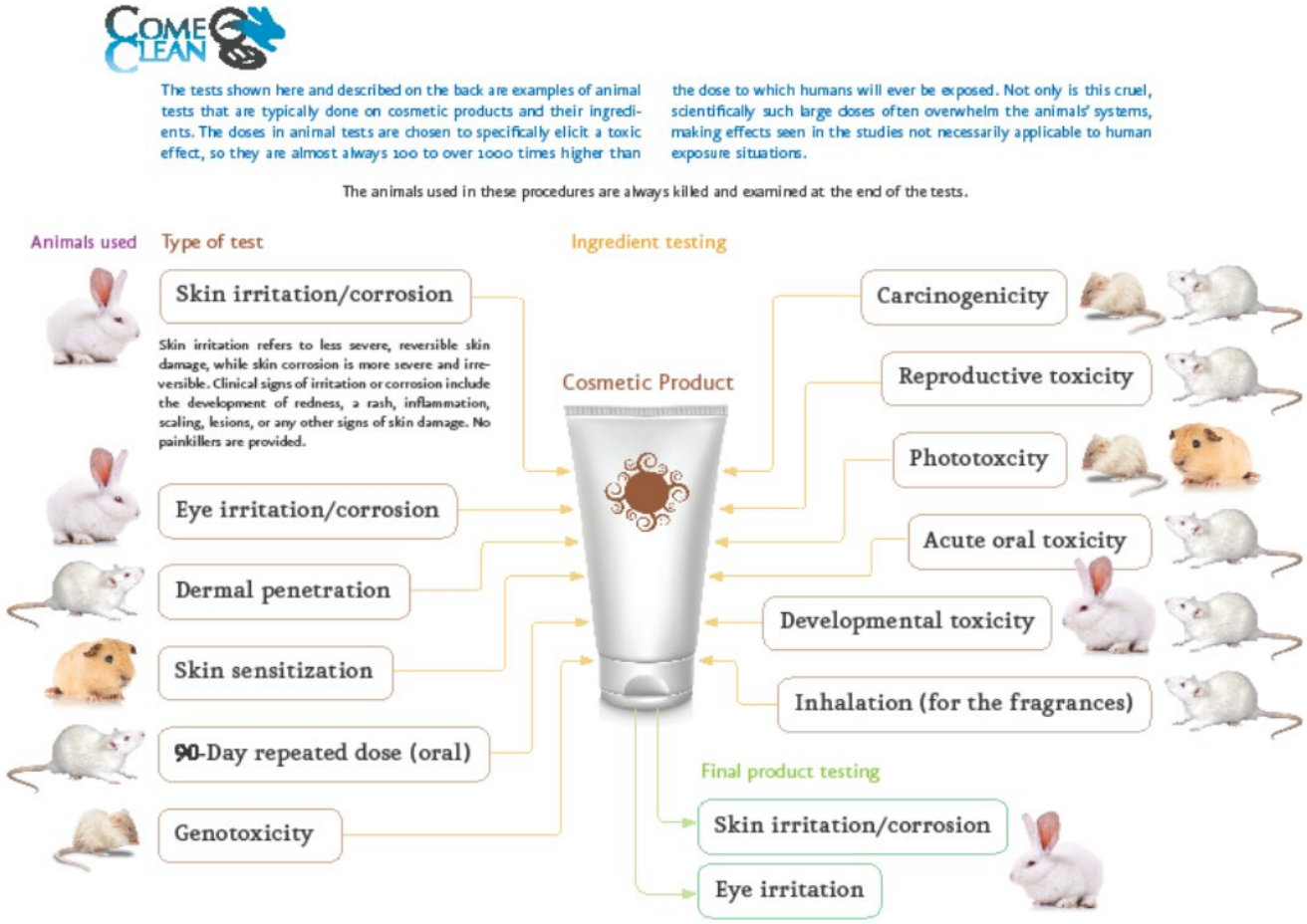
UNIT-II

TOXICITY STUDIES ON COSMETIC PRODUCTS

- **Toxicity:** these are the reactions which are produced during the use of drugs and cosmetic products having the potential of hazards.
- It is based on the series of toxicity studies.
- These studies and tests involved various kinds of animals for the determination of toxicological data.
- These data of the study on animal are compared with the human.
- After comparison the data is used to calculate LD_{50} (lethal dose).



SKIN CORROSIVENESS

- Skin corrosion tests assess the potential of a substance to cause irreversible damage to skin; namely, visible necrosis through the epidermis and into the dermis, following the application of a test substance for up to four hours.
- Corrosivity is not a feature one expects to occur with cosmetics, but occasionally could occur after a manufacturing mistake or misuse by the consumer.
- On the other hand, a cosmetic ingredient that has the intrinsic property to be corrosive, is not necessarily excluded for use in cosmetics. It very much depends on its final concentration in the cosmetic product, the presence of "neutralising" substances, the excipients used, the exposure route, the conditions of use, etc.

