INDUSTRIAL PHARMACY-I

UNIT V- Cosmetics,Pharmaceutical aerosols,Packaging material science

CLASS:37

Topic: Tooth pastes, hair dyes and sunscreens.

Sunscreen preparations

- These preparations help to protect the skin from the harmful effects of UV rays. In cream, lotion and spray under various brand names. Applied to the face, neck and ears prior to going out in sun
- It is a lotion or spray or gel that absorbs or reflects the sun's ultraviolet radiation and prevents the damaging effect of it.
- They can be used as Sunblock or sunscreens
- UV rays damage the skin cells and DNA in the form of Sagging, Wrinkling and Photo carcinogenesis
- UV light is artificially divided into 3 ranges
- UVA → 320-400 nm → Low energy → prevented by Ozone layer, doesnot reach the earth
- UVB → 290-320 nm → High Energy → Cause more immediate damage (Sun burn, Skin cancer)
- UVC → 100-290 nm → Very High Energy → DNA Damage

Mechanism or Principle of Sunscreens

- By reflecting or absorbing UV rays. Eg: ZnO and TiO2
- Filter the mid range UV rays (UVB). But allow the other range. All suntan preparations based on this principle. Eg: Chromophores, Inorganic particles
- Biologically active substances which prevents inflammation due to rays. Antihistamines substances are used to prevent inflammation
- By tanning the skin, which prevents the sun burn Eg: Dioxyacetone, Methoxypsoralene are taken 2 hrs before exposure to skin which induces tanning and avoids sunburn.

- Ideal properties of sunscreens Absorb or filter out UV rays in the region of 2900 to 3300 angstroms.
- Have good absorption and spreadability
- Be stable nontoxic and nonirritating
- Be free from any side effect.
- Have low water solubility
- Retain the sunscreen property for several hours, Non stain and not be absorbed into the skin.

Organic sunscreen agents

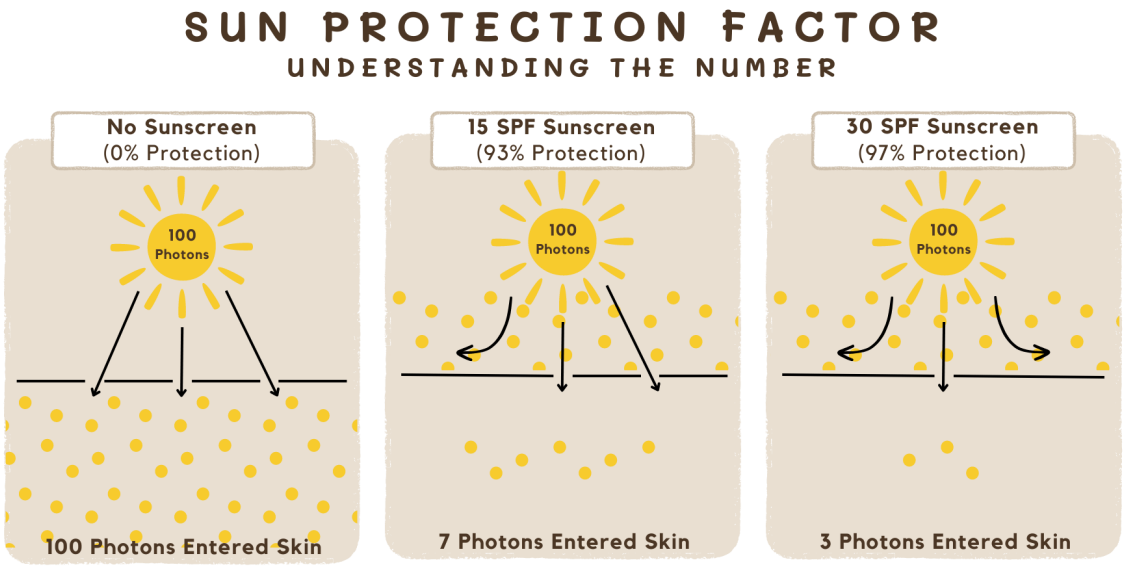
- Reflect UV light absorption and blocks the penetration of UV radiations through the epidermis
- .e.g.Para-amino benzoic acid (PABA), PABA esters, benzophenones, salicylates, cinnamates,butyl-methoxy-dibenzoyl-methane, anisotriazine.

Physical sunscreen agents

- Most common photostable component of routine sun screen products. Protect the skin by reflecting and scattering UV rays.
- E .g.: Titanium dioxide (Ti02) and zinc oxide (ZnO).

