International Journal of Research in Pharmacy and Pharmaceutical Sciences
www.pharmacyjournal.in
ISSN: 2455-698X
Received: 17-07-2023, Accepted: 03-08-2023, Published: 19-08-2023
Volume 8, Issue 3, 2023, Page No. 16-19

To study formulation, evaluation and stability testing methods of herbal cream as regulatory compliance

Arvind Gruwa[1], Rohit Verma[1], Suresh Kumar[1], Surinder Singh[1], Jagtar Singh Chohan[2*]
[1] Department of Pharmaceutics, Lord Shiva College of Pharmacy, Sirsa, Haryana, India
[2] Professor, Department of Pharmaceutics, Lord Shiva College of Pharmacy, Sirsa, Haryana, India

Abstract
Present study was started with an objective to know the formulation of multipurpose herbal cream as available and used in market for therapeutic and cosmetic purposes. Study aimed to know the optimum range of various ingredients used in the stable, effective and safe formulation along with a focus on various evaluation tests as reported in the literature. Finally it was interesting to study stability testing guidelines as a regulatory requirement implemented in various countries of the world. Various Stability Parameters and Stability testing methods are reported as available in literature. This review has been an effort to stimulate budding pharmacists at graduation level.

Keywords: Formulation, budding pharmacists, herbal cream

Introduction

1. Cream

Creams is defined as semisolid emulsions which are oil in water (o/w) or water in oil (w/o) type and these semisolid emulsions are intended for external application. [1] Creams are classified as oil in water and water in oil emulsion. It is applied on outer part or superficial part of the skin and its main ability to remain for a longer period of time at the site of application. [2]

The main function of a skin cream is to protect the skin against different environmental conditions/ weather and gives soothing effect to the skin. [2]

There are many types of creams like cold, foundation, cleansing, vanishing, night, massage, hand and body creams. [1] The main aim of our work is to help a formulator in developing a herbal cream which can give multipurpose effect like moisturizer, reduce acne, and skin irritation, reduce skin diseases like eczema, rashes, psoriasis, dry skin, wrinkles, etc., and also enhancing glow the face. [3]

2. Herbal Cream

It is defined as the beauty products which posses desirable physiological activity such as healing, smoothing appearance, enhancing and conditioning properties because of herbal ingredients. [3] Herbal creams are receiving more concentration in public because of their high quality properties and less side effects. These products are gaining momentum due variety of reasons. Additionally it also helps the skin to gain necessary nutrients and required moisture. [1]

The multipurpose herbal cream is basically water in oil type of emulsion. The natural ingredients chosen for preparation of herbal cream are turmeric, papaya, aloe-Vera, tulsi, and neem etc. The choice of these ingredients is based on their individual properties. [3] Aloe-Vera is used as a moisturizer and anti-acne agent. Turmeric is an Asian cosmetic useful to impart a golden radiance to the complexion. It also provides anti-inflammatory and antiseptic properties that is studied from the various formulation. [4]

3. Advantage of multipurpose herbal cream

In literature we have come across some most important advantages of herbal creams. Below are mentioned some of the most important advantages of multipurpose herbal cream:

3.1 It increases and helps in maintaining moisture in the skin. [2]

3.2 The herbal cream may be applied as acne reducing agent if formulation is composed so. [4]

3.3 This formulation by soothing action may prevent the skin irritation. [3]

3.4 The cream formulated with cosmetic angle, improves the individual's appearance. [5]

3.5 It is helpful in treatment of dry skin as it retains moisture. [6]

3.6 This preparation can remove wrinkles and rashes from the skin. [7]

These are some most important advantages of herbal aloe vera multipurpose cream.

4 Disadvantages of herbal multipurpose cream

An ideal formulation is desired by every formulator. However some undesirable facts are available. [8]

4.1 Manufacturing process is time consuming and complicated. [9]

4.2 In any pharmacopoeias specific procedure and quantity is not given. [10]

Formulation Reorts of Multipurpose Herbal Cream

A safe, effective and stable formulation is desired by every formulator and available information in literature helps a lot for making such formulation. Some of the important findings from literature are reported to help formulators of multipurpose herbal cream.

