Research Article

Formulation and Evaluation of Vitamin E Enriched Cold Cream with Almond oil as an Internal Phase

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ABSTRACT

The aim of the present study is to formulate and evaluate cold cream enriched with vitamin E and almond oil providing moisturizing effect. The cold cream was prepared by incorporating beeswax, borax, sweet almond oil, vitamin E and all other excipients. Fusion method is used for the formulation of the cold cream. Five different formulations are prepared and evaluated for the compliance with the pharmacopoeial parameters. All the prepared formulations are evaluated for the various parameters like pH, color, homogeneity test, viscosity, rheological studies, stability studies, etc. Among all the formulations, F4 shows the best result and all the parameters comply with the IP standards. Stability studies proved that there are no significant changes in the formulated cold cream. Thus, it is concluded that the vitamin E enriched cold cream is well formulated and evaluated with almond oil as an internal phase.

Keywords: cold cream, sweet almond oil, rheological studies, stability studies, homogeneity.

INTRODUCTION

In the pharmaceutical markets, several dosage forms are designed and introduced by considering the patient needs to obtain more patient compliance and providing faster relief. All the dosage forms are having best properties and also some drawbacks are associated with it. Over the last years the treatment of illness has been accomplished by administering drugs to human body via various routes namely oral, sublingual, rectal, parental, topical, inhalation, etc. Among all the dosage form, for the topical application, creams are considered as superior over other dosage forms. Topical delivery can be defined as the application of a drug containing formulation to the skin to directly treat cutaneous disorder or the cutaneous manifestations of a general disease (e.g. psoriasis) with the intent of containing the pharmacological or the effect of drug to the surface of the skin or within the skin semi-solid formulations in all their diversity dominate the system for topical delivery, but foams, sprays, medicated powders, solutions and even medicated adhesive systems are in use.[1]

Cream is a topical preparation used for application to the skin where it gets absorbed through the various layer of the skin and it can also apply on the body parts such as face, hands, legs, skin etc. Creams are defined as, the semisolid dosage forms containing one or more medicinal substances dissolved or dispersed in suitable bases to form a homogenous mass. This term has traditionally been applied to semisolids that possess a relatively fluid consistency formulated as either water-in-oil (e.g. cold cream) or oil-in-water (e.g. vanishing cream) emulsions. Creams are considered as pharmaceutical products and cosmetic products as per their application. Medicated creams are the creams containing the medicinal substances and used to treat the skin related disorders. Un medicated creams are highly used in a variety of skin conditions (dermatoses) but they are not containing any medicinal substances. The use of the fingertip unit concept found to be helpful in guiding how much amount of topical cream is required to cover different areas.

The term has been restricted to products consisting of oil-in-water emulsions or aqueous microcrystalline dispersions of long-chain fatty acids or alcohols that are water washable and more cosmetically and aesthetically acceptable. Creams are used for the multiple purposes like to enhance beauty, to get therapeutic effect, to relieve sun burn, and moisturized skin, as a makeup base, etc. Medicated creams are used for treating various skin related conditions such as psoriasis, dermatitis, burns, vaginal infections (e.g. Triple Sulfa Vaginal Cream), dry skin, etc. Galen, a Greek doctor, discovered the cold cream and in the second century, he prepared the formulation of cold cream which was popularly known as 'Galen's cream'. He prepared the formulation by using an emulsion water and beeswax along with rose petals as the vital moisturizer ingredients of the cold cream. Cold creams not only moisturize the skin but are also used for removing makeup and temporary tattoo marks. The cream is rubbed on tattoo marks and then erased with a cotton ball. Cold cream uses are also associated with preparation of facial paints for kids.

Cold cream is useful for keeping the skin moisturized and emollient all the time, especially all through the winters by protecting the skin from becoming dry and avoids aggravation of skin problems during the cold season. It stretches and then faint lines of crack develop over lips and cheeks. If proper care is not taken, these cracks may further become red. A plethora of cold creams are seen

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flooding the market and you may be confused as to what to pick for your skin.[1]

Table 1: Advantages and Disadvantages of cold cream[2]

Sr.no.	Merits	Demerits
1	Ease of application.	Larger particle size drugs cannot be easily absorbed through the skin pores.
2	Convenient to all the population.	Chances of skin irritation of contact dermatitis due to the any drug interactions.
3	Avoidance of risk.	Poor absorption may result due to the poor permeability of some drugs through the skin.
4	In case of intra- and inter- patient variations, avoid fluctuation of drug levels.	Chances of allergic reactions.
5	No special risk or technician required for application of product.	It can be used mainly for drugs which required very small plasma concentration for action.
6	Achievement of efficacy with lower total daily dosage of drug.	Denaturation of the drugs takes palce due to the prescence of an enzyme in epidermis.
7	High patient compliance.	

MATERIALS AND METHODS

Sweet almond oil (ROGHAN BADAM SHIRIN) and vitamin E (EVION 400) tablets were purchased from the Bakshe Medical stores, Nagpur. All the other chemicals used in the formulation are of analytical grades.

Method of preparation

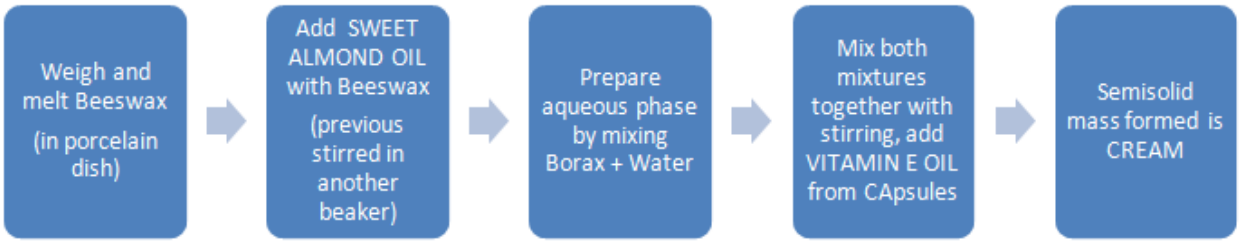

Figure 1: Method of preparation used for the formulation of cold cream

Table 2: Composition required for the formulation of cold cream.

S. No.	Ingredients	F1	F2	F3	F4	F5
1	Bees Wax (g)	8	6	4	3	2
2	Sweet Almond Oil (ml)	6	8	10	12	14
3	Borax (g)	0.2	0.2	0.2	0.2	0.2
4	Vitamin E (mg)	400	400	400	400	400
5	Water (ml)	5.8	5.8	5.8	4.8	3.8
6	Perfume(Rose Water)	q.s.	q.s.	q.s.	q.s.	q.s.

Figure 2: Formulation batches F1, F2, F3, F4, F5 of the formulated cold cream

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Characterization of the Cold Cream

pH of the Cream

The pH of the prepared cream was measured using pH meter and it was calibrated using standard buffer solution. About 0.5g of the cream was weighed and dissolved in 50.0 ml of distilled water and its pH was measured.

Determination of Physical appearance

The physical appearance of cold cream was inspected visually against dark background. The average of three reading is recorded.

Viscosity

Viscosity of the formulation was determined by Brookfield Viscometer at 100 rpm, using spindle no 7. The viscosity of formulated cream bases was determined. The viscosity determinations were carried out on Brook-field viscometer using spindle number S-07 and the determinations were carried out in triplicate and the average of three reading is recorded.

Homogeneity

The formulated cold creamwas tested for the homogeneity by visual appearance and by touch.

After feel

Emolliency, slipperiness and amount of residue left after the application of fixed amount of cream was checked.

Type of smear

After application of cream, the type of film or smear formed on the skin were checked.

Removal

The ease of removal of the cream applied was examined by washing the applied part with tap water.

Irritancy test

Mark an area (1sq.cm) on the left hand dorsal surface. The cream was applied to the specified area and time was noted. Irritancy, erythema, edema, was checked if any for regular intervals up to 24 hrs and reported.