Sun Protection Factor

- (SPF) = Minimal erythemaldose of Photoprotected Skin / Minimal erythemaldose of Unprotected Skin
- MED is minimum dose of radiation which produces erythema; Determined indoors using xenon lamps which approximate the spectral quality of UV radiation.
- Ideal sunscreen should have SPF value of 15 atleast.



Types of skin and SPF

Type	Description	SPF	Character
I	Always burns easily & never tans	More than 8	Sensitive
II	Always burns & tans minimally	6 – 7	Sensitive
III	Burns moderately & tans gradually	4 – 5	Normal
IV	Burns minimally & always tans well	2 – 3	Normal
V	Barely burns & tans profusely	2	Insensitive
VI	Never burns & becomes deeply pigmented	None	Insensitive

Factors affecting effectiveness of SPFs

- Difference in skin types.
- Thickness of the applied sunscreen.
- Time of day.

- Altitude: each 1,000 ft increase adds 4% to the intensity of erythema producing UV radiation.
- Environment: snow/white surfaces reflect 70-90%, and when directly overhead water reflects nearly 100% of UVR.

Vehicle: determines skin penetration of sunscreen.

- Suitable base may be Aqueous, Alcoholic, Fats, Natural oils coconut oil, peanut oil, olive oil have absorption ability of UV light.
- Antioxidants also used in the preparation
- Preparation or Manufacturing of Sunscreen: The product can be
- Aqueous or Oil type: Mixing and Dissolving the sunscreen and other ingredients in vehicle (Water and Oil). Perfume added atlast
- Cream type: These are emulsion type.
- Lotions type: These are solution type or emulsion type
- Gel type: Solution based Viscous preparation. Preparation:
- Cetyl alcohol + Benzophenone + Ethyl hexyl methoxy cinnamate + Stearic acid + Glycerin + Stearyl Dimethicone Silicate → Melt in beaker
- Water + Triethanolamine → Taken in beaker → Heat to 80-85C
- Melted content is addded to the hot water solution slowly and stirred well
- Mixture is cooled to get uniform smooth cream.

FORMULA for sunscreen

- Cetyl alcohol - 2%
- Benzophenone - 1.5%
- Ethyl hexyl methoxy cinnamate - 1.5%
- Stearic acid - 4%
- Glycerin - 2%
- Triethanolamine - 1% Water - 78%
- Stearyl Dimethicone Silicate - 10%

Evaluation of sunscreen

- Photostability
- Water Resistance
- Other Evaluation parameters
- **Spectrophotometric evaluation**: This will evaluate the UV absorption ability using UV Spectrophotometer
- **Erythmeal damage**: Erythema is estimated when the solar energy transmitted thro film of suntan preparation
- **Sunscreen index** - measurement of absorption coeffecient at 308 nm (Which is the effective UV rays wavelength which cause sun burn)
- **Invivo skin testing** - Sunscreens applied on the rabbit skin and exposed to radiation along with control unprotected skin for a period of time. The effects are observed at the end of period.

Dentifrices (Dental Products)

- Oral health care products which are used for Improving and maintaining oral hygiene.
- Dentifrices carry an inert and bioactive substance that helps in maintaining oral hygiene and provides cosmetic and therapeutic benefits.

Classification of dentifrices

- Regular cleansing dentifrices

Medicated (therapeutic) dentifrices

Regular dentifrices

- Used for cleaning and polishing the surfaces of teeth from for maintaining good oral hygiene.
- Help inhibit the formation of unpleasant odors and freshen the breath.
- Medicated dentifrices these are cleansing preparations for preventing tooth decay (cavities) and/ or other periodontal disease.
- Additional medicaments such as bactericidal, bacteriostatic, enzyme inhibiting and acid neutralizing agents.

Toothpaste

- Most popular and widely used preparations for cleansing the teeth and possess largest market share amongst all dentifrices. Though they are more expensive than tooth powders. Properties of toothpaste
- Attractive consistency.
- Better coverage of dental set up.
- Easy to take measured quantity on the tooth brush.
- No spillage and wastage.

Advantages

- Delivers active ingredients such as fluoride or xylitol to help prevent tooth and gum disease.
- Recent advances in toothpaste enable high efficacy of oral health delivery.

Special toothpaste for kids with fluoride and relatively low abrasion value Desensitizing toothpaste.

Whitening toothpaste

- Easy to use, available in collapsible tubes.
- Combination of various contents available as to combat different oral healthcare needs at once.

