WWW.IJRPR.COM

International Journal of Research Publication and Reviews

Journal homepage: www.ijrpr.com ISSN 2582-7421

REVIEW ON FORMULATION AND EVALUATION OF SUNSCREEN LOTION

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ABSTRACT:

The goal of this study was to create sun protection factor (SPF)-rich sunscreen cream compositions with desirable properties. There are disputable aspects to how the sun and skin interact. The most effective method to prevent sunburn and oedema is topical application of sunscreens (together with avoiding severe sun exposure). The water phase is used to make the sunscreen, and it contains citric acid as a preservative, Arabic gum as a thickening, glycerine as a moisturiser, and distilled water as the primary solvent. The stability, safety, and SPF of the sunscreen lotions were assessed after they were made using the three distinct compositions F1, F2, and F3. The sunscreen creams had SPF for normal skin and were non-mutagenic, non-irritating, stable, according to the results. This review study aimed to explain the classification, formulation, quality control, and evaluation of sunscreen use from a scientific standpoint.

Objectives;

1) To comprehend the 1940 Drug and Cosmetic Act and the cosmetics industry.
2) To comprehend the documentation needed for the creation of cosmetics.
3) To research the use of cGMP in cosmetic preparation.
4) Research the ICH Guidelines for stability studies.
5) To comprehend the information on anti-sunburn remedies.
6) To be aware of how sunscreen lotion is made.
7) To research the various production techniques employed in sunscreen lotion.

Introduction;

Cosmetic – Article designed for application, introduction, or alteration of the look without impacting structure or function.

Skin, moisturisers, lipstick, nail polish, eye and facial makeup products, shampoo, deodorant, and any material intended for use as a cosmetic product component are all included in this definition.

Some products have dual uses as drugs and cosmetics.

The term "cosmeceuticals" or "drug cosmetic product" is used to describe these.

Products includes,

Skin care products ,

Hair products

Nail products

Hygiene products

Fig.1:Pharmaceutical Marketing Strategies

All cosmetics are formulated as Solids, Semi-solid or Liquids.

Overview of Drug and Cosmetic Act 1940 and 1945

The Indian Parliament passed the Drug and Cosmetic Act of 1940, which governs the importation, production, and distribution of medications in India.
The main goal of the legislation is to make sure that all medications and cosmetics marketed in India are secure, efficient, and up to par with national standards.
The 1945 Drug and Cosmetic Rules stipulate that pharmaceuticals must be classified according to a schedule, and each schedule has certain storage, sales, display, and prescription requirements.

Prohibition of import of certain drugs or cosmetics.

No individual shall import goods after the date that the Central Government may have established in this regard by announcement in the Official Gazette.

1. any cosmetic or medicine that is not of standard quality: any counterfeit, misbranded, or fake cosmetic

2. any tampered with

3. any cosmetic drug that is imported in violation of the terms and conditions of the licence it was issued for; or any bogus cosmetic drug;

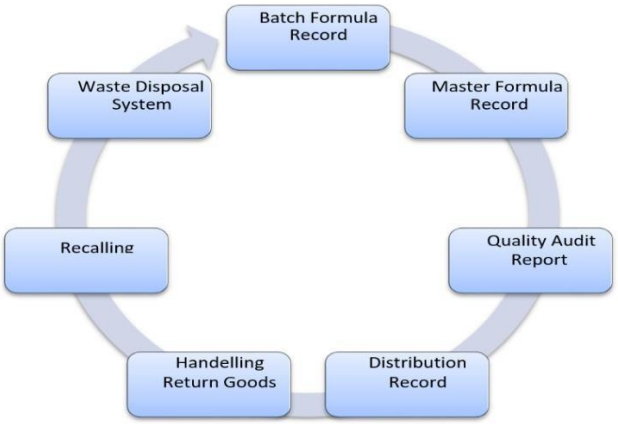
However, nothing in this section prohibits the importation of small amounts of any drug for personal use, under certain conditions, or for testing, analysing, or other purposes.:

Furthermore, it is provided that the Central Government may, following consultation with the Board, authorise the import of any drug that is not of standard quality, subject to any conditions outlined in the notification, by publication of a notice in the Official Gazette.

