



## To review formulation and evaluation of herbal vanishing cream and report regulatory compliance across globe

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### Abstract

The purpose of the present study was to review formulation and suggest general evaluation for vanishing herbal cream. Literature was studied in various National and International Journals regarding formulations of Vanishing herbal cream. A large number of research papers were studied in order to know the composition of various formulations of Vanishing Herbal Cream. Other additives were also studied apart from herbal components. We arrived at the conclusion that the quantity of each component of a Vanishing Herbal Cream varies from formulation to formulation and the inclusion or exclusion of a particular herb in the formulation depends on the need of formulation governed by market or prescription or cosmetic or therapeutic purpose.

**Keywords:** Vanishing herbal cream, evaluation of herbal formulation, therapeutic role, cosmetic value etc.

### Introduction

Herbal extracts are utilized nowadays to improve appearance and attractiveness in cosmetic preparations apart from their therapeutic role. The dosage form, such as cream, powder, soap, or solution, as well as the part or organ to which it would be administered, such as "cosmetic for skin" [1], are used to categorize herbal cosmetics. Creams are semisolid emulsions that are meant to be applied to the skin or mucous membrane. Herbal vanishing cream is a type of cream that, when applied to the skin, transforms into a low-fat moisturizer that vanishes into the skin. Skin is softened without any after-effects [2]. Technically speaking, disappearing creams are (o/w) emulsion-based products that contain both an aqueous phase and an oil phase [3]. When creating an emulsion, the dispersed oil phase makes up a smaller fraction of the mixture than the aqueous phase does. Literature reports that depending on the proportion of water to grease, cream can be water miscible and washed away easily or be thick and sticky. It is perhaps the commonest prescribed topical medicament as it is less oily, messy and sticky; most people find it more user-friendly [4].

Understanding the meaning of the word, Vanishing just means that it is 'vanished or disappeared' after applicators' skin absorbs it. The basic idea of skin care cosmetics lies deeper in the Rigveda where it is found that a variety of properties like antioxidant, antiseptic, anti-inflammatory and antibacterial etc [5]. becomes the logic behind formulating a cosmetic as herbal vanishing cream.

According to research, depending on their medicinal or additive value, this herbal vanishing cream may contain a variety of extracts or dry powders of crude pharmaceuticals, such as *Calendula officinalis*, family-compositae. Similar to this, *Azadirachta indica*, a member of the meliaceae family, provides healing properties for a number of skin problems in addition to its beauty promoting potential. Similar to this, proponents of Turmeric *Viz.*, *Curcuma longa*, family Zingiberaceae, advocate for an expanded function in infectious disorders and inflammation. Additional nutmeg,

*Myristica fragrans*, family Myristicaceae, cinnamon, or *Cinnamomum zeylanicum*, family Lauraceae, Tulsi, also known as *Ocimum sanctum*, family Lamiaceae, and clove, also known as *Eugenia caryophyllus*, family Myrtaceae [3], are useful in vanishing herbal cream both as beautifying agents and for their therapeutic functions.

### 1. Vanishing Cream

This type of cream gets its name because, when applied to the skin, it appears to vanish.

### 2. Herbal vanishing cream

The herbal cream is also prepared by the (o/w) type of emulsion method. Extract/s of herbal crude drug/s is/are used in the preparation of herbal vanishing cream thus that gives a name *viz.* herbal vanishing cream to it.

### 3. Advantages

The herbal vanishing cream plays an important role in moisturising the skin and thus earns it a name as cleanser.

The herbal vanishing cream gives prolonged contact at the site of application.

When herbal vanishing cream is applied to skin it gives no irritation and easily water washable from the skin.

The herbal vanishing cream has negligible side effect because of herbal ingredients that are used in their formulation.

Herbal vanishing cream is easy to apply on the skin due to their high spreading ability.

The Herbal vanishing cream is also used as it is a good skin protector.

In case medicated, more safely drug delivery to a specific site.

### 4. Disadvantages

In the herbal vanishing cream the large particle of herbal excipients delays absorption from topical dosage form.

The inflammation may occur when herbal vanishing cream is applied to skin.

## 5. Types of herbal skin cream

They are divided into two types

1. Oil-in-Water (O/W) creams which are composed of small droplets of oil dispersed in a continuous phase, and an emulsion in which the oil is dispersed as droplets throughout the aqueous phase is termed an oil-in-water (O/W) emulsion.
2. Water-in-Oil (W/O) creams which are composed of small droplets of water dispersed in a continuous oily phase. When water is the dispersed phase and oils the dispersion medium, the emulsion is of the water-in-oil (W/O) emulsion.