- Fluoridated toothpaste can cause fluorosis if swallowe d consistently .
- Triclosan, an active ingredient in many types of toothpaste can combine with chlorine in tap water to form chloroform which is a human carcinogen.
- According to some scientists it can leave unborn babies brain damaged.
- Although in several studies whitening toothpaste show the ability to improve tooth color they have side effects.
- The most significant one is enamel and dentin abrasion which in turn leads to increased tooth sensitivity.

The ideal Characteristics of Toothpaste

- It should be non-toxic and non-irritant to teeth, gums and buccal mucosa.
- Very fine particle size and should be free from grittiness.
- Must clean the dental surface properly without any scratches.
- It should be easily squeezed out to spread on the brush without sinking into it.
- The consistency should be constant
- It should not dry quickly.
- It should not interact with the container parts.

Formulation of Toothpaste

- The raw materials used for manufacture of toothpaste can be classified as

I Basic ingredient

- Abrasives
- Detergents
- Humectants
- Binding agents
- Sweetening Agents
- Flavors
- Preservatives

Special ingredients

- Coloring agents
- Bleaching agents
- Lubricants
- Therapeutic ingredients

Abrasives/dentrifice

- They also help in removing some stains from the teeth. Usually, the amount of abrasive(s) is about half of total weight of a toothpaste.
- Commonly used abrasives are
  - calcium carbonate,
  - tricalcium phosphate,
  - dicalcium phosphate,
  - aluminium sulphate,
  - magnesium trisilicate etc.
- Transparent toothpastes, commonly called gel toothpastes, are prepared by mixing certain abrasives.

Detergents (1-3 %)

- Cleansing action of the detergents (surfactan ts) is due to their lowering of interfacial tension and production of foam thus helping in wetting and dispersion of powdered materials in the paste.
- Detergent helps in penetration tooth paste into the fine cracks and other places thus assisting in removal of food particles and debris.
- By their emulsification capability they help in removal of mucus.

Synthetic detergents

- are widely used surfactants in toothpastes.
- Sodium lauryl sulfate is one of the most commonly used detergents. SLS is currently the most widely used detergent in toothpaste because it satisfies almost all the requirements

.It is a foaming & solubilizing agent that is derived from coconut and palm oil. IT has mild anti-bacterial activity.

- Others are magnesium lauryl sulfate, sodium lauryl sarcosinate, diethyl sodium lauryl sarcosinate.
- Detergents may lower the abrasive effect of toothpastes.

Humectants (20% to 35%)

- Retain moisture and prevent drying out of the toothpaste and thus impart plasticity to the product.
- They prevent loss of water, and subsequent hardening of the paste, when it is exposed to air. Less amount of humectant is used in substances with lower specific gravity.
- Commonly used humectants in toothpaste are
- Glycerin,
- Sorbitol and
- Propylene glycol.
- Of these, glycerin is most widely used. It also imparts some sweetness.

Binding agents

- Binding agents are used in toothpaste to control viscosity and maintain creamy consistency.
- They also prevent separation of toothpaste. Hydrocolloids are used for this purpose usually in concentration of 1-2%.
- Earlier starch, liquid glucose and simple syrup were used; now they are replace by mucilages of
- karaya gum, tragacanth and gum arabic.

Sweetening Agents (0.05-2%)

- These agents are used to improve the taste of the preparation in the mouth. Saccharine sodium is the most commonly used sweetener. The exact amount is determined by the quantity and sweetness of other ingredients present like glycerin.

Flavors

- Flavoring agents are essentially used in toothpaste for fragrance and good feel after its use .
- Flavors are blending of volatile oils which produce a pleasant and refreshing smell in the mouth after use.
- Peppermint oil, spearmint oil clove oil cassia oil, cinnamon oil, menthol etc

