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An Updated Review on Cosmetic Sciences

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Abstract: *Cosmetic products are an important element in human society. The use cosmetics has implications of health hazards; hence, modern cosmetic technology is in search of naturally-derived cosmetics. In this chapter, cosmetics derived from synthetic polymers, polysaccharide-based polymers, protein, and siliconebased materials are discussed. Particularly, synthetic polymers have changed the personal care industry dramatically by increased the use of favorable synthetic polymers that are soluble in various organic solvents like methyl chloride, ethyl alcohol, iso-propanol, toluene, and so forth. This route is environment-friendly, however, there is a tilt in the use of aqueous-based solvents in the cosmetic industry. Polysaccharide-based polymers are readily available from common natural sources. They have been used from centuries, have healing properties, and are nontoxic and noncarcinogenic. Such polysaccharide-based polymers are discussed in great detail. Silicone, being the most abundantly known element, is a suitable candidate for use in cosmetic products. For protein-based cosmetics, their use for such applications is well known from great ancient civilizations. The relevant details are presented in this chapter.*

Keywords: Cosmetics, Documentation, cGMP, ICH guidelines, SOPs, Preparation and evaluation of Shampoo.

I. INTRODUCTION

The cosmetic industry describes the industry that manufactures and distributes cosmetic products. These include colour cosmetics, like foundation and mascara, skincare such as moisturizers and cleansers, haircare such as shampoos, conditioners and hair colours, and toiletries such as bubble bath and soap. The manufacturing industry is dominated by a small number of multinational corporations that originated in the early 20th century, but the distribution and sale of cosmetics is spread among a wide range of different businesses.

Overview of Drug and Cosmetic Act 1940 and Rules 1945

The Drugs and Cosmetics Act, 1940 is an act of the Parliament of India which regulates the import, manufacture and distribution of drugs in India. The primary objective of the act is to ensure that the drugs and cosmetics sold in India are safe, effective and conform to state quality standards.

Classes of Cosmetics Prohibited from Import

- Adulterated drugs;
- spurious drugs ;
- misbranded drugs or drugs which are not of standard quality;
- Patent and proprietary medicine of which formula is not disclosed;
- Drug imported in contravention of the provisions of the act;
- Drugs claiming to cure diseases specified in Sch-J.

Prohibition of Manufacture and Sale of Certain Cosmetics

1. Any cosmetic which is not of standard quality or is misbranded or spurious;
2. Any cosmetic manufactured in contravention of the provision of the Act and rules made these under;
3. Any cosmetic containing mercuric compounds;
4. Any cosmetic containing colours other than prescribed ones;
5. Tooth paste or powder containing tobacco.

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Conditions of Import License:

An Import License is subject to the following conditions:

1. The licensee must observe at all the times the undertaking given by him or on his behalf in Form 9:
2. The licensee must allow any authorized Inspector to:

- Enter the licensed premises where imported drugs are stored.
- Inspect the substances employed for testing.
- Take samples.

3. The licensee must furnish the adequate quantity of sample from the required batches to the licensing authority for examination along with complete protocols of the test applied.
4. The licensee must maintain the record of all sales of imported substances as prescribed under the rules, and should furnish the same during the inspection.
5. The licensee must maintain separate records for the sale or distribution of Schedule-X drugs.

Conditions of license for manufacturers/Sale of Cosmeceuticals:

1. Provide and maintain staff, premises and equipment's (as per Schedule M and Schedule M3 for medical devices).
2. Test raw materials and final products of each batch either in the laboratory approved by the licensing authority.
3. Maintain records of manufacture and testing of each batch as per schedule U.
4. Allow Drug Inspector to enter and inspect, premises, plant, process of manufacture, means of standardization and tests.
5. Allow Drug Inspector to inspect all the registers and records maintained under the rules and to take samples of manufactured drugs.
6. Provide the required information to Drug Inspector for ascertaining compliance for provisions of Act and Rules.
7. Time to time report to the licensing authority:

- Changes in expert staff responsible for manufacture or testing.
- Material alterations in premises or plant.
- Samples of desired drugs and complete protocols of tests applied.