### Ideal properties of herbal vanishing cream

The herbal vanishing cream should be non-dehydrating.

The vanishing cream should be non-greasy and non-staining.

It should be Non hygroscopic.

They should be having high aqueous wash ability.

### 1. Physiological properties of herbal vanishing cream

They should be non irritating when applied to the skin.

It should be miscible with skin secretion.

Do not alter the skin functioning.

### 2. Application properties of herbal vanishing cream

The herbal should have high aqueous wash ability.

It should be easily spread on the surface of skin.

### 3. Role of herbal vanishing cream in therapy

It is used to prevent and treat dry skin.

Treat skin condition such as eczema and acne and blackheads.

The cream also acts as a fairness expert in day-to-day life removing aging sings.

It helps in softens skin.

## Preparation and Evaluation of Herbal Vanishing Cream

### 1. Components of Preparation as reported

Herbal components are selected based on the phytoconstituents present in the herb or herbal part being selected for getting incorporated in the formulation.

### 2. Skin

Skin is the largest organ of the body which is made up of three layers (epidermis layer, dermis layer, hypodermis layer). One of the main functions of the skin is protection. It protects the body from bacteria, germs, etc. also it regulate the body temperature.

### 3. Importance of formulation

In the modern era everyone wants to look smart, attractive, and to have a fair skin. Therefore they start to think and care their skin by applying so many cosmetic especially of Herbal products on the surface of their skin for a variety of purposes. The skin is also used for a transdermal drug delivery technology based designed system though this is not of our much concern in this study.

### 4. Additives in Herbal formulation

There are various herbal formulations of vanishing cream which are available in the market. In the literature we have found that the main ingredients apart from the Herbs/Herbal

extract are steric acid, potassium hydroxide, glycerin, water, methyl paraben, sodium carbonate, and etc.

## 5. Herbal Components

Neem extract, turmeric extract, essential oils etc. are a few to illustrate.

We have studied vanishing cream containing crude drugs. Shined and Chula have formulated vanishing herbal cream by incorporating alcoholic extract of *calendula officinalis*, *azadirachta indica*, *curcuma longa*, *Myristica fragrans*, and *cinnamomum zeylanicum* [7].

In another herbal formulation of vanishing cream Nived krishnan at el. have added an alcoholic extract of *Azadirachta indica* up to 2.38% and alcoholic extract of *Curcuma longa* up to 1.94%. Interesting it was found that they have added alcoholic extract of neem and turmeric 4.32% for best results [8].

On the behalf of another formulation of herbal vanishing cream reported by Mohd Fahad Uddin et al., we found that perfuming agent can be used up to 0.5% in the formulation for a better fragrance [9].

We studied a paper by Saurabh Kumar and Shashikant Msury and we found that the use of stearic acid up to 17-18% and potassium hydroxide up to 0.5% in formulation of herbal vanishing cream [10].

In the another formulation of herbal vanishing cream Seema Y Mendekar at el. we got the point that sodium carbonate can be used up to 0.5% and the other ingredient is incorporated water up to 71% and glycerin up to 6% in the formulation of herbal vanishing cream for getting the better result.

The different-different herbal alcoholic extract like *Azadirachta indica*, *curcuma longa*, *citrus limon*, *mentha piperita*, *apis mellifera*, *prunus dulcis*, *zingerber officinale*, *brassica juncea* and *cicer arietinum* etc. can be used in the formulation of herbal vanishing cream as individual or poly herbal extract for the therapeutic purposes of the cream [11].

Resultant the mixture of these drugs for their formulation the percentage up to 4.5% of the alcoholic extract can be used for the formulation of herbal vanishing cream.

### 5.1 The various crude drugs are used in the formulation of herbal vanishing cream for their different uses

Longa pepper, Nagarmotha plant and Nutmeg are used in the formulation of herbal vanishing cream for their Antioxident property [9].

#### Nagarmotha plant

It is used due to promising role as anti-inflammatory after applying on the skin.

It is a muscles relaxant and useful in the pain reduction.

#### Turmeric

it is used for their anti-inflammatory and anti microbial property in the formulation of herbal vanishing cream.

### In above herbal formulation of vanishing cream various additives are used for their different roles

#### Stearic acid

It is an emulsifying agent which is used as to softener to the skin.

It helps to moisturize the skin and also used as effective stabilizer in the formulation of herbal vanishing cream.

