w/o (water-in-oil) emulsion used as a moisturizer, cleansing cream, and protective agent for the skin.
- It cools the skin, prevents dryness, and provides a protective barrier against external irritants.
- Originally, it was made with beeswax and water, but modern cold creams include emollients, stabilizers, and preservatives.

Objectives of Cold Cream Formulation

1. Provide moisturization and prevent dryness.
2. Be easily spreadable and non-irritating to the skin.
3. Maintain emulsion stability (avoid phase separation)
4. Be pleasant in appearance, odor, and texture.
5. Suitable for daily cosmetic use or as a medicated base



Composition of Cold Cream

Component	Function	Typical Examples / Range
Oils / Emollients	Moisturization, smoothness	Mineral oil, Liquid paraffin (20–30%)
Waxes / Emulsifiers	Emulsion stability, hardness	White soft paraffin, Beeswax (5–10%)
Water / Aqueous phase	Hydration, solubilizes additives	Purified water (60–70%)
Thickening agents	Viscosity, texture	Cetyl alcohol, Stearyl alcohol
Preservatives / Antioxidants	Prevent microbial growth / oxidation	Methylparaben, Propylparaben, BHT
Fragrances / Colorants	Cosmetic appeal	Perfume oils, approved dyes
Optional medicated agents	Therapeutic action	Hydrocortisone, Antibacterials

Functions of Key Components

1. Emollients (Oils)
 - Soften and protect the skin.
 - Provide a glossy, smooth feel.
2. Waxes / Emulsifiers
 - Stabilize water-in-oil (w/o) emulsion.
 - Examples: Beeswax, Spermaceti, Cetyl alcohol.
 - Prevent phase separation.
3. Water / Aqueous Phase
 - Provides hydration to the skin.
 - Dissolves water-soluble additives (e.g., preservatives, humectants).
4. Thickeners
 - Increase consistency and spreadability.
 - Prevent the cream from being too runny.
5. Preservatives / Antioxidants
 - Prevent microbial contamination and oxidative rancidity of oils.

Method of Preparation (Fusion / Emulsion Method)

Step 1: Oil Phase

- Melt waxes and oils together in a water bath (70–75°C).
- Include thickening agents if oil-soluble.

Step 2: Aqueous Phase

- Heat purified water to same temperature as oil phase.
- Dissolve water-soluble additives (preservatives, humectants) in water.

Step 3: Emulsification

- Slowly add aqueous phase to oil phase with continuous stirring.
- Stir until a homogeneous emulsion forms.
- Cool gradually to room temperature with continuous stirring.

Step 4: Addition of Fragrance and Color

- Add perfume oils and dyes at lower temperature (~40°C).
- Mix gently to avoid foam formation.

Step 5: Packaging

- Fill into sterile jars or tubes once cooled.
- Label with product name, batch number, manufacturing date, and expiry date.

Quality Control / Evaluation Tests

Test	Purpose
Appearance / color / odor	Uniform, pleasant cosmetic appeal
Spreadability / Consistency	Ease of application on skin
Emulsion stability	No phase separation during storage
pH	Slightly acidic (5-7), skin compatible
Viscosity	Determines handling and feel
Microbial load	Should comply with cosmetic limits
Moisturizing effect	Sensory evaluation / skin hydration tests

Factors Affecting Formulation

1. Type and proportion of waxes → Controls hardness and emulsion stability.
2. Oil content → Affects moisturizing ability and skin feel.
3. Water-to-oil ratio → Determines emulsion type and consistency.
4. Emulsifier type → Ensures stability (w/o preferred for cold cream).
5. Processing conditions → Temperature and stirring affect smoothness and emulsion uniformity.

Packaging and Storage

- Containers: Sterile jars, tubes, or pump dispensers.
- Labeling: Product name, ingredients, usage instructions, batch number, manufacturing date, expiry date.
- Storage: Cool, dry place; avoid direct sunlight.
- Shelf life: Usually 2-3 years depending on preservatives.

Vanishing Cream

- Vanishing cream is a o/w (oil-in-water) emulsion used as a moisturizer, protective base, or cosmetic cream.
- It is called “vanishing cream” because it disappears on the skin after application, leaving a thin, invisible, non-greasy film.
- Used as a daily cosmetic, sunscreen base, or medicated cream vehicle.