8. Not sell any batch, sample of which is submitted to the licensing authority, until receipt of Certificate of authorization is issued.
9. Withdraw from sale remainder of any batch or recall drugs already issued, if licensing authority directs to do so.
10. Not sell any drug manufactured under the license unless due precautions, necessary.
11. Comply with requirements of "Good Manufacturing Practices" as per schedule M.

Currents Good Manufacturing Practices

cGMP COVERS

1. General considerations
2. Personnel
3. Premises
4. Equipment
5. Sanitation
6. SOPs
7. Raw Materials
8. Self Inspection And Audit
9. Master Formula Records
10. Batch Manufacturing Records
11. Warehousing Area
12. Labels And Other Printed Materials

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13. QA

General Considerations

1. Compliance with GMP
2. Consistent uniform batches
3. Location And surroundings
4. Water system
5. Disposal of Waste

Personnel

Key personnel include :

- The head of production
- The head of quality assurance
- The head of quality control

Premises

1. Receiving and storage of raw materials
2. Manufacturing process areas
3. Quality control section
4. Finished good storage
5. Office
6. Rejected drugs

Equipment

Equipment shall be located, designed, constructed, adapted and maintained to suit the operation to be carried out.
Should be made of no reactive material, such as High grade of steel(316,302)
Equipment should be Checked, labelled, sterilized

Sanitation

Any building used in the manufacture, processing, packing, or holding of a drug product shall be maintained in a clean and sanitary condition. Any such building shall be free of infestation by rodents, birds, insects, and other vermin (other than laboratory animals). Trash and organic waste matter shall be held and disposed of in a timely and sanitary manner. Sanitation procedures shall apply to work performed by contractors or temporary employees as well as work performed by full-time employees during the ordinary course of operations.

SOPs

There shall be written Standard Operating Procedure for each operation It include- For Equipment , sampling, testing, process, Packaging.

Raw material

1. An Inventory should be maintained for Raw materials to be used at any stage of manufacturing.
2. Records should be maintain as per Schedule U.
3. Should be purchased from approved sources.
4. Must be checked by QC department on receipt
5. Should be labeled.

Packaging and labelling

1. Materials examination and usage criteria.
2. Labeling issuance.

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3. Packaging and labeling operations.
4. Tamper-evident packaging requirements for over- the-counter (OTC) human drug products.
5. Drug product inspection.
6. Expiration dating.

Warehousing area

1. Warehousing area should be designed and adapted to ensure good storage conditions.
2. Should be clean, dry and maintained with acceptable temperature limits.
3. Should have appropriate house-keeping and rodents, pests and vermin control.
4. Separate sampling area for active raw material and excipients.
5. Every Material stored should be labeled properly.
6. Fire Prevention

Quality Assurance

The main objective of the quality assurance is to ensure the products are of the quality required for their intended use.

Functions:

1. Adequate are made for manufacturing, supply and the use of correct starting and packing material,
2. Adequate control on starting material, intermediate, and bulk products.
3. Process validation in accordance with established procedures.

ICH guidelines for Stability Studies:

General Considerations :

General

The purpose of stability testing cosmetic products is to ensure that a new or modified product meets the intended physical, chemical and microbiological quality standards as well functionality and aesthetics when stored under appropriate conditions.

General Stability of a Cosmetic Product :

Whether conducted in real time or under accelerated conditions, tests should be done in order to assure:

1. Stability and physical integrity of cosmetic products under appropriate conditions of storage, transport and use,
2. Chemical stability,
3. Microbiological stability,
4. The compatibility between the contents and the container
5. Designing a Cosmetic stability studies
6. Predicting shelf-life
7. Packaging

Accelerated Stability Tests :

Accelerated tests, developed because of the relatively short development cycle for cosmetic products, enable the prediction of stability.

