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FORMULATION AND EVALUATION OF FLAXSEED GEL

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ABSTRACT

Herbal medicines are still the mainstay of about 75-80% of the world's population, mainly in developing countries, for primary health care because of better cultural acceptability, better compatibility with human body and lesser side effects. Herbal medicines consist of plants or its part to treat injuries, diseases or illnesses and are used to prevent and treat diseases and ailments or to promote health and healing. It's a drug or preparation made from a plant or plants used for any such purpose. Herbal medicines are the oldest form of health care known to mankind. Gel formulations prepared with Xanthan gum and flax seed extract showed good homogeneity, no skin irritation, and good stability and anti hyperpigmentation activity. However the xanthan gum based gel proved to be the formula of choice, since it showed the highest percentage of extrudability, good spreadability and rheological properties. When the combination of beetroot juice, liquorice extract and flax seed showed good anti hyperpigmentation activity.

Keywords: Hyperpigmentation, Xanthan gum, Herbal.

INTRODUCTION

Pigmentation

Pigmentation is the process of deposition of pigments in tissue, pigmentation lesion of the oral cavity are due to intensification of melanin production, amplified number of melanocytes or deposition of accidentally introduced exogenous material pigmentation is further classified into exogenous and endogenous based upon the cause. Based on melanin production pigmentation classified into hyperpigmentation and hypopigmentation [1]. Hyperpigmentation is the increased level of melanin production and hypopigmentation is the decreased level of melanin production.

Melanin

Melanin is the pigment responsible for maintaining the normal skin colour and mucosa that includes melanin carotenoids, reduce haemoglobin and oxygenated haemoglobin. Melanin is endogenous and non hematogenous pigment that is produced by melanocytes in the basal layer of epithelium. It is transferred to adjacent keratinocytes via membrane bound organelles called melanosomes [2].

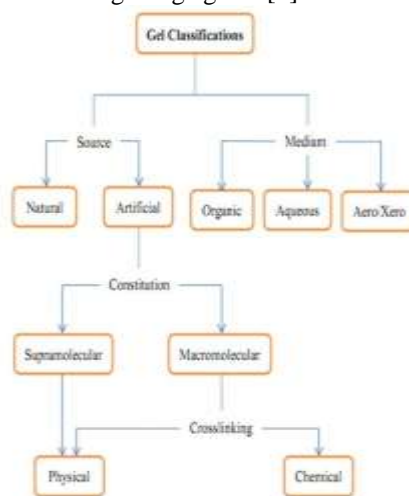
Herbal cosmetics

Herbal cosmetics is defined as the beauty product, which possesses desirable physiological activities, such as

skin healing, smoothing, appearance enhancing and conditioning properties with help of herbal ingredients.

Gels

Gels are transparent and translucent semi solid or solid preparation, consisting of solution or dispersion of one or more active ingredients in suitable hydrophilic or hydrophobic bases. They produce a jelly-like consistency by the addition of gelling agents [3].





Hydrogel

Hydrogen (aquagel) is a network of polymer chains that are water insoluble, sometimes found as a colloidal gel in which water is the dispersion medium. Hydrogels are highly absorbent (they contain over 99% water) natural or synthetic polymers. Hydrogel also possesses a degree of flexibility very similar to natural tissue, due to their significant water content [4].

Uses

Currently used as scaffolds in tissue engineering Environmentally sensitive hydrogel. These hydrogel have the ability to change pH, temperature or concentration of metabolites and release such as the result change as sustained delivery systems provide absorption, deloughing and debriding capabilities of narcotics and fibrotic tissue [5]. Hydrogel is composed of cross linked polymers (polyethylene oxide, poly vinyl pyrrolidone) used in medical electrodes.

Rganogel

An organogel is a non crystalline, non glassy thermo reversible (thermoplastic) solid material composed of a liquid organic phase entrapped in a three dimensionally cross linked network. The liquid may be an organic solvent, mineral oil or vegetable oil. The solubility and particle dimension of the structure are important characteristics for the elastic properties and firmness of the organogel. It is used in a number of applications such as in pharmaceuticals, cosmetics, art conservation and food [6].

Xerogel

A xerogel I'd a solid formed from a gel by drying with unhindered shrinkage. Xerogel usually retains high porosity (25%) and enormous surface area(150-900m²/g),along with very small pore size (1-10nm) when solvent removal occurs under hypercritical (supercritical) conditions, the network doesn't shrink and a highly porous, low density material known as an aerogel is produced. Heat treatment of a xerogel at elevated temperature produces viscous sintering (shrinkage of the xerogel due to small amount of viscous flow) and effectively transforms the porous gel into a dense glass [7].