Objectives of Vanishing Cream Formulation

1. Provide moisturization without greasiness.
2. Be easily spreadable and quickly absorbed.
3. Provide stable emulsion during storage.
4. Compatible with skin pH (~5.5–6.5).
5. Suitable as a base for medicated formulations.



Composition of Vanishing Cream

Component	Function	Typical Examples / Range
Oils / Emollients	Softens skin, provides moisturizing	Light mineral oil, paraffin oil (5–10%)
Emulsifiers / Soap	Stabilizes o/w emulsion	Stearic acid + Triethanolamine, Glyceryl stearate (5–15%)
Water / Aqueous phase	Solvent, hydration	Purified water (70–85%)
Preservatives / Antioxidants	Prevent microbial growth / rancidity	Methylparaben, Propylparaben, BHT
Thickening agents	Texture, spreadability	Cetyl alcohol, Stearyl alcohol
Fragrance / Colorants	Cosmetic appeal	Perfume oils, approved dyes
Optional medicated agents	Therapeutic effect	Sunscreens, antifungals, corticosteroids

Functions of Key Components

1. Oils / Emollients
 - Provide moisturization without leaving greasy residue.
 - Lower concentration than cold cream to allow “vanishing” effect.
2. Emulsifiers
 - Stabilize oil-in-water (o/w) emulsion.
 - Commonly stearic acid + triethanolamine, which forms soap-in-water emulsions.
3. Aqueous Phase
 - Hydrates skin and dissolves water-soluble additives.
4. Preservatives
 - Prevent microbial contamination in multi-use containers.
5. Thickeners
 - Improve consistency, handling, and prevent phase separation.

Method of Preparation (Fusion / Emulsion Method)

Step 1: Oil Phase

- Melt stearic acid, oils, and waxes in a water bath ($\sim 70-75^{\circ}\text{C}$).
- Include fat-soluble additives (antioxidants, fragrance base).

Step 2: Aqueous Phase

- Heat water to same temperature ($\sim 70-75^{\circ}\text{C}$).
- Dissolve water-soluble components (preservatives, humectants).

Step 3: Emulsification

- Slowly add aqueous phase to oil phase with continuous stirring to form o/w emulsion.
- Stir until mixture cools to room temperature.

Step 4: Addition of Fragrance / Color

- Add perfume and approved color once the emulsion is cooled ($\sim 40^{\circ}\text{C}$) to prevent evaporation or degradation.

Step 5: Packaging

- Fill into tubes or jars, seal, and label with product name, batch number, manufacturing date, and expiry date.

Quality Control / Evaluation Tests

Test	Purpose
Appearance / color / odor	Ensure uniform, pleasant cream
Spreadability	Ease of application on skin
Emulsion type	Confirm oil-in-water emulsion (drop in water test)
pH	Skin compatibility (5.5–6.5)
Viscosity	Determines handling and consistency
Microbial load	Should comply with cosmetic limits
Stability	Prevent phase separation, color change, or rancidity

Factors Affecting Formulation

1. Oil-to-water ratio → Determines greasiness and absorption.
2. Type and concentration of emulsifiers → Stability and ease of vanishing.
3. Temperature during emulsification → Affects homogeneity.
4. Additives → Perfumes, antioxidants, and medicated agents influence stability and appeal.

Packaging and Storage

- Containers: Tubes, jars, or pump dispensers.
- Labeling: Product name, ingredients, directions for use, batch number, expiry date.
- Storage: Cool, dry place; avoid direct sunlight.

Toothpaste

- Toothpaste is a therapeutic or cosmetic preparation applied to teeth with a toothbrush to clean teeth, remove dental plaque, prevent dental caries, and maintain oral hygiene.
- Toothpaste may also have medicinal additives like fluoride, desensitizing agents, or antimicrobial agents.
- It is typically a paste or gel with a smooth texture for easy application.

Objectives of Toothpaste Formulation

1. Remove food debris, plaque, and stains from tee th.
2. Deliver therapeutic agents (e.g., fluoride, antimicrobials).
3. Ensure pleasant taste and aroma for patient acceptability.
4. Provide adequate abrasiveness for cleaning without damaging enamel.
5. Maintain stability and microbial safety during storage.