Certificate for the import of cosmetics Registration manufactured.-

For the import of one or more cosmetics made by the same producer, a single application may be submitted and a single Registration Certificate in Form 43 may be given.:

As long as the cosmetics are produced at a single plant or several factories working together as a single manufacturing unit.



1) Batch Formula Record

The batch manufacturing record (BMR) is a crucial piece of quality and GMP paperwork for tracing a batch's or lot's whole manufacturing cycle. BMR could be made in the regional tongue. BMR is a written record created throughout the pharmaceutical manufacturing process from the batch.

2) Master Formula Record

A master document for any pharmaceutical product is called a Master Formula Record (MFR).

- The MFR comprises all data pertaining to the product's production process.
- Manufacturing units prepare batch manufacturing records (BMR) using MFR as the reference standard.
- Master Manufacturing Record and Master Production Record are other names for MFR.

3) Quality Audit

A systematic and independent evaluation to ascertain if actions and associated results adhere to planned arrangements, as well as whether these arrangements are successfully carried out and appropriate to meet goals, is referred to as a quality audit.

4) Distribution Records

Distribution records are written information about how drug goods are distributed from manufacturers to distributors.

It is necessary to create distribution records and set procedures to enable the recall of defective products.

As a form of accountability, all records should be indexed by the production batch, lot number, or packaging control number.

5) RETURNED GOODS:

Pharmaceutical items may be recalled from the market for a number of reasons, including quality issues, unintentional product damage, etc. When such products are returned to stores, the following steps should be performed right away.

i. Examine the returned items' physical condition. Check all the pertinent paperwork, too.
ii. Request the quality control department to assess the received goods' quality and determine if they can be processed again, recovered, or need to be destroyed..

Relabeling, repackaging, and retailing such products after reprocessing or retesting may be considered if it is practicable to reprocess and recover.

6) Recalling

Recall is the term used to describe a company's removal or modification of a marketed product that the Food and Drug Administration believes to be in violation of the laws it oversees and for which the agency would take legal action, such as a seizure, against the company.

- **LIST OF INGREDIENT ON COSMETIC LABEL**

Truthful and accurate information regarding the cosmetic product, its intended use, and how it should be used should be included on the label. Before they can be sold or provided in Singapore, they must be labelled in compliance with the regulations and make promises that will NOT deceive the consumer about the product's contents, quality, or safety. Before providing a cosmetic product, suppliers such as wholesalers and retailers must ensure that the product complies with the regulations. Labels and labelling statements must be legible and written in English.

The following information must appear on the outer packaging or immediate container of thecosmetic products:

a. Name of the cosmetic product
b. Function of the cosmetic product
c. Instructions for use
d. Full ingredients listing
e. Country of manufacture
f. Contents (weight/volume) g. Batch number
g. Manufacturing/ expiry date (expiry date is only required for products with less than 30months

Stability Testing of New Drug Substances and Products
Photostability Testing of New Drug Substances and Products
Stability Testing for New Dosage Form
Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products
Evaluation of Stability Data
Stability Data Package for Registration Applications in Climatic Zones

Cleansing And Care needs ForFace

1. Cleansers are facial care products used to exfoliate dead skin cells, oil, grime, and other impurities from the skin of the face.
2. This facilitates pore cleaning and shields against skin issues like acne.
3. Dry skin needs far less washing force than very dry skin, which may call for a creamy lotion-type cleanser.
4. Choosing an alcohol-free cleanser for use on dry, sensitive, or dehydrated skin may be a smart option.

Cleansing And Care needs For Eye lids

1. Moisten a washcloth with a gentle cleaning solution after washing your hands.
2. Before opening your eyes, gently brush the washcloth along the borders of your eyelids, being careful not to press too hard.
3. Use warm water to rinse..
4. Apply the same procedure with a different washcloth on the opposite eye.

Cleansing And Care Needs For Gums

1. Using a soft-bristled brush and fluoride toothpaste, gently brush all surfaces of your teeth.
2. Every three to four months, change your toothbrush.