SKIN IRRITATION

- Since the skin is often exposed, either intentionally or unintentionally, to cosmetic products, it is clear that the potential for a particular product/ingredient to cause skin irritation or for a particular ingredient to cause skin corrosion needs to be carefully evaluated as part of the overall safety assessment process.
- Dermal irritation is defined as the production of "reversible damage of the skin following the application of a test substance for up to 4 hours".
- It is generally assessed by the potential of a certain substance to cause erythema/eschar and/or oedema after a single topical application on rabbit skin and based on the Draize score

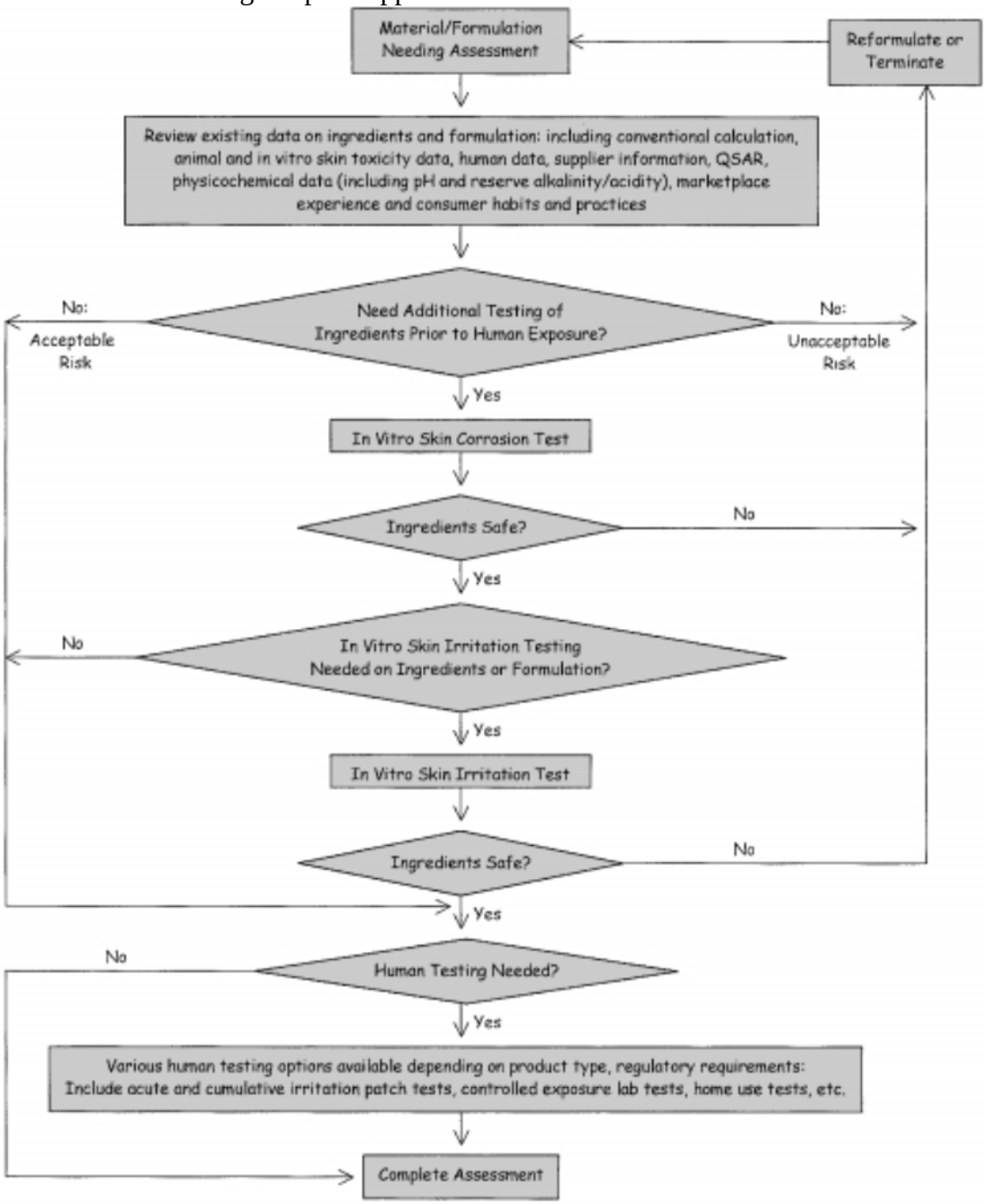


Fig. Flow diagram for a generic safety testing and risk assessment process for human skin corrosion and irritation.

Table. Summary of validated and most advanced alternative methods for skin corrosion and skin irritation

Method	Test System	Endpoint	Applicability
EPISKIN™ human skin model (commercial system)	Reconstructed human epidermal equivalent	cell viability (MTT reduction assay)	general; a few materials may interfere with MTT reduction
EpiDerm™ human skin model (commercial system)	Reconstructed human epidermal equivalent	cell viability (MTT reduction assay)	general; a few materials may interfere with MTT reduction
PREDISKIN™ human skin model (commercial system)	Reconstructed human epidermal equivalent	histology and cell viability (MTT reduction assay)	general; a few materials may interfere with MTT reduction
Pig ear test	Pig ear	trans-epidermal water loss (TEWL)	General
Mouse skin integrity function test (SIFT)	excised mouse skin	TEWL and electrical resistance (ER)	general; a few materials may interfere with either TEWL or ER Determination
CORROSITEX™ (commercial system) (only for skin corrosion)	Reconstructed human epidermal equivalent	cell viability (MTT reduction assay)	mainly acids, bases and derivatives

