A REVIEW ON STUDY OF SKIN PREPARATIONS

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Abstract- The skin is the body’s largest and most superficial organ, capable of continuous regeneration and responsible for physiological functions. Topical formulations are considered to be more acceptable to patients as they can be effortlessly applied on all regions of the skin without imparting a greasy feel. In this study, we will study the recent research about preparation like ferulic acid and elastin, and other cosmetic preparation. The aim of this study is to show that ferulic acid has strong antioxidant properties, which is directly involved with its protective role in cellular structures and inhibition of melanogenesis and elastin for skin elasticity. This study also gives the information about stability testing of skin preparation. The product must remain in specification, being safe, fit for purpose, efficacious and acceptable for the consumer for the duration of the shelf life in order to preserve brand reputation.

Keywords: Skin, Ferulic acid, Elastin, Stability Studies, Antioxidant Properties, Skin Preparations.

INTRODUCTION

The skin is the body’s largest and most superficial organ, capable of continuous regeneration and responsible for physiological functions. Compared to other biological elements of the human body, the skin is subjected to a complex lifelong aging cycle arising from structural and physiological changes caused by factors internal to the body and external to it. (1)

Skin preparation is also known as topical formulation. Topical formulations are commonly applied directly to the skin with the help of a vehicle or base for a specific site of the body. Formulations are designed to maximize the penetration of an active or functional ingredient into the skin. The relationship between nutrition and skin has been a topic of interest for scientists in the field of cosmetic and pharmaceutical areas. From these roots came the concept of “cosmeceutical”, which is the blend of the terms cosmetic and pharmaceutical, and refers to something between a drug and a cosmetic. (2) Topical formulations are considered to be more acceptable to patients as they can be effortlessly applied on all regions of the skin without imparting a greasy feel. (3) In this study, we will study the recent research about preparation like ferulic acid and elastin, and other cosmetic preparation.

INTRODUCTION OF FERULIC ACID

Ferulic acid (FA), 4-hydroxy-3-methoxy cinnamic acid, is a phenolic compound, which provides photoprotection, antioxidant, anti-tyrosinase, and antimicrobial properties. It has strong free radical scavenging activity and absorbs UV light. It can be used as a multifunctional agent in cosmetic products, such as anti-aging, anti-wrinkle, skin lightening, anti-pollution, and photoprotection. (4)

Ferulic acid has low toxicity and possesses many physiological functions (antiinflammatory, antioxidant, antimicrobial activity, anticancer, and antidiabetic effects). It has been widely used in the pharmaceutical, food, and cosmetics industries.

Ferulic acid is most commonly found in whole grains, spinach, parsley, grapes, rhubarb, and cereal seeds, mainly wheat, oats, rye, and barley. One of the most important role of phenolic acids, especially cinnamic acid derivatives, is their antioxidant activity, which depends primarily on the number of hydroxyl and methoxy groups attached to the phenyl ring. Ferulic acid is more easily absorbed into the body and stays in the blood longer than any other phenolic acid. Ferulic acid is considered to be a superior antioxidant. (5) The chemical structure of ferulic acid is given in fig.1.
ANTIOXIDANT PROPERTIES OF FERULIC ACID

The antioxidant action mechanism of ferulic acid is complex, mainly based on the inhibition of the formation of reactive oxygen species (ROS) or nitrogen, but also the neutralization (“sweeping”) of free radicals. In addition, this acid is responsible for chelating protonated metal ions, such as Cu (II) or Fe (II). Ferulic acid is not only a free radical scavenger, but also an inhibitor of enzymes that catalyze free radical generation and an enhancer of scavenger enzyme activity. It is directly related to its chemical structure. Its antioxidating properties are primarily related to the scavenging of free radicals, binding transition metals such as iron and copper, and lipid peroxidation prevention. The mechanism of the antioxidative activity of ferulic acid is the ability to form stable phenoxy radicals, by the reaction of the radical molecule with the molecule of antioxidant. This makes it difficult to initiate a complex reaction cascade leading to the generation of free radicals. This compound may also act as a hydrogen donor, giving atoms directly to the radicals. This is particularly important for the protection of cell membrane lipid acids, from undesired autodestruction processes. As a secondary antioxidant, ferulic acids and their related compounds are able to bind transition metals such as iron and copper. This prevents the formation of toxic hydroxyl radicals, which lead to cell membrane peroxidation. Free radicals may also be formed through natural human physiological processes, such as the cell respiration process. (5)