Designing a Cosmetic Stability Studies

A stability study should include the following considerations :

Identify tests that will “accelerate and predict” the effects of normal conditions of storage and use.

Consider variation in process conditions.

Predicting shelf-life

Some of the reasons for this lack of information are:

- The variety and complexity of cosmetic formulas and packaging.

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- The proprietary nature of many products and stability test methods.
- The variety of types of changes that need to be examined, including physical, chemical, microbial, functional or aesthetic changes.

Packaging

Packaging can directly affect finished product stability because of interactions which can occur between the product, the package, and the external environment. Such interactions may include:

- Interactions between the product and the container (e.g. adsorption of Product constituents
- The container, corrosion, chemical reactions, migration)

Parameter variability during product shelf life

1. Color, odor and appearance,
2. Changes in the container,
3. pH,
4. Viscosity,
5. Weight changes
6. Microbial tests demonstrating the ability of the products to prohibit microbial growth during normal use and other specific tests if necessary,
7. Analytical data in relation to other parameters for specific product types.

Light Stability

Cosmetics whose packaging may allow the product to be exposed to light should undergo light stability testing. The lighting used in testing should simulate the intensity to which the cosmetic will likely be exposed.

Problems related

- **Skin :** Irritant , dermatitis, allergy, acne.
- **Oral cavity:** Oral cancer, dental decay, dry mouth, tooth sensitivity.
- **Hair :** Dandruff, hair loss, dry hair, dull hair,oily/greasy hair.
- **Nail :** Keratin degranulation, peripheral neuropathy, mycobacterium infections, Traumaticanchyloses.

Instruments

Brookfield Viscometer

The Brookfield viscometer is possible to measure viscosity by employing techniques in viscometry. Viscometers (which can also be called viscosimeters) can measure viscosity through the varying flow conditions of the sample material being tested. They employ a spindle on a shaft that is designed to be dipped or immersed into a liquid that is then rotated. The rotation causes the fluid to produce a drag, which is then measured with the applied torque on the liquid's viscosity. They are not designed to measure multiple flow conditions, but are possible with the use of a rheometer instead.

Spray dinstea

Spray drying is a method of changing a dry powder from a liquid or slurry by rapidly drying with a hot gas. This is the preferred method of drying of many thermally-sensitive materials such as foods and pharmaceuticals, or materials which may require extremely consistent, fine particle size. Air is the heated drying medium; however, if the liquid is a flammable solvent such as ethanol or the product is oxygen-sensitive then nitrogen is used.

Cosmetics Processing Equipment

1. Kettles.
2. Tanks.

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3. Agitators.
4. High Shear Mixers.
5. Fluid Transfer.
6. Mixers.
7. Blenders.

Preparation and standardization 100ml of Methi- Shikakai shampoo

Objectives:

1. To prepare the Methi-Shikakai Shampoo.
2. To evaluate the Methi-Shikakai Shampoo.

Requirements: Apparatus

Conical flask, Pipette, Spatula, Pestle and mortar, Glass rod, Beaker, measuring cylinder, weighing balance, pH meter, evaporating dish, canvas paper and stop watch. etc.

Chemicals:

Methi, Shikakai, orange peel, distilled water rose water etc.

Theory:

Herbal shampoos are the cosmetic preparations that with the use of traditional Ayurveda herbs are meant for cleansings the hair and scalp just like the regular shampoo.They are used for removal of oils, dandruff, dirt etc. Mekhi's protein, nicotinic acids and large amounts of lecithin are highly effective against hair fall and provide strength from the roots. The seed contains a special hormone that enhances hair growth and helps repair the hair structure.

Shikakai is excellent for hair as it does not have side-effects unlike shampoo which are loaded with chemicals to add more lather. It does not strip your hair's natural oils, which means that they are stronger from within and do not look rough and dry. It helps in controlling hair fall and also in reducing dandruff naturally due to its antibacterial action.