REPEATED DOSE TOXICITY

- Repeated dose toxicity comprises the adverse general toxicological effects (excluding reproductive, genotoxic and carcinogenic effects) occurring as a result of repeated daily dosing with, or exposure to, a substance for a specified period up to the expected lifespan of the test species.
- Current repeated dose toxicity methodology for the safety assessment of cosmetic ingredients The following in vivo repeated dose toxicity tests are available for assessment of cosmetic ingredients:

1) - Repeated dose (28 days) toxicity (oral)
   -Repeated dose (28 days) toxicity (dermal)
   -Repeated dose (28 days) toxicity (inhalation)
2) - Sub-chronic oral toxicity test: repeated dose 90-day oral toxicity study in rodents

- Sub-chronic oral toxicity test: repeated dose 90-day oral toxicity study in non-rodents

- Sub-chronic dermal toxicity study: repeated dose 90-day dermal toxicity study using rodent species

- Sub-chronic inhalation toxicity study: repeated dose 90-day inhalation toxicity study using rodent species

3) - Chronic toxicity test

- Chemicals are administered daily by gavage (a feeding tube which goes into the animals stomach) to the animal.
- The liver, heart, nervous system, kidneys, and other organs and systems are all dissected and evaluated at the end of the experiment.
- No painkillers are provided.
- Rats are the most common species used.
- In principle, the repeated dose toxicity study yields the following data/information:

- general characteristics of the toxicity
- the target organs of toxicity
- the dose-response (curve) for each toxicity end point
- responses to toxic metabolites formed in the organism
- delayed responses, cumulative effects
- the margin between toxic/non-toxic dose
- NOAEL, NOEL for toxicity
- information on reversibility/irreversibility of the effect

CARCINOGENICITY

- Cancer or an increased rate of cancer development characterizes a carcinogen.
- Animals are exposed to substances through their noses (inhaled), on the skin, in the diet or drinking water, or by oral gavage (a feeding tube which goes into the animals stomach).
- These tests take two years
- then the animals are killed to examine their tissues and organs for evidence of cancer.
- Rodents are more prone than humans to developing cancer.
- No painkillers are provided.
- Mice or rats are the most common species used.

PHOTOTO-INDUCED TOXICITY

- Also called photoirritation, phototoxicity, refers to the skin's reaction precipitated by exposure to a substance and sunlight or ultraviolet radiation (artificial sunlight).
- Clinical signs of phototoxicity include inflammation, rash, or swelling.
- No painkillers are provided.
- In vivo: Guinea pigs or mice are the most common species used.
- 3T3-NRU in vitro phototoxicity test.
- human 3D model EpiDerm-PT.

COLD CREAM

- Cooling effect is produced due to slow evaporation of the water contained in the formulation.
- These are w/o type.

Beeswax Borax type cold cream:

- These contain high percentage of mineral oil.
- This cream contains high amount of mineral oil for cleansing action.
- Basically these are o/w type emulsion. After the cream is being rubbed into the skin sufficient quantity of water evaporates to impart a phase inversion to the w/o type.
- The solvent action of the oil as external phase imparts cleansing property.
- In this type of cream borax reacts with free fatty acids present in the bees wax and produces soft soap which acts as the emulsifying agent and emulsifies the oil phase .

Formulation:

A. Bees wax -2 gm
   Almond oil -50 gm
   Lanolin– 0.5gm
B. Borax-2 gm
   Rose water- 35.5 gm
   preservative –q.s.
C. perfume –q.s

Method of preparation:

- Hot melt fusion method
- Ingredients of oil phase should be taken in increasing melting point to avoid over heating.
- Take separately the ingredients of aqueous phase and mix them and heat to same temperature as oil phase
- Emulsifying agents should be added to specific phase.

- Mix the two phases with continuous stirring until smooth cream is formed
- Finally the product can be milled by triple roller mill.
- Preservative should be dissolved in the water before making cream
- Perfume should be added after the primary cream is formed and cooled but before final milling

VANISHING CREAM

- These are named so as they seem to vanish when applied to the skin.
- High quantity of stearic acid as oil phase used. This provides an oil phase which melts above body temp, and crystsllises in a suitable form, so as to invisible in use and give a non greasy film.
- Main component is emollient esters, stearic acids
- Part of stearic acid is saponified with an alkali & rest of stearic acid is emulsified this soap in large quantity of water.
- The quality of cream depends on the amount of acid saponified & nature of alkali used.
- NaOH makes harder cream than KOH.
- Borax makes cream very white but product has tendency to grain.
- Pearliness can be attained using liq.paraffin, cocoa butter, starch, castor oil, almond oil.
- Ammonia solution has a tendency to discolor creams made with it after some time.
- Cetyl alcohol improves texture and stability at low temperature without affecting sheen.

FORMULATION:

Stearic acid	15gm
Glycerin	5gm
KOH	0.5 gm
water	75.82 gm
NaOH	0.18 gm
preservative &perfume	q.s
Cetyl alcohol	0.50 gm
Propylene glycol	3.0gm

- Stearic acid has whiteness like snow so some times the preparation is called as SNOW.

LOTION

- A **lotion** is a low-viscosity topical preparation intended for application to unbroken skin.