In recent years, several attempts have been made to encapsulate FA with polysaccharides to enhance its stability. Currently, ferulic acid has been successfully encapsulated onto different polysaccharides, such as cyclodextrin, chitosan, and starch. It has been shown that the encapsulation of ferulic acid in polysaccharides enhances its stability and broadens its application in many fields. Therefore, phosphorylated starch is a sound choice to use as an encapsulating agent due to its affordability, absence of waste products, and short preparation time. In recent research, the stability and efficacy of encapsulated ferulic acid in phosphorylated rice starch were investigated for the first time. The chemical and physical characterization of the encapsulated ferulic acid were investigated by several instrumental methods, and its stability was further evaluated by storage under high temperature/80% RH and exposure to light for 1 month. The effect on skin color was evaluated by using a Mexameter; skin firmness, which included gross elasticity, net elasticity, and portions of viscoelasticity, was assessed by a Cutometer; and skin smoothness, roughness, scaliness, and wrinkles were analyzed by Visioscan. (6) There are some examples of preparation that contains ferulic acid, DermaDoctor Kakadu C Vitamin C Serum with Ferulic Acid and Vitamin E, Medix 5.5 Retinol with Ferulic acid Cream.

INTRODUCTION OF ELASTINE

Elastin is a key extracellular matrix (ECM) protein that provides resilience and elasticity to tissues and organs. Elastin is roughly 1000 times more flexible than collagens; thus, the main function of elastin is the elasticity of tissues. It is the dominant protein in extensible tissues and is primarily present in the lungs, aorta, and skin. (6) As its name implies, elastin protein is elastic, meaning can resume its normal shape even after contraction, expansion, or distortion. Therefore, elastic connective tissue not only protects and supports but allows tissues and organs to remain structurally and mechanically malleable under certain physiological conditions. Elastin is found in:

- Skin
- Blood vessels
- Heart tissue
- Lung tissue
- Elastic cartilage
- Tendons: connective tissue that links muscle to bone
- Ligaments: connective tissue that links bone to bone

The skin’s ability to be pulled and then snap back into place is attributed to the presence of elastin. As mentioned, elastin is a protein and a major constituent of elastic fibers. (6) The structure of elastin is given in fig.2
Large quantities of animal by-products come from different processing industries. Statistically, 20 and 10 million tons of discards from processing industries are produced worldwide each year from residues of fish and meat (cattle, pigs and poultry). In general, such by-products are disposed of or refined into fertilisers, animal feed and pet food. These practices are; however, ineffective as high management costs are required and the degradability of these by-products is slow and leads to environmental problems such as unpleasant odours and environmental pollution. This waste from poultry slaughter residues can be converted into valuable materials such as collagen, elastin, keratin, and respective hydrolysates and small peptides. They have high functional and bioactive properties that can be used in various fields including food, biomedicine and pharmaceuticals as well as in highly lucrative sectors such as cosmetics.

Besides, there is a significant increase in customer consciousness about the use of ingredients in skincare and beauty products. This also led to a rise in demand for Halal and natural ingredients for cosmetics. Globally, the estimation of the demand for halal cosmetics at present is to be around $53 billion by the end of 2023. While cosmetic brands are abundant in the market, there used to be a limited choice for halal cosmetics where the Halalness of the ingredients used could also be ambiguous. Natural sources of elastin are obtained mostly from pig aorta, bovine neck ligament and mouse lungs. Recent research shows that the successful attempts at isolating elastin containing bioactive compounds for antioxidant activities from poultry using various approaches have been reported. However, studies on the utilisation of water-soluble elastin from poultry and its potential use in the formulation of functional foods, nutraceuticals, cosmetic and pharmaceutical industry were still in infancy. The physicochemical and microbiological stability of a model moisturiser system containing elastin extracted from poultry skin was investigated. Some examples of elastin containing preparations are, Lawrens collagen elastin cream, Dermadics elastine protien gel, etc.