Composition of Toothpaste

Component	Function	Typical Examples / Range
Abrasives / polishing agents	Remove plaque and stains	Calcium carbonate, Silica, Alumina (20–50%)
Fluoride or therapeutic agents	Prevent dental caries / tooth sensitivity	Sodium fluoride, Stannous fluoride, Potassium nitrate
Humectants / Moisturizers	Prevent drying, maintain paste consistency	Glycerin, Sorbitol, Propylene glycol (20–50%)
Binders / Thickeners	Provide consistency and prevent separation	Carboxymethyl cellulose (CMC), Xanthan gum, Hydroxyethyl cellulose (1–3%)
Surfactants / Detergents	Foaming and cleaning action	Sodium lauryl sulfate (SLS) (1–2%)
Flavors / Sweeteners	Improve taste and palatability	Peppermint oil, Saccharin, Sorbitol
Preservatives / Antioxidants	Prevent microbial growth / rancidity	Methylparaben, Propylparaben, Tocopherol
Colorants (optional)	Cosmetic appeal	Approved dyes (CI numbers)
Water	Solvent / vehicle	20–40%

Functions of Key Components

1. Abrasives / Polishing Agents
 - Remove dental plaque and stains mechanically.
 - Must be non-abrasive to enamel ($RDA < 250$).
2. Humectants
 - Retain moisture, prevent hardening of paste.
 - Provide smooth texture and aid drug dissolution.
3. Binders / Thickeners
 - Maintain uniform paste consistency.
 - Prevent separation of solids and liquids during storage.
4. Surfactants
 - Facilitate foam formation, which helps in spreading paste and cleaning action.
 - Examples: Sodium lauryl sulfate, Cocamidopropyl betaine.
5. Flavors and Sweeteners
 - Improve taste and patient compliance.
 - Mask unpleasant flavors of medicinal ingredients.
6. Fluoride / Therapeutic Agents
 - Strengthen enamel, reduce dental caries.
 - Other additives may reduce tooth sensitivity or gum inflammation.

Method of Preparation (General Procedure)

Step 1: Preparation of Aqueous Phase

- Dissolve water-soluble components such as binders (CMC, gums), humectants, preservatives, and fluoride salts in water or sorbitol/glycerin mixture.

Step 2: Preparation of Abrasive Paste

- Mix abrasives with oils or humectants to form a smooth paste.

Step 3: Incorporation

- Slowly add the aqueous phase to the abrasive phase under continuous stirring to obtain uniform paste.

Step 4: Addition of Surfactants, Flavors, and Colorants

- Add surfactants and mix gently to avoid excessive foam.

- Add flavors, sweeteners, and colorants at lower temperature ($\sim 40^{\circ}\text{C}$).

Step 5: Homogenization

- Homogenize the paste to achieve uniform consistency, smooth texture, and particle distribution.

Step 6: Packaging

- Fill into laminated toothpaste tubes or plastic tubes under hygienic conditions.
- Seal and label with name, composition, batch number, manufacturing date, expiry date, and usage instructions.

Quality Control / Evaluation Tests

Test	Purpose
Appearance / color / odor	Ensure uniform, pleasant cosmetic appeal
Consistency / Viscosity	Smooth application, prevents separation
pH	Oral compatibility (usually 6–8)
Abrasive activity / RDA	Ensure safe cleaning without enamel damage
Foaming ability	Facilitates cleaning and spreading
Fluoride content / Drug assay	Ensure therapeutic efficacy
Microbial load	Ensure safety for oral use
Stability	Prevent separation, color change, or rancidity

Factors Affecting Toothpaste Formulation

1. Abrasive type and concentration → Cleaning efficiency and enamel safety.
2. Surfactant selection → Foam formation and cleaning efficacy.
3. Humectant type → Moisture retention and texture.
4. Binder type → Prevent phase separation and maintain viscosity.
5. Flavor and sweeteners → Consumer acceptability and masking unpleasant taste.