- Lotions are applied to external skin with bare hands, a brush, a clean cloth, cotton wool, or gauze.
- Lotions can be used for the delivery to the skin of medications such as:

-Antibiotics -Antifungals

-Antiseptics -Corticosteroids

-Anti-acne agents

-Soothing, smoothing, moisturizing or protective agents (such as calamine)

PRODUCTION

- Most lotions are oil-in-water emulsions using a substance such as cetearyl alcohol to keep the emulsion together, but water-in-oil lotions are also formulated.
- The key components of a skin care lotion, cream or gel emulsion (that is mixtures of oil and water) are:

- Emulgent
- fragrances
- Humectants- glycerol
- petroleum jelly,
- dyes
- preservatives,
- stabilizing agents

- Since thickness and consistency are key factors in lotions and creams, it is important to understand the manufacturing process that determines viscosity.
- Manufacturing lotions and creams can be completed in two cycles:

1. Emollients and lubricants are dispersed in oil with blending and thickening agents.
2. Perfume, color and preservatives are dispersed in the water cycle. Active ingredients are broken up in both cycles depending on the raw materials involved and the desired properties of the lotion or cream.

CLEANSING LOTION

A typical formulation

Mineral oil 38%

Bees wax 2%

Triethanolamine stearate 8%,

Water to make 100%

Preservative & Perfumes –q.s.

MOISTURIZERS

- **Moisturizers** or **emollients** are complex mixtures of chemical agents specially designed to make the external layers of the skin (epidermis) softer and more pliable.
- They increase the skin's hydration (water content) by reducing evaporation.
- Naturally occurring skin lipids and sterols, as well as artificial or natural oils, humectants, emollients, lubricants, etc., may be part of the composition of commercial skin moisturizers. They usually are available as commercial products for cosmetic and therapeutic uses, but can also be made at home using common pharmacy ingredients.

FUNCTIONS:

Preservation of normal skin: Such moisturizers often contain lightweight oils, such as cetyl alcohol, or silicone-derived ingredients, such as cyclomethicone.

Dry skin: heavier, oil-based moisturizers that contain ingredients such as antioxidants, grape seed oil or dimethicone.

For very dry, cracked skin, petrolatum-based products are preferable, as they are longer-lasting than creams and are more effective in preventing water evaporation.

Oily skin: For oily skin, water-based moisturizers that are specifically non-comedogenic are preferable, as there is less risk of comedo formation.

Aging skin: Appropriate moisturizers to keep aging skin soft and well hydrated are oil-based ones that contain petrolatum as the base, along with antioxidants or alpha hydroxy acids against wrinkles.

Sensitive skin: On sensitive skin (which otherwise is susceptible to skin irritations, redness, itching or rashes), it is preferable to use moisturizers which contain soothing ingredients such as chamomile or aloe, and that minimize potential allergens such asfragrances or dyes, as well as irritants such as acids.

Eczema: Some common emollients for the relief of eczema include Oilatum, Balneum, Medi Oil, Diprobase, bath oils and aqueous cream. Sebexol, Epaderm ointment, Exederm and Eucerin lotion or cream may also be helpful with itching.

Recently, ceramides, which are the major lipid constituent of the stratum corneum, have been used in the treatment of eczema.

MECHANISM OF ACTION:

Three methods are used to moisturize skin:

1. Occlusives: These work by forming a thin film on the surface of the skin to prevent loss of moisture.
2. Humectants: These attract water vapor from the air to moisturize the skin.
3. Restoration of deficient materials: These are more complex and try to restore natural moisturizing factors on the skin, such as amino-lipids.

POWDERS

These are categorized as face powder, body powder, and Compacts.

The powders should have following properties:

- Must have good covering power so can hide skin blemishes.
- Should adhere perfectly to the skin & not blow off easily.
- Must have absorbent property.
- Must have sufficient slip to enable the powder to spread on the skin by the puff.
- The finish given to the skin must be preferably of a matt or peach like character.

The raw materials used to manufacture of various powders are classified with example as follows:

RAW MATERIAL FOR POWDER IMPARTING	**EXAMPLE**
Covering prop	Titanium dioxide,zno,kaolin,zn stearate
Adhesion prop	Mg.stearate,talc,mg & ca salt of myristic acid
Slip & Softness	Zn/mg undecanate,aluminium hydrosilicate
Absorbency prop	Starch, colloidal kaolin,bentonite,pptd chalk
Peach like finish	Rice starch,silica,powdered silk
Frosted look	Guanine, bismuth oxychloride,mica,Zn,Al
Color & perfumes	Iron oxides

Types of Face Powders:

A. Loose face powder

B. Compact face powder

C. Talcum powder

D. Body powder

A) LOOSE FACE POWDER: The essential feature of a good face powder includes Covering power, slip, Adhesiveness, Absorbency, Bloom, Coloring, Perfuming.

Type:

b) Light type

c) Medium type

d) Heavy type

Type of face powder	**purpose & composition**
LIGHT	Dry skin, contains large amount of talc
MEDIUM	Normal or moderately oily skins, lesser talc & zinc oxide
HEAVY	Extremely oily skins ,low talc but higher amount of Zinc oxide

TYPICAL FORMULATION OF FACE POWDERS:

LIGHT POWDER	**MEDIUM POWDER**	**HEAVY POWDER**
Talc ---------63gm	**Talc---------39.7gm**	**Talc---------20.0gm**
Kaolin --------20 gm	Kaolin-------39.5 gm	Kaolin(light)-20 0gm
Cal. carbonate(l) 5 gm	Cal. carbonate(l) 5 gm	. Cal. carbonate(l) 39 g
Zinc oxide ---5.0gm	**Zinc oxide ---7.0gm**	**Zinc oxide ---15.0gm**
Zinc stearate-5.0gm	Zinc stearate-7.0gm	Mg.stearate—5.0gm
Mg.carbonate—1.0gm	Mg.carbonate—1.0gm	Color ------0.5gm
Color ------0.5gm	Color ------0.2gm	Perfume------0.5gm
Perfume------0.5gm	Perfume------0.6gm	

B) COMPACT FACE POWDER: It is a dry powder which has been compressed into a cake. The pressure for compaction is very important. The powder must come off easily when rubbed with puff.