Preservatives

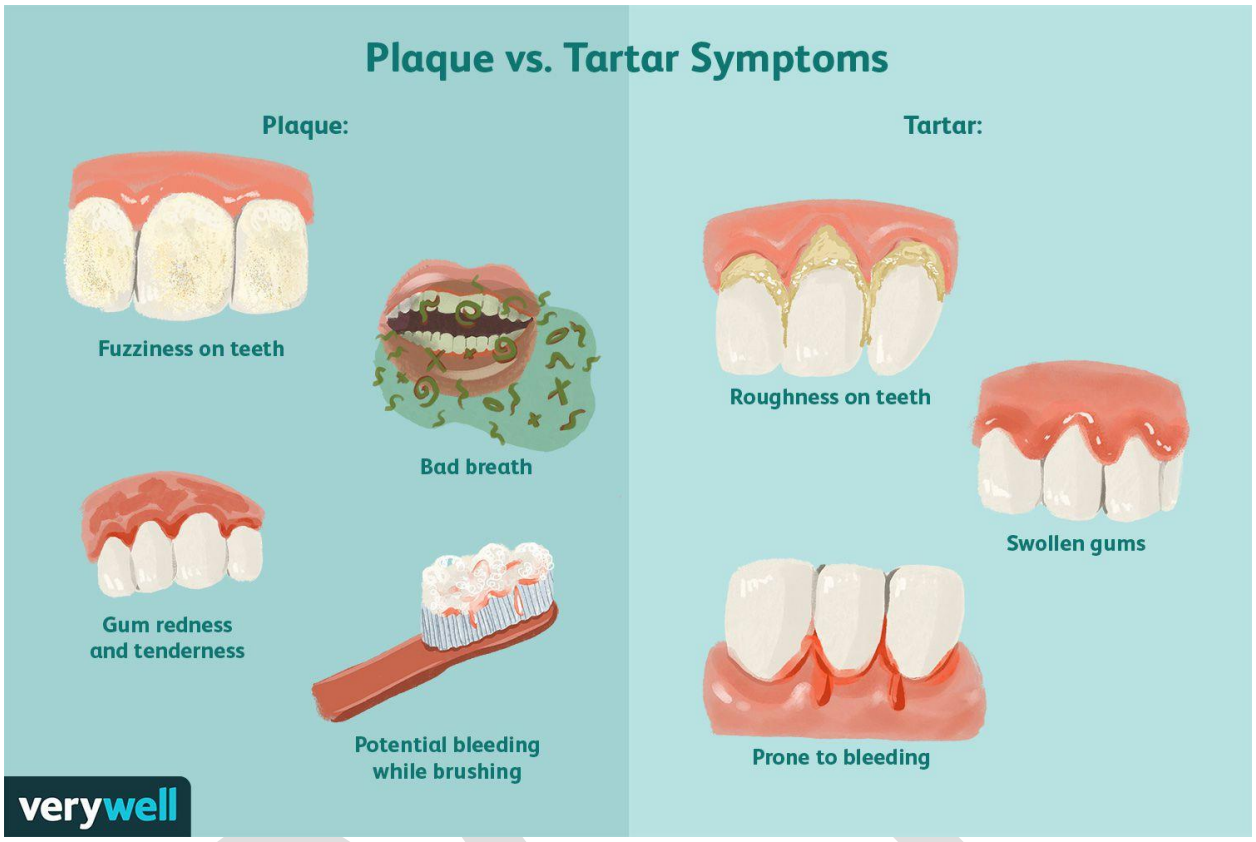
- Preservatives are essentially added in toothpaste to prevent microbial growth due to presence of gum and water.
- Sweetening agents like glycerin and flavors may add to antimicrobial action of the preservatives.
- Commonly used preservatives in toothpaste are
- methyl para hydroxybenzoate (0.15%) and
- propyl para hydroxybenzoate (0.02%).

Specialized ingredients used in toothpaste

- Anti-cavity Agents-Prevents formation of cavity
- Sodium Monofluorophosphate (Na2PO3F)
- Sodium Fluoride (NaF)
- Organo (amine) Fluorides
- Stannous Fluoride (SnF2)

Anti-tartar Toothpastes

- Dental plaque leads to tartar built-up (it is yellow or brown colored deposit when plaque hardens on your teeth.
- Tetra sodium pyrophosphate (TSPP)
- Tetra potassium pyrophosphate (TKPP)
- Disodium dihydrogen pyrophosphate Clinical studies have shown that, starting from a clean mouth, toothpastes containing 3.3%
- pyrophosphate ion can inhibit the growth of tartar by approximately 30 % after three months of regular use.



Example of a tooth paste preparation

- Ingredients %w/w
- Calcium carbonate 56.0
- Sodium lauryl sulfate 1.0
- Gum Tragacanth 1.5
- Glycerin 22.0
- Saccharine sodium 0.1
- Water 19.4
- Flavor q.s.

Preservative q.s

Procedures for preparation of toothpastes

- Toothpastes can be made in stainless steel mixer or planetary mixer or any other mixer used for used for making semisolid preparations.
- Mix the gum with a suitable quantity of humectant without any water.
- Other colloids like methyl cellulose may be dispersed with cold water. Ethyl cellulose should be mixed in warm water.
- Pass the other powder ingredients through a suitable sieve and add gradually to the above binder mixture with continuous stirring.
- Then add the above mixture to the aqueous medium. Finally add the flavor and detergent and stir further to obtain the final product

Evaluation of dental care products

Abrasiveness (visual observation)

- Abrasiveness can be tested by rubbing the toothpastes or toothpowders on extracted Dental set and then observing the abrasive function visually or mechanically.