Properties

Many gels show thixotropy; they become fluid when agitated but resolidify when resting. In general, gels are apparently solid jelly like materials. By replacing the liquid with gas it is possible to prepare aerogel,a material with exceptional properties including very low density, high specific surface areas and excellent thermal insulation properties.

Advantages

- Gels are used to achieve optimal cutaneous and percutaneous drug delivery systems.
- They can avoid gastrointestinal drug absorption difficulties caused by gastrointestinal pH.
- Gels have the property to avoid the enzymatic activity and drug interactions with food and drinks.
- They can substitute for oral administration of medication when the route is unsuitable.
- They can avoid the first pass effect, that is they initial pass of drug substance.
- They avoid systemic and portal circulation following gastrointestinal absorption
- Gels are not deactivated by liver enzymes because the line is bypassed.
- They have non invasive and have patient compliance
- They are applied over skin for slow and prolonged absorption
- They have a localised effect with minimum side effects.

Gel Forming Agents

Natural Polymers

- A) Proteins: collagen, gelatin
- B) Polysaccharides: agar, malignant acid sodium or potassium Carrageenan tragacanth, pectin, guar gum, cassia Tora, xanthan ,gallium gum

Semisynthetic Polymers

Cellulose derivatives: carboxymethyl cellulose, methyl cellulose, hydroxy propylene (methyl cellulose), hydroxyethyl cellulose.

Synthetic Polymers

- A) Carbomer: carbopol 940, carbopol 934
- B) Poloxamer
- C) Poly acrylamide
- D) Polyvinyl alcohol
- E) Poly ethylene and its polymer

Inorganic Substances

- A) Aluminium hydroxide gel
- B) Brij-96

Advantages

- Gels are possibility of allergic reactions

- Enzymatic in epidermis may denature the drugs of gels
- Drugs of larger particle size do not absorb through the skin
- They have poor permeability of some drugs through the skin
- Selection of the area to be examined carefully during application of the gels
- Gels which are used for the introduction into body cavity or the eyes should maybe sterilize
- They may cause an application side reaction
- They may cause skin allergy during application

Skin

The skin is the most extensive and readily accessible organ of the human body. The skin of the average human being covers an area of about 2 square metres and weighs 4.5-5kg, about 16% of body weight. It also receives $\frac{1}{3}$ rd of the total blood supply. Most topical preparations are meant to be applied to the skin and hence basic knowledge of skin and its physiological function and biochemistry is very important for designing topical formulations.

The PH of the skin varies from 4 to 5.6. Sweat and fatty acids secreted from sebum influences the PH of the skin surface. It is suggested that acidity of the skin helps in limiting or preventing the growth of pathogens and others organisms.

Anatomy- Physiology of Skin

The skin is a multilayered organ and anatomically has many histological layers. Skin is an anatomic barrier between the body and its environment and contributes to about 16-18% of normal body weight. The overlaying outer layer is called epidermis; the layer below epidermis is called dermis. Beneath the dermis are subcutaneous

MATERIALS

Liquorice root

Synonym: Glycyrrhizae radix, glycyrrhiza, liquorice root
Biological sources: liquorice is the dried, peeled or unpeeled roots, rhizomes or stolons of glycyrrhiza glands Linn

Family: leguminosae

Geographical sources: Spain, sub Himalayas tracts

Chemical constitutes: Glycyrrhizin/ glycyrrhizic acid (glycoside), Glycyrrhetic acid (aglycone), Glucuronic acid, Liquiritoside- isoliquiritoside, liquiritin, isoliquiritin (flavonoid), Sugar- glucose, mannitol, Starch

Benefits:

For skin: Soothe and hydrate skin, Natural remedies for skin disorders, Fade dark spots, Natural sun protection, Helps hyperpigmentation, Carries glycyrrhizin a powerful antioxidants, Containing glabridin , a UV fighting super ingredient, Protect skin with licochalcone-A.

Licochalcone-A: It helps your skin produce higher levels of antioxidants, fortifying your skin's defence and preventing UV damage in the process.