Type of binder	**Examples**
1) Dry binder	Zn/Mg.stearate
2) Oil binder (water repellant)	Mineral oil, isopropyl myristate, Lanolin derivative
3) Water soluble binder	PVP, CMC, Cellulose, Acacia, Tragacanth
5) Emulsion binder	Triethanolamine stearate, Glycerol monostearate

(C) TALCUM POWDER: It is used as an adsorbent for making the skin from the excess moisture. Light magnesium carbonate added to mix perfume.

Formula:

Zinc oxide ……... 50

Zinc stearate …… 50

Chlorhexidine diacetate ……3

Light magnesium carbonate.....100

Talc …….797

Perfume…….0.2

D) BODY POWDER: It consists of mainly talc, with small portion of a metallic stearate, precipitated chalk, magnesium carbonate(light). Talcum/body powders containing antiseptic substances are also used for prickly heat, and fungus infections. Boric acid act as antiseptic.

A typical formulation:

Talc - 75 gm

Aluminum stearate – 4 gm

Colloidal Kaolin –10 gm

Boric acid – 0.3 gm

Colloidal silica--- 5 gm

Perfume --- 0.7 gm

Magnesium Carbonate- 5 gm

FACE WASH

Facial washes, offered either as clear liquids or opaque base creams, have been around for some time. The primary performance characteristics include: a creamy lather with some level of foam that spreads without dripping, exhibits low irritation, imparts a soft/silky after-feel, is non-drying and is easy to rinse off. In the case of facial wash, it is appropriate to reduce the surface cleaning properties so as not to strip away desirable lipids on the skin surface.

KEY COMPONENTS:

Surfactant system: is the key building block to any facial wash.

Anionic surfactants such as carboxylic acid, sulfates, sulfonic acids and phosphoric acid derivatives are incorporated for their surface activity and have negatively charged polar head groups.

Cationic surfactants have positively charged polar head groups, such as amines, alkylimidazolines, alkoxylated amines and quaternary ammonium. These materials are used for their substantivity and electrostatic attractive properties to skin.

Nonionic surfactants, which have no charge, are incorporated into facial washes as emulsifiers, conditioning agents and solubiliziers/coupling agents. These surfactants have a diverse representation, including alkylene oxides, polyglucosides, fatty alcohols, ethanolamines and dimethylamine oxides.

Amphoteric surfactants are used in facial care washes as secondary surfactants to help boost foam, improve conditioning and reduce irritation. They are zwitterionic and can be positively or negatively charged, depending on the pH of their environment.

Stabilizers

Besides the surfactant system, other important components in a facial wash are stabilizers such as fatty alcohols, emollients and moisturizers including glycerin, fatty acid esters and polymers, rinse-off aids, chelating agents, pH adjusters, viscosity modifiers such as salt and gums, UV stabilizers for colorants, and antioxidants.

EVALUATION:

The prepared face wash gel was evaluated for various parameters as follows:

Colour: The colour of the face wash gel was checked visually

Odour: The formulation was evaluated for its odour by smelling it.

Consistency: It was determined manually.

Viscosity: Viscosity of the gel was determined using Brookfield viscometer. The values obtained for the sample and for water were noted.

Spreadability: The spread ability of the gel was found manually by applying the gel on the skin with gentle rub.

Washability: The product was applied on hand and showed under running water.
Foamability: Small amount of gel was taken in a beaker containing water. Initial volume was noted, beaker was shaken for 10 times and the final volume was noted.

Grittiness: The product was checked for the presence of any gritty particles by applying it on the skin.

FACE PACK

- Traditional facial masks are temporarily applied to the face in a thick layer without massage. This film is known to dry quickly, and the residual film is peeled or rinsed off. Some are massaged until they aggregate into easy-to-eliminate rolls.
- The application site and amount applied largely determine the rheological properties of facial masks. They are formulated to resemble viscous gels, pastes or thick emulsions.
- In general, they are shear-thinning products that are easily and homogeneously distributed on the face with the fingers. Once applied, the mask layer should remain in place and not drip. This is necessary to keep the product out of the eyes and mouth.
- **The main cosmetic objectives of facial masks are to provide:** fast, deep moisturization; skin replenishment and restitution; sebum absorption and elimination; and skin rejuvenation. In addition, an immediate radiant complexion is expected by consumers after removing the mask. In other cases, and more frequently in esthetic practices, facial masks are applied over

a face cream to help the penetration of actives by promoting intense skin hydration. In this case, they remain longer on the skin and are gently removed by wet wipes.