STABILITY TESTING OF SKIN PREPARATION

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 as functionality and aesthetics when stored under appropriate conditions. Because the development cycle of cosmetic products is relatively short each manufacturer should design their own stability testing program such that it is economically reasonable and efficiently addresses the testing required. Because of the wide variety of cosmetic products “standard” stability tests cannot be prescribed. Manufacturers require the flexibility to modify testing protocols and to build a sound scientific basis for assessing stability of their own products. Thus, specific tests may be developed in order to address new or unusual technologies, or to be adapted to products having extended shelf lives. Stability tests can be conducted in real time or under accelerated conditions and should address the stability of a product under appropriate conditions of storage, transport and use. Basically, there are three forms of stability tests: physical and chemical integrity tests which evaluate colour, odour / fragrance, pH value, viscosity, texture, flow, and emulsion stability (signs of separation); microbiological stability tests which evaluate the degree of contamination with bacteria, mold, and yeast; and packaging stability tests which evaluate the impact of packaging on the contained product.

PHYSICAL / CHEMICAL STABILITY TESTS

These describes approaches to predicting how well cosmetics will resist common stresses such as temperature extremes and light. Typically, manufacturers determine whether to perform such specialized testing based on the vulnerabilities of the particular cosmetic product and its anticipated shipping, storage display and use conditions. Common test procedures include:

- Colour: Colour changes may be caused by chemical interactions between raw materials in the formulation such as oxidation or grouping effects of ingredients used. Generally, it was observed that no significant changes found in the colour test for products with changes in temperature until Week 12. Fig.1 shows that there is no change in the colour. However, the colour changes are still within an acceptable range, which is ± 10% from the initial colour reading.
• **pH measurement**: The pH of a product is very important because any changes in reading could provide information on product instability or contamination that occurred directly or indirectly during product preparation. Changes in pH values also indicate the possible chemical reaction might occur between the raw materials used in the product formulation as well as affecting the efficacy and the safety of the product. The pH of human skin is usually between 4.5 and 6.0. Therefore, the pH of skin care products should be included in this range to allow a formulation to be approved for industrial use. The changes in the pH probably due to the growth of yeast and mold. However, the decrement of data is within the acceptable limit which is ± 10% from the initial pH measurement. Fig. 2 shows that there is no change in the pH of the product until 12 weeks. The pH of cosmetic products should remain within a certain range, so that the colour, viscosity, skin feeling, and physicochemical stability remain intact throughout their shelf life and by the user throughout their application. (1)

• **Temperature Variations**: High temperature testing is now commonly used as a predictor of long-term stability. Most companies conduct their high temperature testing at 37°C (98F) and 45°C (113F). If a product is stored at 45°C for three months (and exhibits acceptable stability) then it should be stable at room temperature for two years. Of course, the product must be stored at 25°C (77F) for a period of one year. A good control temperature is 4°C (39F) where most products will exhibit excellent stability. The product should also be subjected to -10°C (14F) for three months.

• **Cycle Testing**: The product should pass three cycles of temperature testing from -10°C (14F) to 25°C (77F). Place the product at -10°C for 24 hours and place it at room temperature (25°C) for 24 hours. This completes one cycle. If the product passes three cycles, then you can have a good degree of confidence in the stability of the product. An even more rigorous test is a -10°C to 45°C five-cycle test. This puts emulsions under a tremendous stress and, if it passes the test, indicates that you have a really stable product.
• **Centrifuge Testing**: The dispersed phase (of an oil-in-water emulsion) has a tendency to separate and rise to the top of the emulsion forming a layer of oil droplets. This phenomenon is called creaming. Creaming is one of the first signs of impending emulsion instability and should be taken seriously. A good test method to predict creaming is centrifugation. Heat the emulsion to 50°C (122°F) and centrifuge it for thirty minutes at 3000 rpm. Then inspect the resultant product for signs of creaming. This test is an absolute necessity for those products that contain powders of any kind such as liquid/cream make-up.

• **Light Exposure Testing**: Both formulas and packaging can be sensitive to the UV radiation. All products should be placed, in glass and the actual package, in the window and if its available a light box that has a broad-spectrum output. Place another glass jar completely covered with aluminium foil in the window to serve as a control. All too often we will see significant discoloration of the product and sometimes of the package also. This discoloration may be due to the fragrance or some other sensitive ingredient. Usually all that is needed is the addition of a UV absorber (e.g., 0.1% of benzophenone).