1. Composition of Formulation

1.1 Quality of a cosmetic formulation is depends upon the choice of ingredients used by the formulator. Normally literature has supported incorporation of Aloe-vera, Turmeric, Neem, Amla, Beeswax, Liquid Paraffin, Stearic

Acid, Tulsi, Borax, Methyl Paraben, Rose Oil, Distilled Water and Propyl Paraben in herbal Aloe-Vera multipurpose cream. [2] Aloe-Vera is an active ingredient in formulation due to its uses. [3]

1.2 The quantity of a herbal ingredient incorporated, varies from formulation to formulation. In some formulations the powdered form of Aloevera, Turmeric, Neem, Amla, Beeswax, Liquid Paraffin, Stearic Acid, and Tulsi etc., is used. Borax, Methyl Paraben, Rose Oil, Distilled Water and Propyl Paraben are also mentioned in literature as used for the preparation of herbal multipurpose cream. [1, 3]

1.3 It is has been noted that the extracts of ingredients like Aloevera, Turmeric, Neem, Amla, Tulsi, etc. have been formulated with Beeswax, Liquid Paraffin, Stearic Acid, Borax, Methyl Paraben, Rose Oil, Distilled Water and Propyl Paraben to receive best results of preparation. [6, 7]

1.4 After going through composition of various formulations we have arrived at that Aloe-Vera when incorporated in powdered form in the formulation the lower to higher percentage range is from 13.33%W/v to 21.05%W/v. In the study of another formulation the aloe vera is taken in the liquid extract form that varies the quantity from 7.5% v/v to 14.3%v/v. [2, 4]

1.5 Similarly, the quantity of Turmeric in powdered form in different formulation is reported from 5.26%w/v to 6.66%w/v in the formulation of herbal multipurpose cream. [4]

1.6 In the case of Neem as herbal ingredient the quantity used ranges from 5.26% w/v to 13.33% w/v in the formulation of herbal cream by formulator and in another formulation it the quantity is reported from 2.2% v/v to q.s. [7]

1.7 Similarly, Beeswax is included in formulation as emulsifier, stabilizer, and thickener agent and its quantity is used may be from 6.66%w/v to 21.05%w/v. [1]

1.8 In the study of different different formulation the quantity of amla is given from the 6.66% w/v to 10.52% w/v. [4]

1.9 In one study in a formulation it is found that the ingredient *Viz.* Liquid Paraffin is used from 19.6%w/v to 21.05%w/v and in another formulation the liquid paraffin is taken up to 50%v/v in the formulation of herbal multipurpose cream. [2, 5]

1.10 Likewise the use of stearic acid for the formulation of herbal multipurpose cream is found to vary from 13.33% w/v to 15.78% w/v. [3]

1.11 Rose oil is used in the formulations from 0.001%v/v to 0.25%v/v. [1, 2]

1.12 It is found that the inclusion of Tulsi varies in cream formulations from 5.2% v/v to 7.5% v/v. [7, 10]

1.13 The borax is used in the preparation and formulation of herbal multipurpose cream, varies from the 0.1% w/v to 0.4% w/v. [1]

1.14 Similarly the ingredient methyl paraben is included in the formulation may be from 0.002% v/v to 0.4% v/v. [1, 7]

1.15 The quantity of distilled water is taken by formulator from 14.6% v/v to 16.3% v/v in the preparation of various herbal multipurpose cream. [1, 5]

2 Importance of Ingredients

The success of a formulation of multipurpose herbal cream rests in the selection and incorporation in optimum amounts. In last section we have reported the range of each ingredient which varies not only from one formulation to another formulation but also from one formulator to another formulator. The ingredients lend themselves for inclusion in the formulation owing to their role. Some of the uses mentioned in literature are reported as under.

2.1 Aloevera is good protector against UV rays of sun or short wave radiation. It is an antiageing, anti-inflammatory, moisturizer, reduce acne and pimples. [2]

2.2 Neem helps in fighting the skin infections, promotes wound healing, combat signs of skin aging, relieves skin dryness, itching and redness. [4]

2.3 Bees wax is emulsifying agent, stabilizer and gives thickness to the herbal cream. This can create a protective layer on the skin. [3]

2.4 Liquid paraffin is a lubricant that is used in the treatment of dry Skin in herbal aloe-vera cream. [2, 4]

2.5 Rose oil good for dark circles, oily skin, and skin whitening. Rose oil is well known for its antidepressant, antiseptic, antispasmodic, and anti-viral properties shown on face. [8, 10]

2.6 Tulsi preventing blackheads, acne and relieves skin infections. It is used to add glow to the skin and to promote wound healing. [3]

2.7 Borax is used in the herbal cream to prevent or slow bacterial growth. Alkaline agent which reacts with emulsifying agent to form herbal cream. [5]

2.8 Methyl paraben is most common used for antimicrobial preservation in the herbal aloe-vera cream. [2, 3]

2.9 Distilled water dissolves many of the ingredients that impart skin benefits. [1]

2.10 Turmeric can glow your skin and given as antiseptic, anti- inflammatory properties in herbal cream. [10]

2.11 Amla is used in herbal cream for antioxidant properties. [7]

2.12 Stearic Acid is used as emulsifier agent in the multipurpose herbal cream. [4]

2.13 Propyl Paraben is used for preservation of herbal cream and give an effective result for dry skin. [7]

Evaluation of Multipurpose Herbal Cream

Formulated herbal cream is required to be further evaluated by using the following physical parameter physical parameter color, odor, consistency, and state of the formulation. The formulation should be evaluated for different tests. Through the study of different research articles or review articles it is noted that the following different evaluation tests are performed for stability testing of herbal multipurpose cream.