FORMULATION

- From a physicochemical point of view, facial masks can be divided into three main types: emulsions, gels and suspensions.
- Formulation methods for masks do not have peculiar characteristics, in comparison with standard cosmetic recipes, but some examples are given here.
- Exceptions are facial masks containing high amounts of solids that are either swelling or non-swelling. In these cases, ionic or nonionic surfactants are required to stabilize suspensions of micronized solids, in synergistic association with thickening polymeric ingredients or "concentrators." It seems that interactions between polymeric macro chains, micelles formed by surfactants and solid particles make the systems more stable.
- For the high viscosity of a facial mask, powders such as talc, kaolin, silica gels and clays must be incorporated into the formulation while avoiding the excessive incorporation of air.

Peel-off Masks

Peel-off masks are applied as an even layer to the face and removed in continuous, peelable film after the given amount of time.

- **Formula 1:** this suspension formulation is a blend of mostly solid powder ingredients. The dry blended powders are mixed 10:24 with water just before application onto the skin. The association between vegetal thickeners and absorbing porous silica is evident in this formula. Magnesium oxide and calcium sulfate form a compact mask after drying, maintaining facial contours.
- **Formula 2(gel-type):** the process of transformation from aqueous gel to dry, transparent film can be tailored in terms of evaporation speed by the amount of volatile (alcohol) and non-volatile, e.g., propylene glycol, isopentyl diol, glycerin, etc., hydrophilic solvents. The only drawback is the length of time necessary to dissolve the polyvinyl alcohol granules in water, as they require adequate and slow mixing. After complete dissolution, other ingredients can be incorporated. Typically, the amount of polymer used is between 5% and 15%, and soothing, refreshing or nourishing actives may be added at the end. An ethoxylated surfactant is added in this case to dissolve the fragrance in the aqueous system. This formula could be kept as a model, to which one could add an assortment of fillers, colors and pearls to make it more attractive. An important development element is that care should be taken to check the

influence of each addition to the evaporation time and mechanical resistance of the peelable film.

- **Formula 3(gel-type):** In this mask, the **hydrophilic solvents** are carefully blended to obtain progressive evaporation but also an immediate moisturizing effect. Long term skin hydration is provided by sodium hyaluronate. Adequate **thickening and elasticity** characteristics are obtained with the use of xanthan gum. The formula is claimed to have **excellent storage** behavior due to the citrate-buffered pH. Tocopherol is added to protect fragrance from oxidation. Polyoxyethylenated compounds in association with solvents also ensure good **potential for dissolution** and the absorption of all sebaceous materials from the skin surface into the polyvinyl alcohol layer.

Wash-off Masks

- **Formula 5:** is an **emulsion-type** facial mask with a light texture, In this formula, the **thickening** properties are provided by a combination of magnesium aluminum silicate and xanthan gum. **Absorption** of sebum is provided by kaolin, and the other ingredients somewhat resemble a standard face cream for greasy skin—except for the amount of beeswax, which provides some occlusion and helps skin moisturization. Refined milk lipids and oat flour also contribute to **skin conditioning**.
- **Formula 6:** shows several cosmetic activities in a suspension-type mask. Sebum absorption and thickness are provided by the blend of bentonite and kaolin, while their dark color is lightened with titanium dioxide. Viscosity is obtained by carbomer. Cleansing and powder wetting are achieved with the surfactant ammonium laureth sulfate and triethanolamine stearate, a mild combination commonly used in East Asia for cleansing creams. EDTA is added for better color stabilization, i.e., complexing with iron traces, and to help preserve the system. A good amount of vegetal butters and oils, including pistachio and jojoba, are emulsified in the system, which along with vegetal jojoba proteins improve skin complexion and radiance.

ROLE OF EXFOLIATING AGENTS

Exfoliation involves the removal of the oldest dead skin cells on the skin's outermost surface.

TYPES:

Mechanical:

This process involves physically scrubbing the skin with an abrasive.

- microfiber cloths

- adhesive exfoliation sheets
- micro-bead facial scrubs
- crepe paper
- crushed apricot kernel or almond shells
- sugar or salt crystals
- pumice and abrasive materials such as sponges, loofahs, brushes, and simply fingernails.
- Microdermabrasion

Chemical:

- Chemical exfoliants include scrubs containing salicylic acid, glycolic acid, fruit enzymes, citric acid, or malic acid.
- Chemical exfoliation may involve the use of products that contain alpha hydroxy acids (AHAs), beta hydroxy acids (BHAs), or enzymes that act to loosen the glue-like substance that holds the cells together, allowing them to ease away.
- This type of exfoliation is recommended for people treating acne.
- In beauty spa treatment on continental Europe, the chemical properties of wine producing grapes are exploited in the practice of vinotherapy which is becoming increasingly popular.

With hair removal:

Some methods of hair removal also exfoliate the skin.

- Waxing is a mechanical process that is performed with the intention of plucking the hair, which also functions as a mechanical exfoliant.
- Nair is an example of a chemical hair removal product which also functions as a chemical exfoliant. It is done more frequently than waxing (once a week rather than once a month) since it only destroys hair partially below the skin, rather than destroying the entire root as with waxing.
- Wet shaving

ANTI-AGING AGENTS

- **Anti-aging supplements** are a set of products that often include powdered supplements, skin creams, vitamins, and facial masks. They are designed to reduce or diminish the effects of aging. Many products seek to hide the effects of aging while others claim to alter the body's chemical balances to slow the physical effects of aging. A comprehensive grading scale for anti-aging of the skin has been validated and categorizes skin aging as: laxity (sagging), rhytids (wrinkles), and the various categories of photoaging,

including erythema (redness), dyspigmentation (brown discolorations), solar elastosis (yellowing), keratoses (abnormal growths), and poor texture.