Packaging and Storage

- Containers: Laminated tubes, plastic tubes, or dispensers.
- Labeling: Product name, ingredients, fluoride content, usage instructions, batch number, expiry date.
- Storage: Cool, dry place; avoid direct sunlight.
- Shelf life: Usually 2–3 years depending on preservatives and packaging

Hair Dyes

- Hair dyes are cosmetic preparations used to color natural hair either for beauty, fashion, or covering gray hair.
- They can be temporary, semi-permanent, or permanent depending on duration of color retention and mechanism.
- Hair dyes may be oxidative (permanent) or non-oxidative (temporary/semi-permanent).

Classification of Hair Dyes

Type	Duration	Mechanism
Temporary	1–2 washes	Coat hair surface; no chemical reaction; removed on washing
Semi-permanent	4–6 washes	Penetrates hair cuticle; no oxidation; gradually fades
Permanent (Oxidative)	Long-lasting	Oxidation of dye precursors inside hair cortex; requires oxidizing agent (H_2O_2)

Objectives of Hair Dye Formulation

1. Provide desired color and intensity.
2. Ensure uniform penetration and color stability.
3. Minimize hair and scalp damage.

Composition of Hair Dyes

Component	Function	Typical Examples / Range
Coloring agents / Dye precursors	Impart color	p-Phenylenediamine, p-Aminophenol, Resorcinol (permanent dyes)
Oxidizing agents (permanent dyes)	Develop final color	Hydrogen peroxide (3–6%)
Alkaline agents / Activators	Open hair cuticle for dye penetration	Ammonium hydroxide, Ethanolamine
Solvents / Vehicles	Dissolve ingredients and ease application	Water, Propylene glycol
Conditioners / Emollients	Reduce hair damage and improve feel	Cetyl alcohol, Lanolin, Polyquaternium
Fragrances	Mask chemical odor	Perfume oils
Stabilizers / Antioxidants	Prevent premature oxidation	Sodium sulfite, Sodium bisulfite
Preservatives	Prevent microbial growth	Methylparaben, Propylparaben

Method of Preparation (Permanent Hair Dye Example)

Step 1: Preparation of Dye Base

- Dissolve color precursors (e.g., p-Phenylenediamine, resorcinol) in solvent/vehicle.
- Add stabilizers and antioxidants to prevent premature oxidation.

Step 2: Addition of Alkaline Agent

- Add ammonium hydroxide or ethanolamine to maintain slightly alkaline pH (~9–10) for cuticle opening.

Step 3: Incorporation of Conditioning Agents

- Mix in emollients and conditioners to minimize hair damage.

Step 4: Packaging

- Fill dye base in one container and oxidizing agent (H_2O_2) in separate container for two-part kits.
- Label with instructions for mixing before application.

Method of Application (Consumer Use)

1. Mix dye base with oxidizing agent just before use.
2. Apply evenly to hair, covering gray or target areas.
3. Leave for 20–45 minutes depending on desired intensity.
4. Rinse thoroughly with water.

Quality Control / Evaluation Tests

Test	Purpose
Appearance / Color	Uniform color and no separation
pH	Maintain alkaline pH for effective penetration
Viscosity / Spreadability	Easy application on hair
Stability	Prevent premature oxidation of dyes
Oxidation / Color Development	Ensure consistent final hair color
Microbial load	Safe for scalp application
Patch test	Assess potential skin irritation or allergy

Factors Affecting Hair Dye Formulation

1. pH → Alkaline pH opens hair cuticle for dye penetration.
2. Type and concentration of dye precursors → Determines final color intensity.
3. Oxidizing agent → Strength and stability affect color development.
4. Conditioners / Emollients → Protect hair from chemical damage.
5. Processing / Storage → Premature oxidation leads to poor color or product degradation.

Packaging and Storage

- Containers: Tubes or bottles for base; separate bottles for oxidizer in permanent dyes.
- Labeling: Name, shade, ingredients, mixing instructions, batch number, expiry date.
- Storage: Cool, dry place; avoid sunlight and high temperature

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Sunscreens

- Sunscreens are topical preparations that protect the skin from harmful UV radiation (UVA and UVB).
- They prevent sunburn, photoaging, hyperpigmentation, and skin cancer.
- Sunscreens may be chemical (absorbing UV) or physical (reflecting/scattering UV), and are available as creams, lotions, gels, or sprays.

