

COSMETIC PRODUCTS SAFETY
&
RISK INFLUENCING FACTORS
A REVIEW

Presenter

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OVERVIEW

- **Cosmetics are being regulated under the provisions of D&C Act & Cosmetics Rules 2020 {GSR 763(E) Dt. 15thDec 2020}.**
- **There is no significant systemic absorption of Cosmetics through skin, some products are intended to be applied on mucous membrane or skin surrounding the mucous membrane, which may result in significant absorption on repeated use.**
- **Serious health hazards has not been reported yet but in some cases severe reactions such as; Allergy, Irritation, Comedogenicity, Genotoxicity, Photosensitivity etc. has been reported.**
- **Long term and repeated usage of certain Cosmetics/ Functional Cosmetics are in trend, hence Safety and Efficacy evaluation is the most desirable step prior to release in market is the key responsibility of the manufacturer.**

Contd...

- **ICCR (International Cooperation On Cosmetics Regulation) advises that the ingredients in a product shall be characterized through relevant Physico-Chemical data, Purity profile/ Impurities profile and chemical structure identification etc.**
- **Profound knowledge on the exposure of the product must be established, how the product is used, the quantity used in single application, frequency of usage, duration of intended use, target users etc.**
- **Based upon such exposure data of a product , the “safety margin” and “exposure margin” are calculated using the relevant dose.**
- **Safety assessment of a product may lead to conclude fitness of the product.**
- **PMS shall be conducted to support the continued Safety and Efficacy of the product.**

Why Safety Evaluation...?

- **The size of Cosmetics segment in the country is about \$15billion, Cosmetics are exported to 156 countries to the tune of \$123 million.**
- **Data reflects that on an average an adult Male uses 9 products daily and Female uses 15 or more products daily.**
- **Cosmetics, Toiletries, Personal Hygiene and Skincare products including Sunscreens are the major contributors for hospital referrals with allergic contact dermatitis.**
- **1-3% of the population are allergic to either cosmetics or to their individual ingredients**
- **3.3% incidences of contact allergic dermatitis are with use of hair dyes, lipsticks and shaving creams (59.2% population),photo allergic dermatitis as adverse reaction has been seen in 35% of population.**
- **Product must be evaluated for safety, to comply with Consumer/Patient safety norms and to gain confidence of the consumers.**

Why Efficacy Evaluation...?

- **Now a days many of the Cosmetic products available in the market are with larger claims viz; Anti-wrinkles/Antiaging, Skin eventoning, Sun screening agents, Facewash/ Masks, Hair Rejuvenator etc., at high prices.**
- **Claims with manufacturing technologies adopted such as; Encapsulation, Timed Release, Triggered Release, Targeted Site Delivery System, Sub-micron Technology, Liposomes, Nanotechnology etc.**
- **Thus Efficacy Evaluation is necessary to prove that the claimed benefits are being accurately communicated and delivered by the product (Claim Substantiation).**
- **COLIPA Guidelines, Efficacy Evaluation Of Cosmetic Products (The European Cosmetics Association) are available.**

IMPURITIES/RESIDUAL CONTAMINANTS

- **Impurities are minor constituents of RM and are often naturally present from the start, they are there in traces (0.01% or in ppm).**
- **Impurities can either be Desirable or Undesirable.**
- **Impurities can be identified through Chemical or Instrumental method along with their percentage/ppm.**
- **Whereas Residual impurities may be from water or contact parts of the machinery equipment or container or RM or Finished product.**
- **Impurities/Residual contaminants presence in the RM/ Finished Products can be acceptable within the specified limits and in harmless concentration.**

HARMFUL IMPURITIES

Some examples of harmful impurities:

- **1,4 Dioxane (In Propanediol)**
- **Di-ethylene Glycol (In PEG)**
- **Heavy Metals (Hg , Sb , As, Cr, Ni, Pb, Co, Cd)**
- **Butylated hydroxyanisole (BHA)**
- **Bisphenyl A**
- **Nitrosamines**
- **Formaldehyde**

IMPACT OF IMPURITIES

- **Contact Dermatitis**
- **Carcinogenicity**
- **Endocrine disruption**
- **Vital organ damage**
- **Hair loss**
- **Genotoxicity**
- **Neurotoxicity**

INGREDIENTS TO BE AVOIDED

- **Parabens**
- **Carbon Black**
- **Triclosan**
- **Petroleum Jelly**
- **Phthalates**
- **Ethanolamines**
- **Formaldehyde**
- **Oxybenzone**
- **Mineral oils**
- **Aromatic Hydrocarbons**
- **Waxes**
- **Parafins**
- **Synthetic Fragrances**

FACTORS RESPONSIBLE FOR CONTAMINATION/ CROSS CONTAMINATION

- **Heavy Metals**
- **Microbial Contamination**
- **Organic Hydrocarbons -Container & Closures**

DISPLAY OF INGREDIENTS

- **Rule 34 of Cosmetics Rules 2020 mandates for labeling of Cosmetics products**
- **Both inner and outer label shall bear name of ingredients present in more than 1% concentration shall be listed in descending order of weight or volume at the time they are added, followed by those in conc. of less than or equal to 1%**
- **Rule 33 deals with Prohibition against false or misleading claims**
- **Rule 39 deals with Standards of Cosmetics (Ninth Schedule)**

Issues To Be Addressed Before CDSCO

- **Development Of Guidelines For Evaluation Of The Efficacy Of Cosmetic Products.**
- **Development Of Guidelines For Evaluation of Safety Of Cosmetic Products.**
- **Development Of Guidelines For Claim Substantiation Of certain products especially with larger claims. (Backend/Scientific data)**

THANKS