Ingredients:

As well as more conventional moisturizing ingredients, anti-aging creams usually contain anti-aging ingredients such as:

- Retinoids (for instance, in the form of retinyl palmitate). In various formulations it has been shown to reduce fine lines and pores.
- Epidermal growth factor, a 53 amino acid protein. In various research, epidermal growth factor has been shown to reduce fine lines, wrinkles and sagging. It also has healing (wounds and burns) and anti-inflammatory properties when applied to skin.
- Fatty acids are often added and derived from naturally occurring substances such as sandalwood, barley, and Phellodendron bark, which are designed to maintain skin moisture and seal in other moisturizing agents within the cream.
- Alpha hydroxy acids (AHAs) and beta hydroxy acids or other chemical peels. These help to dissolve the intracellular "glue" that holds the dead cells together on the skin. Peptides, such as acetyl hexapeptide-3 (Argireline), Matryxil, and copper peptides.
- Coenzyme Q10 -MitoQ
- Anti-oxidants are substances that may protect cells from the damage caused by free radicals.
- Sunscreens. A high level of UV protection is recommended as UV radiation is associated with aging effects such as wrinkles.
- Vitamin C

Alternative approaches:

- Traditional moisturizers or sunscreens
- Mechanical exfoliation is an alternative to chemical peels using ingredients such as crushed apricot kernels, salt, sponges or brushes.
- Resveratrol and rapamycin currently being tested in human trials.
- Another method, other than creams, is plasma gel.

SUN PROTECTION FACTOR (SPF)

- The sun protection factor is a measure of the fraction of sunburn-producing UV rays that reach the skin.

- For example, "SPF 15" means that 1/15th of the burning radiation will reach the skin, assuming sunscreen is applied evenly at a thick dosage of 2 milligrams per square centimeter (mg/cm^2).
- A user can determine the effectiveness of a sunscreen "by multiplying the SPF factor by the length of time it takes for him or her to suffer a burn without sunscreen."
- Thus, if a person develops a sunburn in 10 minutes when not wearing a sunscreen, the same person in the same intensity of sunlight will avoid sunburn for 150 minutes if wearing a sunscreen with an SPF of 15.
- It is important to note that sunscreens with higher SPF do not last or remain effective on the skin any longer than lower SPF and must be continually reapplied as directed, usually every two hours.

Active ingredients:

In addition to moisturizers and other inactive ingredients, sunscreens contain one or more of the following active ingredients, which are either chemical or mineral in nature:

- Organic chemical compounds that absorb ultraviolet light.
- Inorganic particulates that reflect, scatter, and absorb UV light (such as titanium dioxide, zinc oxide, or a combination of both).
- Organic particulates that mostly absorb UV light like organic chemical compounds, but contain multiple chromophores that reflect and scatter a fraction of light like inorganic particulates. An example is Tinosorb M. The mode of action is about 90% by absorption and 10% by scattering.

BABY CARE PRODUCTS

- Baby Care Products Intended for use on new born babies to children upto 5year
- Functional rather than decorative
- Criteria for consideration during development

- High quality raw material
- Non irritant substances
- Allergen free
- pH- skin friendly
- Addition of anti-oxidants, chelating agents, skin barrier protective ingredients

BABY SOAPS

- Baby soap shall possess good cleaning and lathering properties, is normally a mixture of alkali salts of long- chain fatty acids.
- Triglycerides for example tallow, palm oil and coconut oil, provide the basic 'fats' from which the fatty acid mixture used for soap are derived
- The finished soap properties are primarily dependent on the mixture and ratio of triglycerides used.
- Tallow, for example, gives a much harder soap than coconut oil.
- Potassium soap are much softer than their sodium based counterparts , although, in practice, they are rarely used.
- The finished soap bar can be modified by the addition of other ingredients. Such as emollients, opacifiers and chelating agent.

FORMULATION:

1. Sodium laurelh sulphate (cleansing/ foaming agent)
2. Sodium palmitate (cleanser/ emulsifier)
3. Sodium lauryl isothionate (wetting agent)
4. Sodium oleate
5. Sodium cocoate
6. Olive oil with vit E (skin softner)

EVALUATION:

1.Determination of nickel:

Isolation of metal from soap:

- 50g of soap dissolve in hot water
- Add 40ml of conc. HCL , heat until fatty acid layer separates
- Add 20g paraffin wax, stirr and allow to settle cool to room temp
- Remove wax cake, rinse with water, add rinsings to aq. phase of evaporate to 60ml
- Make up to 100ml (test soln)

Determination of nickel content:

- Take 50ml of aliquot (evaporate to 15ml)
- Add 3ml bromine water (1mts)
- Add 5ml liquor ammonia (ppt formed)
- Filter, add 10ml dimethyl glyoxime soln and add 15- 20ml 95%ethanol
- Kept for 5min for development of colour

- The sample shall be considered to have passed the test if no pink colour develops

2.Determination of iron:10ppm

- 5ml of test soln (metals are isolated from soap)
- Add 4ml citric acid add 0.02ml methyl red +liquor ammonia (yellow colour)
- Add 3ml liq.ammonia in excess
- Cool and add 3ml thioglycollic acid
- Make upto 25ml , filter
- Measure absorbance at 540nm using water as blank
- Prepare calibration curve with std from soln and determine iron content of soap sample from it