Cleansing And Care needs For Hairs

1. The word "hair care" refers to all aspects of hygiene and cosmetology that pertain to body hair, facial hair, pubic hair, and other hair that develops from the human scalp. Depending on a person's culture and the physical attributes of their hair, several hair care regimens are used.
2. Hair can be coloured, cut, shaved, plucked, or removed in other ways using procedures like waxing and threading.

TABLET PUNCHING MACHINE

Standard Operating Procedure:

1. Ensure that the die-locking screws are tight; otherwise, an accident may occur.
2. Verify that punches can move freely in the cam and die tracks.
3. Position the compression machine's force feeder/feed frame to minimise contact with the turret.
4. Put on the secondary overgown before beginning the procedure.
5. Avoid cleaning the compression machine while it is in use.
6. When the shift is over and the compression machine is stopped for an excessive amount of time, do not leave any grains in the hopper.

BROOKFIELD VISCOMETER

Standard Operating Procedure

1) Prepare gel using gel-forming materials (gelling agents) like carbopolor any other suitable polymer.
2) Keep the gel for at least whole one day for uniform dispersion andhomogenization.
3) After 24 hours, until there is enough gel in the beaker or gel holder provided by the manufacturer, at any moment when the gel is fully formed.Set up the base level of instrument using level indicator on the top of instrument andattach plug in for constant electric supply.
4) Clean the spindle and attach to the instrument

5) Rotate the spindle in the gel till you get the constant dial reading on the display of theviscometer.

COLONY COUNTER

Standard Operating Procedure

1. Ensure the instrument is kept clean and in the appropriate location.
2. Join the device to the primary power source..
3. Turn the instrument on.
4. Put the glass plate with the wolffhuegel grid on which the petridish holding the bacterial colonies is placed.
5. The instrument has a 100 mm-diameter magnifying lens and an auto penmarker that are attached to the 3 pin socket on the right side of the instrument.
6. Using the automatic marker pen, mark each colony by pressing the pen tip; the digital counter will then begin counting each colony one by one.
7. By pressing the centre push button switch, the counter may be reset to zero.
8. By pressing the pushbutton switch on the panel's lower front right side, counting can also be done manually without the use of a pen marker. The device shows four digit counters and emits a beep after each count.

CAPSULE FILLING MACHINE

Standard Operating Procedure

1. Fill the empty capsules in the loading tray.
2. Position the loading tray over the mattress.
3. Operate the cam handle to separate the capsule capsfrom their bodies.
4. Place the powder tray in proper position & fill itwith accurate quantity of powder.
5. Collect excess of powder on platform of powdertray.
6. Lower the pin plate while pressing the powdered mixture. The remaining powder is then added to the capsule bodies, and the pin plate is raised.Remove the powder tray after complete filling.
7. Place cap holding tray in position.
8. To lock the caps and bodies, lower the plate with the rubber top and pull the lever.
9. Remove the loading tray & collect the filled capsules.

HOMOGENIZER

Standard Operating Procedure

1. Wash the probe by using methanol.
2. Power on the switch.
3. Insert the probe into the sample and increase speedslowly by using external speed control unit.
4. After homogenising, gradually reduce the speed, turn off the homogenizer, and clean the probe by first wiping it with tissue paper to get rid of the majority of the sample ingredients, then using a toothpick to push particles out of the cutters. Rinsing with distilled water again and collecting the water in a waste container come next.
5. The probe shall then inserted into a 250 ml beaker containing distilled water andhomogenizer turn on for about 1 min. to flush the majority of remaining particlesfrom internal component of the shaft.
6. After finishing, cap the probe with a rubber stopper.

EXPERIMENTAL / HANDS ON ACTIVITIES Preparation and Evaluation of Sunscreen

Lotions Introduction

Sunscreen is a lotion or liquid that is applied to the skin to shield it from the sun's damaging rays and avoid sunburn.

Sunscreen, often known as sun-cream, sun block, suntan lotion, or any other topical preparation that reflects or absorbs some ultraviolet (UV) rays from the sun, aids in preventing sunburn.