### **Glycerin**

It helps to soften and protect the skin.

Glycerin also act as a humectant which helps to prevent the herbal vanishing cream dry out.

### **Methyl Paraben**

Methyl paraben act as a preservative in the formulated herbal vanishing cream.

### **Potassium hydroxide**

It is a highly alkaline ingredient which is used in small amount in herbal vanishing cream to modulate their pH.

### **Sodium carbonate**

Sodium carbonate is used as it breaks down the dirt and oil from the hair and the skin.

### **Evaluation of Herbal Vanishing Cream**

The basic three requirements of a cosmetic or therapeutic herbal vanishing cream or other herbal products are their safety, effectiveness and stability. Evaluation tests need equal attention of analyst as required by the formulator during formulation. Literature mentions following tests for testing herbal vanishing cream.

#### **1. Spreadability test**

For this test, 500mg of the herbal vanishing cream is sandwiched between 2 glass slides. A weight of 100gm is placed on upper slide. The weight is removed and extra formulation is to be scrapped off. The analyst has to fix lower slide on board of apparatus and upper slide is fixed with non flexible string on which 20g load is applied. Time taken by upper slide to slip off has to be noted down<sup>[12]</sup>. An ideal formulation gives Uniform Spreadability with a value of around 30 g.cm per second.

#### **2. Dye test**

The test is performed to know whether the inversion of emulsion phases has taken place or not. Test initiates with the mixing the cream sample with red dye followed by placing the drop of cream on a slide and is covered with cover slip. It is observed under microscope. If the dispersion phase appears in red colored globules it implies that the cream is an O/W type of emulsion and in contrary, if the continuous phase catches red color, the cream is believed to be w/o type<sup>[12]</sup>.

#### **3. Determination of organoleptic properties**

The appearance of the cream is judged by sense organs. Evaluator notes color, pearlescence and roughness and gives grade to the herbal formulation<sup>[12]</sup>.

#### **4. pH**

The pH meter is required to be calibrated and is used to measure the pH by placing the measuring rod in the beaker containing 20mg of the cream<sup>[14]</sup>.

#### **5. Determination of homogeneity**

The formulations were tested for the homogeneity by visual appearance and by touch.

#### **6. Determination of viscosity**

The viscosity determination is carried out using a Brookfield Viscometer (DV II+ Pro model) using spindle

number S-64 at a 20 rpm at a temperature of 25°C. The determinations are carried out in triplicate and the average of three readings is recorded<sup>[15]</sup>.

#### **7. Irritancy test**

The cream has to be applied on left hand dorsal side surface of 1sq.cm and observed in equal intervals up to 24hrs for irritancy, redness and edema<sup>[16]</sup>.

#### **8. Appearance**

Test is carried out by physical testing. Appearance of the cream is observed by identifying its colour and opacity and data is recorded.

#### **9. Smear Test**

The test is conducted after applying a sample of cream on the skin and a smear is allowed to be formed. The nature of oily or aqueous formed smear is reported.

#### **10. Removal**

The removal of the cream must be easy and without any external friction or rubbing. Part of the skin on which cream was applied is washed under tape water with minimal force to remove the cream.

#### **Stability Testing Parameters across Globe**

As reported by Jung-Hoon Kim *et al.*, 2019, regulatory authorities worldwide have issued regulations or guidelines for stability, safety and efficacy testing parameters and testing procedures for herbal vanishing cream stored in proposed conditions. These testing parameters and methods for finished herbal vanishing cream are detailed in the guidelines and regulations issued by 5 global authorities and 15 countries, that is,

1. The Association of Southeast Asian Nations (ASEAN),
2. The Eurasian Economic Commission (EEC),
3. The European Medicines Agency (EMA),
4. The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH),
5. The World Health Organization (WHO).

The fifteen countries which have issued above guidelines are named in alphabetical order as follows: Australia, Brazil, Canada, China, Egypt, Hong Kong, India, Japan, Kenya, Republic of Korea, The Philippines, Qatar, Switzerland, USA, and Zambia.

The stabilities of herbal vanishing cream can be determined by testing for properties susceptible to storage conditions and include physical (organoleptic characteristics, physical condition, particle size, etc.), chemical (assays of active components, pH, identification, etc.), microbial, and toxicological properties. These properties can all affect the quality, safety, or the efficacy of herbal vanishing cream, and thus, the shelf lives of vanishing herbal cream should be determined by stability testing<sup>[17]</sup>.