3.Determination of copper: 3ppm

- 20ml aliquot+10ml zinc dibenzyl dithiocarbonate+25ml sulphuric acid shake for 1min
- Collect the lower ccl4 layer in a vf
- Wash the aq. Layer with ccl4 layer in a vf
- Make up the volume, absorbance at 435nm
- Prepare calibration curve with std copper soln
- Determine the copper content of soap sample from curve

BABY SHAMPOO

- pH : 6-7
- Mild surfactants (e.g. – non ionics & amphoteric)
- Avoidance of eye contact
- Polysorbate 20 & PEG 600 distearate – controls viscocity

Formulation:

Magnesium Laureth Sulfate	mild foaming agent
Cocamidopropryl Betaine	Amphoteric Surfactant
Polysorbate 20	non ionic detergent
PEG 600 Distearite	Emulsifier
Tetrasodium EDTA	Chelating Agent
Citirc Acid	Buffering Agent

Ingredients	**% w/w**
Magnesium Laureth Sulfate	11.00
Cocamidopropyl Betaine	5.00
Polysorbate 20	1.00
PEG 600 Distearate	3.50

Preservative	q.s.
Perfume	q.s.
Citric Acid to pH 6.0	q.s.
Colour	q.s.
Water (deionized)	100.00

EVALUATION:

1.Clarity: Cloud point & Clear point - difference not more than 10^0 C

2.Viscosity:- Rotational Viscometer 1- 100 rpm at 23.2± 0.4^0 C

-500-1500 cps

3.pH: pH meter, undiluted shampoo 6.5-8.5

4.Surface Tension: Traube Stalagmometer , 10% shampoo (20^0 C)

5.Detergency & Cleansing Action: Gravimetric method - % sebum removed after washing is calculated

6.Foam Quality: -Foam Volume – DLS stirrer, 500 rpm, 10 sec

-Foam Density – rubber stopper method

7.Wetting Action: Canvas Disc sinking test – time reqd. to sink disc

BABY CREAM AND LOTIONS

- Face/Body – Moisturizing effect
- Napkin Zone – protect from aggressions
- O/W cream W/O cream or water free ointment – talc, kaolin, ZnO
- Barrier Creams – winter

FORMULATION OF BABY CREAM:

Water	Vehicle
Glycerine , propylene Glycol	Humectant
Mineral Oil, petrolatum	Prevents water loss
Cetyl Alcohol, Stearyl Alcohol, Stearic Acid	Emulsifiers
EDTA	Prevents rancidity
Dimethicone (silicone)	Gives silky feel

Ingredients	**%w/w**
Mineral Oil	30.00
Pertrolatum	2.00
Stearic acid	1.20
Stearyl alcohol	1.00
Cetyl alcohol	0.70
Triethanolamine	0.65
Propylene glycol	1.00
Water	63.45

Perfume, preservatives, etc.	q.s.

FORMULATION OF BABY LOTION:

Water	Vehicle
Glycerine , propylene Glycol	Humectant
Polysorbate	Non-ionic surfactant
Glyceryl stearate, Stearic Acid. Oleic acid	Conditioning agent
Alkyl benzoate	Emollient/thickening agent
Sorbitol stearate	Emulsifier
Cetyl alcohol	Co-emulsifier
Bees wax	Spreading agent/base
Dimethicone (silicone)	Gives silky feel (conditioning agent)

EVALUATION:

1.pH: pH meter 4.5 – 6 (skin pH)

2.Viscosity: Brook-Field Viscometer, spindle no. S-06

3.Spreadabilit: Parallel plate method

4.Centrifugation Test: 5000 rpm, 10 min (20^0 C) = effect of gravity for 1 yr.

- 24 hr , 7, 14, 21, 28 days – no phase separation

5.Rheological Studies: Beaker inclined – checked for consistency

6.Electrophoretic properties: Zeta potential – assess flocculation – sign of oil droplet aggregation and instability

7.Determination of Total Fatty Substance: Oil phase extracted with ether – extracts filtered and weighed.

BABY POWDER:

- These powders are intended to make the infant feel more comfortable and to help prevent skin rashes that arise from or aggravated by excess moisture
- Main ingredients are stearates, colloidal clay starch and talc
- These powders are usually only lightly perfumed and not perfumed at all
- These powders are free from boric acid

FORMULATION:

Ingredients	**%w/w**
Talc	77.90
Starch	20.00
Zinc Oxide	2.00
Perfume	0.10

EVALUATION:

1.Determination of matter insoluble in boiling water: 1g (wetted with spirit) + 200ml H_2O – boiled – filtered - dried and weighed

2.Test for solubility of colors: 1g + 50ml H_2O – boiled – filtrate 10ml soln. + 15 ml spirit & filtered) – colorless/faintly colored

3.Determination of fineness: 10g in 150µ sieve – running tap water – residue dried & weighed

4.Determination of moisture and volatile matter: 5g in porcelain dish – dried & weighed

5.Determination of pH of aq. Suspension: 10g + 90ml H 2 O – suspension(within 5min) – pH meter

6.Pay off: -Measure of adherence to the puff or skin

-Incorrect compaction, adversely effects this pressure

7.Pressure Testing: -Penetrometer

- Penetration of a sharp metal point into pressed powder

8.Breakage Testing: Godet dropped onto a wooden board from 8-10 in. height – chip or break