Classification of Sunscreens

Type	Mechanism	Examples
Chemical / Organic	Absorb UV radiation and convert to heat	Octyl methoxycinnamate, Avobenzone, Oxybenzone
Physical / Inorganic	Reflect or scatter UV radiation	Zinc oxide, Titanium dioxide
Broad-spectrum	Protects against UVA and UVB	Combination of chemical and physical filters

Composition of Sunscreens

Component	Function	Typical Examples / Range
UV Filters	Block or absorb UV radiation	Octyl methoxycinnamate, Oxybenzone, Zinc oxide, Titanium dioxide (5–20%)
Oils / Emollients	Enhance spreadability and skin feel	Mineral oil, Caprylic/capric triglyceride
Waxes / Thickeners	Viscosity and stability	Cetyl alcohol, Stearyl alcohol
Aqueous Phase	Vehicle for water-soluble components	Purified water
Preservatives / Antioxidants	Prevent microbial growth / oxidation	Methylparaben, Tocopherol
Emulsifiers	Stabilize oil-in-water (o/w) or water-in-oil (w/o) emulsions	Polysorbates, Glyceryl stearate
Fragrance / Colorants	Cosmetic appeal	Approved dyes and perfumes
Film formers / Humectants	Improve adherence and moisture retention	Glycerin, Polyvinylpyrrolidone (PVP)

Objectives of Sunscreen Formulation

1. Protect skin from UVA (320–400 nm) and UVB (290–320 nm) radiation.
2. Ensure uniform application and coverage.
3. Be stable under sunlight and heat.
4. Provide pleasant cosmetic feel (non-greasy, easy to spread).
5. Maintain compatibility with skin pH and avoid irritation.

Functions of Key Components

1. UV Filters
 - Chemical filters absorb UV radiation; physical filters reflect/scatter UV.
 - Proper combination provides broad-spectrum protection.
2. Oils and Emollients
 - Enhance spreadability and provide smooth, non-greasy feel.
3. Emulsifiers and Thickeners
 - Stabilize emulsion and maintain viscosity and consistency.
4. Preservatives and Antioxidants
 - Ensure microbial safety and prevent oxidation of oils and UV filters.
5. Humectants and Film Formers
 - Maintain skin moisture and improve adherence to prevent wash-off.

Method of Preparation (Cream / Lotion Base)

Step 1: Oil Phase

- Melt waxes, oils, and oil-soluble UV filters in a water bath (~70–75°C).
- Add oil-soluble antioxidants.

Step 2: Aqueous Phase

- Heat water to same temperature.
- Dissolve water-soluble components (humectants, preservatives, thickeners).

Step 3: Emulsification

- Slowly add aqueous phase to oil phase with continuous stirring to form stable emulsion (o/w or w/o depending on formulation).

Step 4: Addition of Fragrance / Color

- Add fragrance, colorants, and heat-sensitive UV filters once the emulsion cools to $<40^{\circ}\text{C}$.

Step 5: Homogenization

- Homogenize to ensure uniform dispersion of UV filters and smooth texture.

Step 6: Packaging

- Fill into tubes, bottles, or pump dispensers under hygienic conditions.
- Label with SPF value, broad-spectrum indication, ingredients, batch number, and expiry date.

Quality Control / Evaluation Tests

Test	Purpose
Appearance / color / odor	Uniform, pleasant cosmetic appeal
pH	Skin compatibility (5.5-7)
Viscosity / Spreadability	Smooth application on skin
SPF testing	Confirm sun protection factor
Emulsion stability	Prevent phase separation on storage
UV filter assay	Confirm correct concentration and efficacy
Microbial load	Safety for topical application
Photostability	Stability under sunlight exposure

Factors Affecting Sunscreen Formulation

1. Type and concentration of UV filters → SPF and broad-spectrum protection.
2. Emulsion type (o/w or w/o) → Spreadability, greasiness, water resistance.
3. pH and preservatives → Skin compatibility and stability.
4. Oils and emollients → Texture, adherence, and cosmetic feel.
5. Storage conditions → Prevent degradation of UV filters and antioxidants.

Packaging and Storage

- Containers: Tubes, bottles, pump dispensers.
- Labeling: SPF, broad-spectrum protection, ingredients, usage instructions, batch number, expiry date.
- Storage: Cool, dry place; avoid direct sunlight.
- Shelf life: Usually 2–3 years depending on preservatives and UV filter stability.