Composition of Shampoo:

Sr. No.	Name of Ingredients	Quantity for 100ml
1	Methi	12.5gm
2	Shikakai	5gm
3	Orange peel	Handful
4	Water	QS 100ml

Procedure:

1. Crush the all ingredients in to powder form.
2. Dissolve all the ingredients in to water and make up the volume.

Standardization of Shampoo

- **Physical Appearance/Visual Inspection:** The formulation prepared was evaluated for the clarity, color, odor and foam producing ability.
- **Determination of pH:** The pH of 10% v/v shampoo solution in distilled water was measured by using pH meter at room temperature. **Moisture content at 1050C:** Weight about 1 gm of material into large weighing bottle and heat on a steam bath under a jet of air for 30 min. Continuous heating at 105cc in oven for 2 hrs, cool in desiccator, weight and report nonvolatile matter.

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Ash Content at 6000C:
Weigh 5ml of material place in a flat bottom platinum dish and heat on a steam bath under a jet of air for I hr. Remove and add l gm of ash less cellulose powder, keep the material in dish and heat in a 1k heating lamp till 600cc in muffle furnace.
Note the difference in weight.

Determination of % of solid content:
4 gm of shampoo were placed in a previously clean dry and weighted evaporating dish. The dish and shampoo were weighed again to confirm the exact weight of shampoo. The liquid portion of the shampoo was evaporated by placing the evaporating dish on the hot plate. The weight and thus % of the solid contents of shampoo left after complete drying was calculated.

Foam test:
Shake the drug/ sample extract vigorously with water. Persistent foam observed, confirms the presence of saponins.

Hemolytic test:
Add drug/ sample extract or dry powder to one drop of blood placed on glass slide.
Hemolytic zone appears.

Saponification test:
Add few drops of 0.5N alcoholic KOH to a small quantity of various extract along with a drop of phenolphthalein separately and heat on a water bath for I hour the formation of alkali indicates the presence of fixed oil and fats. 5 drop of sample, add pinch of sodium hydrogen sulphate, pungent odour indicate presence of glycerin.

Net content:
At the beginning of experiment mark the outside of bottle at the surface level of liquid, at the end of experiment empty the bottle and note the volume of water required to fill it to the mark.

Dirt Dispersion:
Two drops of shampoo were added in a large test tube contain 10ml of distilled water.1 drop of India ink was added; the test tube was Stoppard and shakes it ten times. The amount of ink in the foam was estimated as none, light, moderate or heavy.

Wetting Time:
The canvas was cut into 1-inch diameter discs having an average weight of 0.44g. The disc was floated on the surface of shampoo solution of 1%w/v and the stop watch started. The time required for the disc to begin to sink was measured acutely and noted as the wetting time.

Surface Tension measurement:
Measurements were carried out with a 10% shampoo dilution in distilled water at room temperature. Thoroughly clean the stalagnometer using chronic acid and purified water, because surface tension is highly affected with grease or other lubricants. The data calculated by following equation given below:
R2 = (W3-W1) n1× R1 (W2-W1) n2
Where, W1 is weight of empty beaker.
W2 is weight of beaker with distilled water. W3 is weight of beaker with shampoo solution. n1 is no. of drops of distilled water. n 2 is no. of drops of shampoo solution.
RI is surface tension of distilled water at room temperature.
R2 is surface tension of shampoo solution.
Water Content = Volume of water (ml) ×100/ weight of sample

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Observation :

Sr. No.	Parameters	Observation
1	Colour	Cream Colour
2	Odour	Characteristics
3	Clarity	Unclear
4	Foam producing Ability	Good ability
5	pH	Neutral
6	% of solid content	Sufficient 20.12
7	Dirt Dispersion	Light
8	Surface tension	Adequate 128.18
9	Foaming ability and foam stability	Good
10	Wetting time test	3 Sec
11	Specific Gravity	1.118

Result

100 ml of Methi-Shikakai shampoo was prepared and standardized.

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