1. **pH:** The pH of prepared herbal cream is measured by using digital ph meter. The pH meter is calibrated using standard buffer solution. [5] About 0.5g of the cream is weighed and dissolved in 50.0 ml of distilled water and its pH is measured. [2]

2. **Color and order:** The color and order of the herbal multipurpose cream is observed by visual examination and compared to same given in regulatory guidelines issued by Authoritiies. [1]

3. **Homogeneity:** The herbal multipurpose cream are tested for the homogeneity by visual appearance and by touch. [12]

4. **Type of emulsion under dye test:** The scarlet red dye is mixed with the cream. A drop of the cream spread on a microscopic slide, then it enclosed with a cover slip and examined under a microscope.[14] If the disperse globules appear red and the ground is colorless, the cream is O/W type. The reverse condition occurs in W/O type cream i.e. the disperse globules appear colorless in the red ground. [15]

5. **Viscosity:** Viscosity measurements of the herbal multipurpose cream is determined using rotational-type viscometer (Brookfield DVII, Germany TA spindle, 25±1°C). [9] Measurements are taken in 3 replications in 100 rpm (n: 3). The viscosity values recorded in centipoises (cP). [4]

6. **Type of smear:** After application of cream, the type of film or smear formed on the skin are checked. [16]

7. **Irritancy test:** Mark an area (1sq.cm) on the left hand dorsal surface. The cream is applied to the specified area and time is noted. [12] Irritancy, erythema, and edema, are checked if any for regular intervals up to 24 hrs and reported. [4]

8. **Accelerated stability testing:** Accelerated stability testing of prepared herbal multipurpose cream is conducted for 2 most stable formulations at room temperature, studied for 7 days. [8] They are at 40ºC ± 1ºC for 20 days. The herbal multipurpose cream are kept both at room and elevated temperature and observed on 0th, 5th, 10th, 15th and 20th day for the different parameters. [16]

Stability Testing Methods and Storage conditions used for long-term stability of herbal multipurpose cream

1. It is observed from evaluating the different articles and reviews of research published by different formulators that the global regulations for the stability testing of finished herbal multipurpose cream under long-term, accelerated, and intermediated conditions require that the frequency of stability studies be sufficient to establish a herbal cream stability profile throughout its proposed shelf-life, especially for long-term stability testing.
2. Herbal multipurpose cream should be evaluated in terms of thermal stability or moisture susceptibility based on consideration of durations of storage, transportation, and use. [6]
3. Moreover, the effects of storage temperature and moisture (relative humidity) should be adequately considered as they are the most influential factors for quality of herbal multipurpose cream. [16]
4. Herbal multipurpose cream are packed in either general, semipermeable (allows solvent or moisture migration through the container surface), or impermeable containers, which influence the effects of storage temperature and relative humidity. [14, 16]
5. The Long-term stability testing (real-time stability testing), accelerated testing, and intermediate testing (if necessary) are usually undertaken according to established period to confirm the shelf-life of herbal multipurpose cream during the proposed testing period under storage conditions. [15]
6. Long-term testing for herbal multipurpose cream is carried out for less than 12 months by most authorities, though some including ASEAN, China, Hong Kong, Korea, and Zambia conduct long-term testing for more than 12 months. The storage test temperatures used are 25°C± 2°C or 30°C± 2°C with relative humidity of 60% ± 5%, 65% ± 5%, or 75% ± 5% (in general containers), or 35% ± 5% or 40% ± 5% (in semipermeable containers) under ambient storage conditions.[6] For refrigeration of herbal multipurpose cream, the testing temperature used for general containers by most authorities is 5°C± 3°C, except by Chinese authorities who adopt 6° C ± 2°C for general containers. All authorities use a freezing temperature of − 20°C± 5° C. [15]
7. Most global authorities and countries conduct accelerated testing for a herbal multipurpose cream for ≤6 months, except Korea (>6 months). [16]
8. Ambient testing temperature for herbal multipurpose cream is 40°C± 2°C with 75% ± 5% RH for in general container or 12 months) at 30°C± 2°C by all authorities and an RH of 65% ± 5% for general and semipermeable containers uses for a herbal multipurpose cream or RH of 35% ± 5% for semipermeable containers as required by the EEC, WHO, and Republic of Korea for herbal cream. [6]
9. Accelerated stability testing of formulations is conducted for 2 most stable formulations at room temperature, studied for 7 days at 40oC ± 1oC for 20 days. The formulations are kept both at room and elevated temperature and observed on 0th, 5th, 10th, 15th and 20th day for the different parameters. [5]