One cosmetic product category, sunscreen, has been very popular in recent years due to extra health advantages beyond aesthetic ones. UVA and UVB radiation are the parts of ultraviolet (UV) radiation that are biologically active. The primary concurrent cause of skin photosensitization and phototoxicity is UVA radiation.

Advantage:

- Sunscreen guards against skin damage and lowers your chance of skin cancer and skin pre-cancers.
- Sunscreen protects every skin type.
- If you have a darker complexion, your skin's melanin provides some protection against sunburns, but you should still shield your skin from the sun's harmful ultraviolet rays.
- No specialised tools are required for preparation.
- Renewable resources.

Preparation:

Table 1: Formula of Sunscreen Lotion

	Ingredients	**Quantity wt% (gm)**	**Uses**
Fatty phase	Lanoline	4.5	moisturises the skin.
	Cocoa butter	2.0	Protective Barrier
	Bees Wax	3.0	Emollient
	Stearic acid	2.0	Lubricant and emulsifier
Aq. Base	Water	72.0	Vehicle
	Sorbitol	5.0	Humectant
	Triethanolamine	1.0	Stabilizer
	Benzyl alcohol	0.5	Preservative
UV Filter	Zinc oxide	10.0	Block uv rays
	Perfume	q.s.	Fragrance

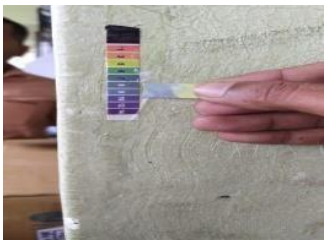
Procedure of sunscreen lotion:

1. Fill beaker A with the fatty phase ingredients and zinc oxide. Place beaker B on top.
2. Fill Beaker B with the aqueous phase components. Both are heated to 800C. until they dissolved.
3. After that, while continuously stirring, add the materials to beaker Binto A gently.
4. When the lotion reaches room temperature, add scent and pour it into the container.

- **Evaluation parameters:**

pH:

Measuring the pH! In order to measure the pH at 27°C using the pH metre, g of cream was dissolved in 9 ml of distilled water. The measured PH is 7.2, which is good for skin..



Determination of viscosity:

Procedure: Using spindle L3, the Brookfield Viscometer was used to measure the viscosity of the formulation at a speed of 25 rpm.

Spreadability:

The most popular technique for assessing the spreadability of semisolid preparations is the parallel plate approach. an altered Spreadability was assessed using lab equipment. Two glass slides are used in the arrangement, which also includes a tripod platform on which extra Lotion (3g) is placed.

between two glass slides, was applied. The lower slide was firmly fixed and the upper slide is moveable.

Irritation on Skin: To determine the lotion's impact on skin, it is applied to the skin. It is the best skin preparation if it has no negative effects on the skin.

Evaluation Test Result

Test	Specification	Result
Appearance	Colorless or White	White
pH	5.5-7.5	7.5
Homogenicity	Homogeneous or Consistent	**Homogeneous**
Texture	Smooth	**Smooth**
Washability	**Washable**	**Washable**

Outcomes:

I understood after finishing the paper on the preparation and evaluation of sunscreen lotion.

1. Recognised the 1940 Drug and Cosmetic Act and the cosmetic industry.
2. Recognised the need for documentation in the manufacture of cosmetics.
3. Researched the use of cGMP in cosmetic preparation.
4. Researched the stability study ICH guidelines.
5. Acquired understanding of sunburn prevention measures.
6. Recognised how sunscreen products are made.
7. Researched the various sunscreen lotion manufacturing procedures.

Conclusion:

A crucial part of sun protection is the application of sunscreen. UV radiation exposure is linked to a lower risk of a variety of skin problems and malignancies when used regularly and appropriately. Patients must also be warned not to rely only on the application of sunscreen. Thus, it can be said that there is a large market for sunscreen chemicals, whether they are synthetic, natural, or a combination of both, due to the awareness of the need for protection from harmful UVA and UVB rays.

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