Beta vulgaris

Synonym: beetroot, tablet beet, garden or common beet

Family: chenopodiaceae

Geographical sources: Europe and Africa

It contains three basic varieties:

Chard- grown specifically for its leaves

Beets- grown for its bulbous roots with edible leaves

Sugar beets- grown for making sugar from long thick root

Benefits:

For skin: Beetroot helps in giving skin a natural blush and rosy cheeks, In the presence of vitamin-C in beets help in decreasing melanin formation and therefore results in hyperpigmentation, It's an important vitamin for skin repair and collagen synthesis, The antioxidants present in the vegetable revives dull skin and repair the skin



Flax seeds

Synonym: linseed, flaxseed, alsi

Biological sources: linseed is the dried, ripe seeds of linum usitatissimum Linn

Geographical sources: south America, India, United state, Canada

Chemical constituents: Fixed oil: 30 to 40%, Proteins: 25%, mucilage: 6%, Cyanogenic.

Benefits: It helps to clear blemishes, reduce acne scars and pigmentation Marks, The essential omega-3- fatty acids in flaxseeds for smoothness skin appearance and makes it super soft, It retains water on skin and moisturized, Also act as a gelling agent, Used to make demulcent preparation.

Xanthan gum

A polysaccharides, Used as food additive and theology modifier, Production involves fermentation of

glucose or sucrose by the bacterium, *Xanthomonas campestris*.

Experiment

Method:

Preformulation Study

Preformulation studies are needed to ensure the development of a stable as well as effective and safe dosage form. It is a stage of development during which the pharmacist characterised the physical chemical properties of the drug substances and its interaction with various formulation components. Goals of preformulation study:

To determine the necessary physicochemical parameters of a new drug substance

To establish its incompatibility with recipients of formulation.

Pharmacognostic Investigation

1. Collection and authentication:

The fresh fruit of beetroot, dried seeds of linseed and roots of liquorice were collected at the following stage in Maharashtra, Indian Himalayas.

2. Organoleptic characterization:

Colour, odours, shape, test and size of the rhizomes and bark were observed.

3. Physicochemical characters:

After botanical evaluation, the shade dried plant material were subjected to size reduction to get coarse powder and then passed through sieve No.43 to get uniform powder. Then the uniform powder was subjected to standardization with different parameters as per literature.

Table 1. Composition of herbal gel formulation

Composition	F1	F2	F3	F4
Xanthan gum	6	5	4	3
Flaxseed powder	5	5	5	5
Beetroot powder	2	2	2	2
Lemon juice	4	4	4	4
Purified water	100	100	100	100
Glycerine	Q.s	Q.s	Q.s	Q.s

EVALUATION

Physical appearance

The prepared gel formulation containing *Glycyrrhizae radix*, *beta vulgaris*, *Linum usitatissimum* Linn were inspected visually for their colour, homogeneity, consistency and phase separation.

Measurement of PH

The PH of developed gel formulations was determined using a digital PH metre. 1gm of gel was dissolved in 100ml distilled water and kept aside for two hours. The measurement of PH of each formulation was done in triplicate and average values are calculated.

Spreadability

Spreadability was determined by the apparatus which consists of a wooden block, which was provided by a pulley at one end. By this method spreadability was measured on the basis on slip and drag characteristics of gels. An excess of gel (about 2gm) under study was placed on this ground slide. The gel was then sandwiched between this slide and another glass slide having the dimension of fixed ground slide and provided with the hook. A one kg weighed was placed on the top of the two slides for 5min to expel air and to provide a uniform film of the gel between the slides. Excess of the gel was scrapped off from the edges. The top plate was then subjected to pull of 80 gm.

With the help of strong attached to the hook and the time(in sec.)required by the top slide to cover a distance of 7.5 cm be noted. A shorter interval indicates better spreadability. Spreadability was calculated using the following formula:

$$S = M \times L / T$$

Where, S= spreadability

M= weight in the pan (tied to upper slide)

L= length moved by the slide,

T= time(in. sec)

Stability study

The optimised gel formulations were prepared; packed in aluminium collapsible tubes and subjected to stability studies at 40°C/ 75% RH for a period of 3 months as per ICH guidelines. Sample were withdrawn at 1 month time intervals and evaluated for physical appearance, PH, theological properties, spreadability and extrudability.

CONCLUSION

It can be concluded from the present investigation that proper selection of polymers and drug is a prerequisite for designing and developing a transdermal drug delivery. Gel formulation was prepared with xanthan gum and flaxseed gel showed good homogeneity, no skin irritation, good stability and anti hyperpigmentation activity.

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