Stability Testing Parameters and Research Studies for herbal multipurpose cream

We studied from the different different review articles the stability of a herbal multipurpose cream containing Glycyrrhiza uralensis pH, UV absorbance, viscosity, and color changes at different temperatures (4°C, 25°C, 37°C, and 45°C) and in sunlight for 12 week. [6] We studied that a Neem (*Azadirachta indica*) and Turmeric (*Curcuma longa*) extract containing ointment and evaluated color, odor, pH, spreadability, extrudability, consistency, diffusion, solubility, washability, and irritancy after storage at different temperatures (2°C, 25°C, and 37°C) over four weeks. [14]

Results

We arrived at following results;

1. From this study we have come to know about different herbal components and other additives which are used to formulate a stable, safe and effective multipurpose herbal cream.
2. We are satisfied after going through various regulatory guidelines to understand the requirements of stability parameters and stability methods.

References

1. Vanarase NF, Tambe B. Formulation and evaluation of herbal multipurpose cream. International Journal of Pharmaceutical Research and Applications,2023:8(2):514-518.
2. Navindgikar NN, Kamalapurkar KA, Chavan PS. Formulation and evaluation of multipurpose herbal

cream. International Journal of Current Pharmaceutical Research,2020:12(3):25-30.
3. Davkhar SS, Bhandari AS, Akolkar SA. Formulation and evaluation of multipurpose herbal cream. A Multifaceted Review Journal in the Field of Pharmacy,2023:14(1):23-28.
4. Dhyani A, Chander V, Singh N. Formulation and evaluation of multipurpose herbal cream. Journal of Drug Delivery and Therapeutics,2019:9(2):341-3.
5. Patil B, Yadav N, Yadav G, Yadav S, Yadav S, Takarkhede S. Formulation & evaluation of multipurpose herbal cream. Journal of Emerging Technologies and Innovative Research,2022:9(3):310320.
6. Kim J-H, Lee K, Jerng UM, Choi G. Global comparison of stability testing parameters and testing methods for finished herbal products. Evidence based Complementary and Alternative Medicines,2019:(4):1-14.
7. Mali as, Karekar P, Yadav AV. Formulation and evaluation of multipurpose herbal cream. International Journal of Science and Research, 2013, 1495-1498.
8. Banjare L, Kashyap P. Formulation and evaluation of herbal multipurpose cream. International Journal of Pharmacy & Therapeutics,2014:5(1):5-8.
9. Sharma P, Kharkwal A, Kharkwal H, Abdin MZ. A review on the pharmacological properties of Aloe Vera. International Journal of Pharmaceutical Research and Science,2014:29(2):31-37.
10. Sawant SE, Tajane MD. Formulation and evaluation of herbal ointment containing neem and turmeric extract. Journal of Scientific and Innovative Research,2016:5(4):149-151.
11. Singh M, Sharma S, Khokra SL, Sahu RK, Jangde R. Preparation and evaluation of herbal cosmetic cream. Pharmacology online,2011:2:1258-1264.
12. Sharma P, Tomer L, Bachwani M, Bansal V. Review on neem (Azadirachtaindica): thousand problems one solution. International Research Journal of Pharmacy,2011:2(12):97-102.
13. Kumar KPS, Bhowmik D, Chirnjib, Biswajit, Pankaj, Tripathi KK, *et al*. Traditional indian herbal plants tulsi and its medical importance. Research Journal Of Pharmacognosy and Phytochemistry,2010:292:103-108.
14. Sonalkar MY, Nitave SA. Formulation and evaluation of polyherbalcosmetic cream. World Journal of Pharmacy and Pharmaceutical Science,2015:5:772-779.
15. ICH Q1A (R2) Stability testing of new drug substances and drug products. European Medicines Agency, 2003.
16. Rignall A, ICHQ1A (R2) stability testing of new drug substances and product and ICHQ1C stability testing of new dosage form. ICH quality guidelines, 2017.