• **Mechanical Shock Testing**: In order to determine whether or not shipping movements may damage the cosmetic and its packaging mechanical shock testing is often conducted. Vibration testing (e.g. on a pallet shaker) can help to determine whether demixing (separation) of powders or granular products is likely to occur.

• **Monitoring**: For all the above-mentioned tests you should monitor the colour, odour / fragrance, viscosity, pH value, and, if available, particle size uniformity and/or particle agglomeration under the microscope.

**MICROBIOLOGICAL STABILITY TESTS**

Microbial contaminants usually come from two different origins: during production and filling, and during the use of the cosmetic by the consumer. From the moment the cosmetic unit is opened by the consumer, a permanent microbial contamination of the cosmetic is introduced caused by contact with the consumers hands and body. Microbial preservation of cosmetics is important to ensure the microbial safety of cosmetics for the consumer, maintain the quality of the product, and confirm hygienic and high-quality handling. Although only a small number of cases of microbial infections of the consumer has been reported, microbial contamination of cosmetic products may spoil them or seriously reduce the intended quality. Therefore, it is necessary to carry out routine microbiological analysis of each batch of the finished product coming on the market. Pseudomonas aeruginosa, Staphylococcus Aureus and Candida Albicans are considered the main potential pathogens in cosmetic products. These specific potential pathogens must not be detectable in 0.1 g or 0.1 ml of a cosmetic product. The parameters examined, the criteria and methods used, and the results obtained per batch should be documented.

• **Screening Tests**: There are various easy testing kits available on the market (e.g. dipslides or plate counts) which provide quick and semi-quantitative results whether a cosmetic product is significantly contaminated or not. Sampling and evaluation of the results is simple and can be performed also by personnel without any microbiological training.

• **Quantitative Tests**: Quantitative tests determine the actual count level of bacteria, mold and yeast in a cosmetic product. These tests are very sophisticated and laborious and can be performed only by professional microbiological testing laboratories. Typically, methods for isolation of microorganisms from cosmetic products include direct colony counts and enrichment culturing.

**PACKAGING STABILITY TESTS**

Packaging can directly affect finished product stability because of interactions which can occur between the product, the package, and the external environment. For example, product constituents may be absorbed into the container or may chemically react with the container. In addition, the container may not fully protect the product from the adverse effects of atmospheric oxygen and/or water vapor, or volatile product constituents (e.g. fragrances) may evaporate through the container.

• **Glass Tests**: Glass is the most inert material and does not react with a cosmetic product in any way. For this reason all testing should be done in glass and the actual packaging. In this way you can determine if the cause of product failure is the formula or the package.

• **Weight Loss Tests**: To determine evaporation (water loss through the container wall or closure gaps) weight loss evaluation is one of the most important tests that must be conducted. This testing (performed in the actual package with the cap torqued to 100% of target torque) is done at room temperature and at 45°C (113°F) for a period of three months. The weight loss should not exceed 1% per month for the package to be considered acceptable.

**Leaking Tests**: It may be advisable to test the packaged product in various orientations (upright, inverted, on its side, etc.) to determine whether the packaging may leak (especially during transport). 

(10)
CONCLUSION
The aim of this study is to show that ferulic acid has strong antioxidant properties, which is directly involved with its protective role in cellular structures and inhibition of melanogenesis and elastin for skin elasticity. This study shows that recent research on the encapsulation of the ferulic acid from phosphorylated rice starch and elastin from poultry.

This study also gives the information about stability testing of skin preparation. The product must remain in specification, being safe, fit for purpose, efficacious and acceptable for the consumer for the duration of the shelf life in order to preserve brand reputation. Stability testing is essential in evaluating a product shelf life and yet it is not set out in regulation how the test should be performed. Global cosmetic associations IFSCC and Cosmetics Europe have published suggested protocols however these were in 1992 and 2004, respectively. The recent work of Postles encourages the use of real-time stability testing, however this is suggested to be 6–12 months ahead of an industrial scale up which is at odds with a brands desire to move quickly to market. Traditional accelerated testing could be accompanied by additional tests such as cycling, freeze–thaw and centrifuging.

REFERENCES: