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Design and development of cosmeceutical cream for hyperpigmentation and anti-aging

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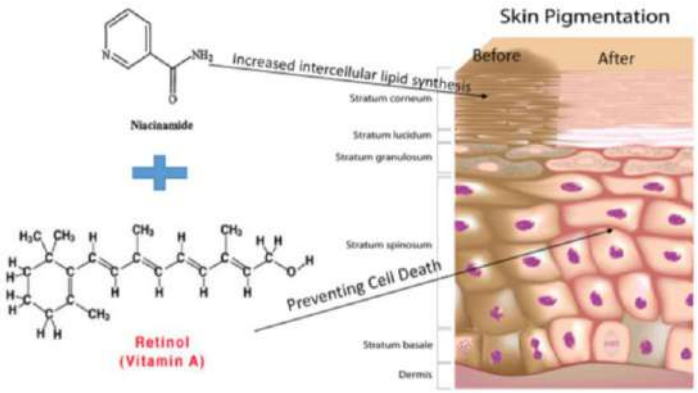
Abstract
Since last decade cosmeceutical industry growing surprisingly. Pharmaceuticals/Cosmeceutials needed new skin care formulations as per demand of peoples and industrial market. Target of present research is to design new cream which reduce hyper pigmentation and act as anti-aging with moisturizing effect. Presented cream is complex emulsion of niacinamide and retinol which benefits as superb skin treatment. Accelerated stability testing of cream sample has been conducted in the environmental chamber with temperature 25 ± 1 ^{0}C and humidity 60 ± 10% RH. The products were found to be stable with no sign of phase separation and no change in the color. The patch test for sensitivity testing has also been done and no evidence of skin irritation and allergic signs. The work mainly focuses on microbial quality control and antioxidant activity of formulated cream. In future this formulated cream will give promises to Skin care and nourishment with therapeutic effects.

Keywords: Cosmeceuticals, Skin care, hyperpigmentation, Skin aging

Introduction
The accession of an aesthetically pleasing skin pigmentary appearance has been main focus of many pharmaceuticals and therapeutic based industries. hyperpigmentation is result of production of high concentration of melanocytes and or melanocytes are highly active, skin is largest organ of body and it can affect anyone specially teens and over 40's.The causes of hyperpigmentation are many more including acne vulgaris, Inflammation of skin, over exposure of UV light/Sunlight. Hyperpigmentation diseases of the skin such as melasma, agespots or solar lentigo can result from the overproduction and accumulation of melanin. Melanocytes, produce a specialized lysosomal related organelle termed the melanosome. Within the melanosome, biopolymers of the pigment melanin are synthesized to give hair and skin, as well as other tissue, its color. This melanin synthesis involves a bipartite process in which structural proteins are exported from the endoplasmic reticulum and fuse with melanosome-specific regulatory glycoproteins released in coated vesicles from the Golgi-apparatus. Melanin synthesis ensues subsequent to the sorting and trafficking of these proteins to the melanosome. (Raymond E. Boissy, 2009) [4].Vitamin B3 (nicotinamide, 3-pyridinecarboxamide) Niacinamide act as a precursor to the co-factors nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP). Along with their reduced forms NADH and NADPH, these enzymes participate in numerous enzymatic reactions and also ac . (Wenyuan Zhu, 2008) [1]



Aging is cumulative damage to the genes and proteins derived thereof, result in compromised function and homeostatic failure. This leads the organism towards premature aging and death, which in turn shall depend on its repair systems. The somatic cells have telomeres at the terminal portion of the eukaryotic chromosomes which consist of many hundreds of TTAGGG predetermining the number of times the cell can divide before it senesces. The enzyme DNA polymerase that replicates cellular chromosomes during mitosis cannot replicate the final base pairs of each chromosome, resulting in progressive telomere shortening with each cellular division (Yaar and Gilchrest 2001) [2]. Skin aging is result of exposure of UV light which produce ROS, Sugar and aldehydes. Retinol (Vitamin A alcohol) is a precursor for synthesis of endogenous retinal and retinoic acid, it was used as potential antiaging agent since last two decades, so we decide to make formulation which work as nourishment of skin with therapeutic effects.