Particle size

Determined by microscopically or by sieving. The particle size should be ideal in order to provide good abrasiveness without any gritty feel and to minimize damage to the gums

Volatile matter and moisture

- A predetermined quantity of the product is taken in a dish and is dried till a constant weight is obtained. Change in weight will indicate the percentage of moisture and volatile matter.

Limit test for heavy metals

- The dental products are also tested for the content of arsenic and lead as these are very toxic metals and can harm the user if found in excess quantity.
- **Consistency -**The viscosity of the paste and rheology of the powders should be optimum to ensure smooth flow of product from the container.
- **Cleansing action -**This can be assessed by brushing the teeth for 2 weeks with the toothpaste/powder and then examining the appearance of the teeth before and after use by comparing the photographs.

- **pH of the product-** A 10% dispersion of the product is made in water and pH is determined. It should be optimum so as not to damage the teeth and the gums.

Foaming property

- This test is essential for evaluation of foam producing dentifrices.
- A fixed amount of the product is mixed in sufficient quantity of water and stirred vigorously.
- The foam generated is then observed for its nature, density, stability and washability.

Hair dyes

- These are colourants or the cosmetic preparations which are used to change the natural hair color and to mask the greying of hair Ideal properties
- Color distribution should be even
- Should not damage the hair and scalp
- Should remain for longer duration
- Natural moisture of hair should be retained

Formulation

- depends on the Classification of hair dye:
- 1. Temporary hair colourants
- 2. Semi permanent hair colourants/ Direct dyes
- 3. Oxidative dyeing systems
- 4. Gradual hair colorants
- 5. Natural dyes

Temporary hair colorants

- : They are leave in preparation. Not rinsed after application.
- Absorbed into the cuticle and cannot enter into the cortex of hair.
- It consists of dyestuff and acid. Dyes are azodyes, anthroquinone dyes, benzoquinoneimine dye, Triphenyl methane dye.
- Available in Powder, Crayons, Liquids and Shampoos

Semipermanent Hair Colourants

- Direct dyes:
- Retain color for longer duration.
- Doesnot contain H2O2 and so it doesnt get bleached
- Composition of semipermanent hair colorants are
- Dye - O nitro anilines, Aminonitrophenols & their ethers, Azo dyes, Nitrodiphenylamine, Anthroquinone •
- Aliphatic primary amines, Fatty acid, Thickener, Surfactant
- Water, Organic solvent,Perfume

Oxidative Dyeing Systems

- Also called Para dyes. Colorants are based on chemical reaction, produces color.
- Mostly oxidation, coupling and condensation reactions involved
- Composition are,

- Dyes - Aromatic compounds, Resorcinol, m-phenylene diamine, Diaminoanisole, hydrogen peroxide
- Vehicles - Water, Ethyl alcohol, Glycerine, Ethylene glycol monostearate
- Oxidizing agent - Induces the oxidation reaction with hair Eg: Ferric chloride, Kmno4, Alkalis - Oxidation dyes are active in alkaline medium Eg: Ammonium hydroxide, Amm. Carbonate, Mono ethanol amine, Guanidine or Arginine, Diethanol amine
- H2O2
- Antioxidant - During manufacturing, the amino dyes are darken in presence of air. Nitrogen is supplied in manufacturing vessel or Sodium sulfite are added

Gradual Colourant

- This colorants require several applications on hairs to achieve required darkness
- It contains heavy metals like Lead, Bismuth salts in their composition
- But it produces negative effect on health

Natural dyes

- Plant contain color pigments, which are used as Hair colorants
- It has very less side effects
- **Henna**: Leaves are powdered and it is mixed with water to form paste. It gives reddish to reddish brown color to the hair.
- Active constituent is 2 hydroxy 14 napthoquinone (Lawsone). Indigo leaves or synthetic indigo is added to henna to alter the color
- **Chamomile**: Flowers of chamomile are used to obtain the colour.
- Powder is mixed with hot water to form paste. Navy blue color is achieved

Preparation or Manufacturing of Hair dye

- Dye chemicals premixed with hot water
- Other ingredients like alkalis, surfactants, oxidizing agent, viscosity enhancer and buffers are dissolved in suitable solvents
- Dye Premix and Other mixtures are pumped in to manufacturing vessel and mix well.
- Remaining volume is makeup with water

EVALUATION

- pH,
- Viscosity
- Assay for H2O2
- Residue on ignition