Rheological studies

The formulated cream was found to be Non-Newtonian. Take a fixed quantity 10gms of cream in a 10 ml beaker. Keep it impact for 1 hr. The beaker was inclined to one side see whether the cream is liquefied or not. Beaker is shaken to and fro for continuous 5 min and checked whether consistency has changed or not. The beaker was again tilted and checked for pourability of the cream.

Accelerated stability testing

Accelerated stability testing of prepared formulations was conducted for 2 most stable formulations at room temperature, studied for 7 days. They were formulation number 3 and 4 at 40°C ± 1 °C for 30 days. The formulations were kept both at room and elevated temperature and observed on 0th, 5th, 10th, 20th and 30th day for the following parameters[11-15]**.** Since the period of stability testing can be as long as two years, it is time consuming and expensive. Therefore it is essential to devise a method that will help rapid prediction or long-term stability of drug.

The accelerated stability testing is defined as the validated method by which the product stability may be predicted by storage of the product under conditions that accelerate the change in defined and predictable manner. The stability studies of formulated cream were carried out 40°C/RH) and at room temperature for one month. The effects of temperature, humidity and time on the physical characteristics of the creams were for assessing the stability of the prepared formulations.

The stability studies were carried out when the room temperature was 20 to 25°C. [7,8]

RESULTS AND DISCUSSION

The prepared cold cream was evaluated for the above mentioned parameters and the result was observed as follows:

Table 3: Evaluation of formulated cold cream

S. no.	Formulation batches	pH	Colour	Homogeneity	Type of smear	Irritancy test	Removal test
1	F1	3.96	Yellowish	Good	Thin	No	Easy removal
2	F2	4.11	Yellowish	Good	Thin	No	Easy removal
3	F3	4.32	Yellowish	Good	Thin	No	Easy removal
4	F4	4.51	Yellowish	Uniform	Thin	No	Easy removal
5	F5	5.01	Yellowish	Good	Thin	No	Easy removal

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Table 4: Determination of the viscosity

Batch no.	Angular Velocity (RPM)	Spindle No.	Run Time	% Torque (dynes-cm)	Viscosity (cP)
F4 .	0.5rpm	Spindle No.95	30Sec	32.9	134500
	1.0rpm	Spindle No.95	30Sec	30.3	69550
	2.0rpm	Spindle No.95	30Sec	18.4	39727
	4.0rpm	Spindle No.95	30Sec	22.9	41500
	5.0rpm	Spindle No.95	30Sec	39.8	34936
	10rpm	Spindle No.95	30Sec	36.0	23350
F5	2rpm	Spindle No.96	30Sec	27.1	124700
	3rpm	Spindle No.96	30Sec	21.3	66700
	4rpm	Spindle No.96	30Sec	17.4	38800
	5rpm	Spindle No.96	30Sec	21.7	40100
	10rpm	Spindle No.96	30Sec	44.0	41250
	20rpm	Spindle No.96	30Sec	35.2	16500