Materials and Methods

Chemicals

Niacinamide was obtained gift sample (lasons, India. Pvt. Ltd), other chemicals such as EDTA, Antioxidants, Preservatives, emollients (Loba Chemie Mumbai, Maharashtra, India) Remaining all the materials were obtained commercially and used as such.

Formulation Method

We divided chemicals in 3 phases (table no 1),firstly added water and EDTA in to heat resistance glass beaker and stirred well, on other hand with the help of stick blender make and solution of carbomer, added TAE until phase 1 becomes viscous with heating at 65 ^{0}C-75 ^{0}C, added phase 2 melted ingredients and mixed well at same temperature with constantly stirring, after that used homogenizer for mixing phase 3 to above prepared emulsion with little drop of aroma when it goes hand warming or lower than 40 ^{0}C and mixed well until we got smooth and uniform texture. Stored at room temperature.

Evaluations parameters

Take 5 gm of cream in clean platform and observe visually

A. Physical Characteristics

The formulated creams were observed visually for their color, homogeneity, consistency, spreadability and phase separation. The pH was measured with help of pH meter. (Table no 2)

B. Viscosity

The viscosity of formulated creams was measured by Brook field Viscometer in triplicate (figure no 1)

C. Stability studies

The stability studies were carried out as per ICH guidelines. The cream filled in bottle and kept in humidity chamber maintained at 30 ± 2°C/ 65 ± 5% RH and 40 ± 2°C / 75 ± 5% RH for three months. At the end of studies, samples were analyzed for the physical properties and viscosity. (table no.3)

D. Patch Test

About 1-3gm cream to be tested was placed on a piece of fabric and applied to the sensitive part of the skin e.g. skin behind ears. The cosmetic to be tested was applied to an area of 1sq.m.of the skin. Control patches were also applied. The site of patch is inspected after 24 hrs. (ZHANG, 2009) [5]

E. Spreadability studies

An important criteria for semisolids is that it posses good spreadability (Table no.4). Spreadability is a term expressed to denote the extent of area to which the cream readily spreads on application to the skin. The therapeutic efficacy of a formulation also depends on its spreading value. A special apparatus has been designed to study the spreadability of the formulations. Spreadability is expressed in terms of time in seconds taken by two slides to slip off from the formulation, placed between, under the application of a certain load. Lesser the time taken for the separation of the two, better the spreadability. Two glass slides of standard dimensions were selected. The formulation whose spreadability had to be determined was placed over one of the slides. (Akash Mali, 2015) [3] The other slide was placed on top of the formulations was sandwiched between the two slides across the length of 5 cm along the slide. 100 g weight was placed up on the upper slide so that the formulation between the two slides was pressed uniformly to form a thin layer. The weight was removed and the excess of formulation adhering to the slides was scrapped off. One of the slides was fixed on which the formulation was placed. The second movable slide was placed over it, with one end tied to a string to which load could be applied by the help of a simple pulley and a pan. A 30g weight was put on the pan and the time taken for the upper slide to travel the distance of 5.0cm and separate away from the lower slide under the direction of the weight was noted. The spreadability was then calculated from the following formula:

$$\text{Spreadability} = m \times l / t$$

m = weight tied to the upper slide (30g) l =length of glass slide (5cm) t =time taken in seconds

F. Microbiological studies

The formulated creams were inoculated on the plates of agar media by streak plate method and a control was prepared by omitting the cream. The plates were placed in to the incubator and are incubated at 37 ^{0}C for 24 hours. After the incubation period, plates were taken out and check the microbial growth by comparing it with the control. (ROY, 2007) [6]

Result and discussion

Formulated 100 gm cream has bright white color with smooth texture. pH of formulation found to be 5.20. The stability studies of the various parameters like visual appearance, nature, pH of the formulations showed that there was no significant variation after three months of the study period. (table no 5) The formulation shows no redness, edema, inflammation and irritation during Patch Test studies. These formulations are safe to use for skin. The formulated creams were tested for the presence of pathogenic microorganisms by culturing it with agar medium. There were no signs of microbial growth after incubation period of 24 hours at 37 ^{0}C and having antimicrobial property. (Figure 2 (a,b) Presented formulation posses good spreadability. We dident found any allergic conditions but we advice to consult with physician or pharmacist and should be prescribed in case of pregnant women or who are planning to pregnancy.