In context of development of herbal vanishing cream a global harmonization of stability testing is emphasized or sharing of information and experience of Herbal Scientist can find the ways for adopting of international standards.<sup>18</sup>

In the present study we have tried to focus on stability testing parameters and methods used Herbal vanishing Cream.

We have collected the information from the guideline and regulation formed by global authorities. (Viz. WHO, ICH, ASEAN, EEC, EMA). Apart from this we have taken the information from guidelines and regulation issued by individual Nation. (Viz. As mentioned above.)

### Stability Testing of Herbal Vanishing Cream

We have collected guidelines and regulations from global authorities and countries where the stability testing is required for quality maintenance for herbal vanishing cream. Testing parameters provided according to long term accelerated and intermediate testing. Guidelines and regulation which require quality of therapeutic extract were used in the herbal vanishing cream.

#### 1. Stability Testing Parameters as required by global regulatory Authorities

Regulatory authorities worldwide have issued regulations or guidelines for stability, safety and efficacy testing parameters and testing procedures for various preparations. We are focusing on the regulatory compliance as it applies to herbal vanishing cream stored in proposed conditions. These are given as under.

##### 1.1 ASEAN

ASEAN issues the stability testing guidelines for the semisolid preparations for the better quality, safety, and efficacy. The ASEAN authorities provide the some organoleptic characteristics, assay, viscosity, pH and microbial content for testing the herbal vanishing cream.

##### 1.2 The EEC

The EEC requires storage stability studies for the Herbal Vanishing Cream. In the EEC the medicament Herbal Vanishing Cream is tested to test the transparency, homogeneity, pH value microbiological purity and weight loss<sup>[19]</sup>.

##### 1.3 The EMA

The EMA requires product specific storage stability testing of herbal vanishing cream. The EMA authorities tested the purity and microbial content in the vanishing cream. For the better storage stability some preservatives are added in finished herbal vanishing cream.

##### 1.4 ICH

ICH guidelines provide general requirements for the storage stability testing of herbal vanishing cream that cover chemical substances with respect to description, identification, assay, and impurity contents. The ICH guideline are also applicable to herbal vanishing cream as global documents regulated by EMA, Australia, Japan, Switzerland are conducted in accordance with ICH guidelines. The parameter for stability testing for herbal vanishing cream is same as given in EMA, EEC authorities<sup>[20]</sup>.

##### 1.5 WHO

The WHO expert committee publishes technical reports annually on specifications for pharmaceutical preparations and guidelines on good herbal vanishing cream and on stability testing for creams is clarity, homogeneity, pH, viscosity. General requirements of the stabilities of *finished pharmaceutical products* include appearance, assay, and degradation products and preservative and antioxidant content.

## 2 Regulatory Compliance for stability Parameters' testing in Individual Countries

### 2.1 Australia

Australian govt. provides mandatory guidelines for the stability testing of vanishing herbal cream is direct comparison. Stability testing for determining shelf lives and recommended storage conditions is performed as described in the EMA guideline, Guideline on stability testing: stability testing of existing active substances and related finished herbal vanishing cream.<sup>21</sup> Products with significant water content for example: creams are likely to support microbial growth. Such products should include tests and limits for microbial content in both the batch release and expiry specifications.

### 2.2 Brazil

Brazilian Health Regulatory Agency (ANVISA) adopts the position that stabilities herbal products depending on environmental factors (temperature, humidity, and light) as well as product-related parameters like physical and chemical properties of active substances and excipients, pharmaceutical form, product composition, manufacture, and properties of packaging materials. ANVISA provides these stability parameters for creams; description, pH, uniformity of dose unit, average weight, phase separation, and active component content.

### 2.3 Canada

Canadian government requires storage stability testing for natural herbal vanishing cream to determine shelf lives after packing and storage conditions. These tests address purity, physical characteristics, level of medicinal ingredients quantity per dosage unit, and potency

### 2.4 Hong Kong

The legislative council of Hong Kong prescribes that stability assessment of proprietary Chinese medicines is necessary to determine the shelf lives in sales packaging at room temperature or under proposed storage conditions, as described by *Product quality documents Technical guidelines*<sup>[23]</sup>. The Hong Kong government provides stability testing parameters for herbal vanishing cream. It should not be skin irritant.

### 2.5 India

Indian govt. specifies the requirements for the quality test of herbal vanishing cream used in Ayurvedic, Sidhha, and Unani system of medicine. The herbal vanishing cream is tested in tradition system of medicine<sup>[24]</sup>.

### 2.6 Japan

The Japan govt. has provided the quality testing parameters for herbal vanishing cream under guidelines of Ministry of health, labor and welfare. The quality parameters of herbal vanishing cream is; uniformity of dosage, irritation level.

### 2.7 Republic of Korea

The ministry of food and drug safety (MFDS) requires the result of stability test conducted which provides the accelerated and intermediate storage condition to herbal vanishing cream. The microbial limits, particle size distribution, and uniformity of dosage is must be tested<sup>[25]</sup>.

## 2.8 The Philippines

The food and drug bureau of the Philippines requires the stability testing of finished herbal vanishing cream for the appropriate storage condition and shelf life. The govt. also requires the quality standards and test for the herbal vanishing cream like pH, melting point, microbial test, homogeneity [26].

## 2.9 Switzerland

The Switzerland govt. provides the quality testing parameters for the herbal vanishing cream according to ICH guidelines which include the parameter such as identity, loss on drying, assay, and microbial purity [27].

## 2.10 USA

The food and drug administration (FDA) requires the stability of herbal vanishing cream. The herbal vanishing cream will be monitored using stability related analytical methods or biological assay. The quality testing is done by testing microbial limits.

## 2.11 Zambia

The Zambian govt. requires specification and testing methods of herbal vanishing cream with their guidelines for the registration of herbal cream, which includes the physical, chemical, and biological parameters like purity, transparency, assay, microbial limits.

## 3. Common Testing Parameters of Herbal Vanishing Cream

As per the global authorities requirements of herbal vanishing cream it should pass the testing parameters which are categorized in the three forms:

### 3.1 Physical parameters

The transparency / clarity / homogeneity must be required in the formulated herbal vanishing cream as per the guidelines of global authorities.

The weight variation and uniformity of dose is essential in the formulated herbal vanishing cream as per the global authorities' guidelines.

Optimum viscosity of herbal vanishing cream is essential as per the guidelines; variation in viscosity may cause fluidity of vanishing cream.

### 3.2 Chemical parameters

The optimum pH is required in herbal vanishing cream as per the guidelines; variation in the pH may cause skin irritancy.

The minimum extractable volume to be decided as per the global authorities guidelines, which must be fulfilled by the herbal vanishing cream.

### 3.3 Biological parameters

The herbal vanishing cream must be sterile and microbial free as per the guidelines of global authorities, if the cream not be sterile the microbial contamination will start in the cream and it will reject by the global authorities.

## Stability Testing Conditions for herbal vanishing cream Across the Globe

Global regulations for the stability testing of finished herbal vanishing cream under long term, accelerated and intermediated conditions requires that the frequency of

stability studies must be sufficient to establish a stability profile and throughout its proposed shelf life especially for long term stability testing. The herbal vanishing cream should be evaluated in terms of thermal or moisture susceptibility based on duration of storage.

In general Long-term stability testing or real-time stability testing, accelerated testing, and intermediate testing incase necessary, are usually undertaken according to established period to confirm the shelf-life of herbal products during the proposed testing period under storage conditions.

It is reported from above study that long term testing is carried out for less than 12 months by most authorities and Specific guidelines issued by many countries, though some including ASEAN, China, Hong Kong, Korea, Zambia have guidelines to conduct long term testing for more than 12 months. The storage test temperatures used for stability studies are  $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$  or  $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$  or  $30^{\circ}\text{C}$  with corresponding relative humidity of  $60\% \pm 5\%$ ,  $65\% \pm 5\%$ , or  $75\% \pm 5\%$  for product in moisture permeable containers, and at  $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$  or  $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$  with corresponding relative humidity of  $40\% \pm 5\%$  or  $45\% \pm 5\%$  for a product packed in semi-permeable containers under ambient storage conditions [28].

In the world, most global authorities and countries have provisions to conduct accelerated testing for less than 6 months, except Korea where time exceeds six months. Ambient testing temperature is  $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$  with  $75\% \pm 5\%$  RH for in general container or below 25% for in semi-permeable containers in most cases. The Chinese guideline adds  $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$  and  $65\% \pm 5\%$  RH for testing ointments and creams including vanishing herbal cream [29-30].

Seeing regulatory provisions for Intermediate testing, as required by the EEC, WHO, and Republic of Korea, the tests are is conducted for less than 6 months at  $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$  by all authorities and an RH of  $65\% \pm 5\%$  for general and semi-permeable containers or RH of  $35\% \pm 5\%$  for semi-permeable containers. To this there is an exception for Korea which has a provision of 12 months or more [25].

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