Table 1: Formulation and Roles (100 Gm)

Phase 1

Ingredients	Role	Quantity (gms)
Glyceryl monostearate	Emulsifier	0.3
Sorbitol	Moisturizing Thickener & Texturizer	4.0
Ammonium lactate	moisturizer	0.3
EDTA	Chelating Agent	0.3
Carbomer	Gelling Polymer Thickener	0.5
dd Water	Diluent	74.6

Phase 2

Polysorbate	Surfactant	5.0
Stearic Acid	Emulsifying Thickener with Softening Effect	3.0
Squalane light	Emollient & *Moisturizer*	6.0

Phase 3

Niacinamide	Active Ingredient	3.0
Retinol	Active Ingredient	2.5
Glucose complex	Active enhancer to retinol	0.1
Methyl paraben	Preservative	0.2
Propyl paraben	Preservative	0.2

Table 2: physical characteristics

Sr. No.	Properties	Formulation
1	Color	Bright white
2	Odor	Characteristics
3	Appearance	Semi-Solid
4	Texture	Smooth

Table 3: Thermal Stability and Ph Determination

Sr. No	Parameters	formulation
1	Thermal Stability (RH 65% and30 ± 40 ºC)	Stable, No oil Separation
2	pH (27ºC ± 2 ºC)	5.20

Table 4: Spredability Test

Formulations	Time (Min)	Spreadability(g cm/sec)
New Research	16	11.4
Marketed Cream	18	11.5

Table 5: accelerated stability studies

Months/ Tests	Formulation		
	After one month	After second month	After third month
Physical appearance	Semi-solid	Semi-solid	Semi-solid
Texture	Smooth	Smooth	Smooth
color	White	White	White
Odor	Characteristic	Characteristic	Characteristic
pH value	5.2	5.2	5.3
Thermal stability	ok	ok	ok
Degradation of product	nil	nil	nil
consistency	ok	ok	ok

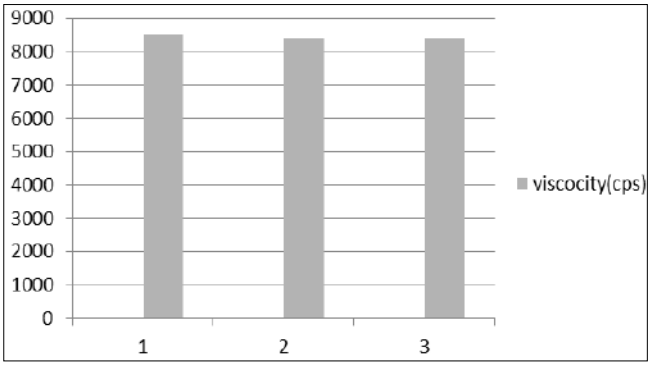


Fig 1: Viscosity of Formulation (Cps)

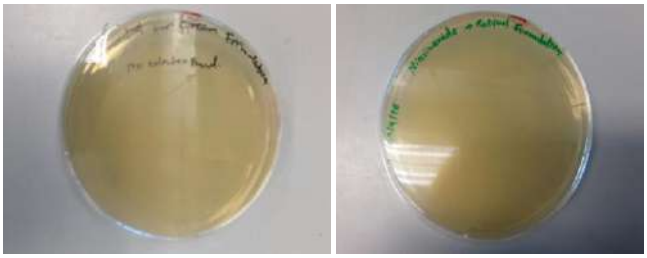


Fig 2: microbiological assay a. control (marketed antimicrobial agent) b. Formulation with niacinamide

Conclusion

Present research focuses on improvement of cosmeceuticals with highly therapeutic effect, uses of biological active ingredients (vitamins) for nourishing, anti-aging, and reduce hyperpigmentation which give beneficial effects to dermatology, this formula will give promising skin care in future. The prepared formulations showed good spreadability, no evidence of phase separation and good consistency during the study period. Stability parameters like visual appearance, nature and fragrance of the formulations showed that there was no significant variation during the study period.

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