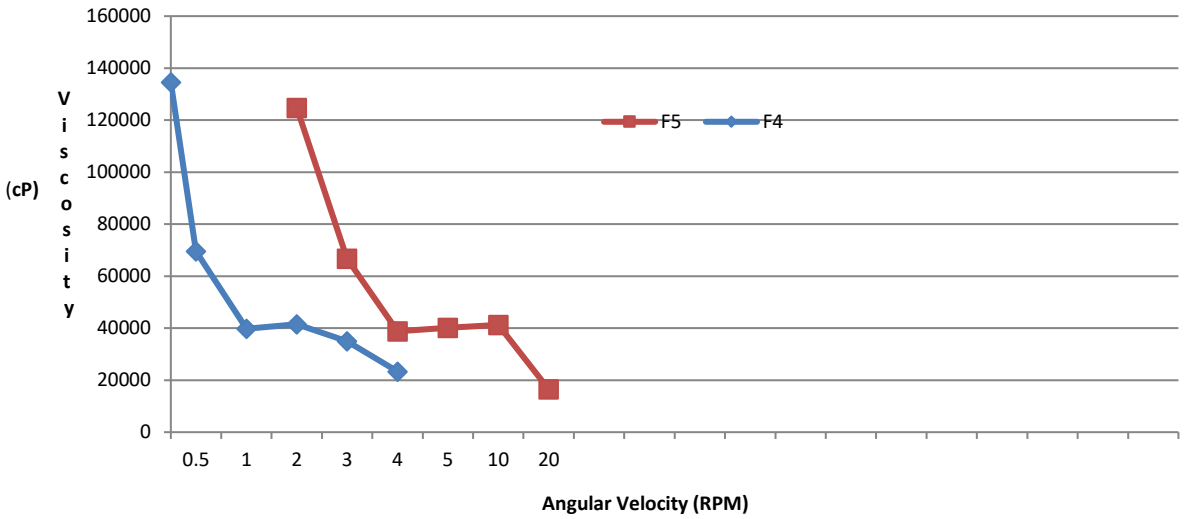

Figure 3: Rheogram showing curves: Angular Velocity (RPM) v/s Viscosity (cP) for formulations F4 and F5

The prepared cold cream formulations were subjected for stability study as per ICH guidelines for the period of one month. The stability evaluation data were performed and mentioned. The physicochemical characteristics in both the formulations i.e. F4 & F5 were found to be satisfactory from the result and it is clearly evident that the physicochemical parameters like appearance, pH, colour, homogeneity, viscosity, etc. in both the formulations were found to be satisfactory. The cold cream was formulated using sweet almond oil and vitamin E and it was evaluated for the various parameters and the results were observed. The pH of the cream was found to be in range of 4-5.5 which is good for skin pH. All the formulations were shown pH nearer to skin required. After application of the cream, the type of smear formed on the skin were non greasy. All the formulations produce uniform and homogeneous distribution of extracts in cream confirmed by visual appearance and touch. When formulations were kept for long time, it was found that no change in color of cream. Emolliency, slipperiness and amount of residue left after the application of fixed amount of cream was found. After application of the cream, the type of smear formed on the skin were non greasy. The cream applied on skin was easily removed by washing with tap water. Among all the formulation F4 and F5 shows no redness, edema, inflammation and irritation during irritancy studies. Rheological behavior of the cream was studied and confirmed that the cream had pseudo plastic flow behaviour. All the formulations showed no thixotropic (shear thinning) characteristics. Accelerated stability testing was studied. The viscosity of was cream was in the range 16500-134500 cP which indicates that the cream is easily spreadable by small amounts of shear. But F4 and F5 shows good spreadable property than other formulations.

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Table No 5: Physical parameters of F3 and F4 cream on room temperature and accelerated time

Days	Temperature	Formulation	Parameters						
			pH	X_1	X_2	X_3	X_4	X_5	X_6
0	RT 40 ºC + 1 ºC	F4	4.5	**	NCC	**	E	NG	ES
		F5	5.0	*	NCC	**	E	NG	ES
		F4	4.5	**	NCC	**	E	NG	ES
		F5	5.3	*	NCC	*	E	NG	ES
5	RT 40 ºC + 1 ºC	F4	4.6	**	NCC	**	E	NG	ES
		F5	5.2	**	NCC	**	E	NG	ES
		F4	4.6	**	NCC	**	E	NG	ES
		F5	5.2	*	NCC	**	E	NG	ES
10	RT 40 ºC + 1 ºC	F4	4.6	**	NCC	**	E	NG	ES
		F5	5.3	*	NCC	**	E	NG	ES
		F4	4.4	**	NCC	**	E	NG	ES
		F5	5.1	*	NCC	**	E	NG	ES
20	RT 40 ºC + 1 ºC	F4	4.5	**	NCC	**	E	NG	ES
		F5	5.3	*	NCC	*	E	NG	ES
		F4	4.6	**	NCC	**	E	NG	ES
		F5	5.6	**	NCC	*	E	NG	ES
30	RT 40 ºC + 1 ºC	F4	4.5	**	NCC	**	E	NG	ES
		F5	5.4	*	NCC	*	E	NG	ES
		F4	4.5	**	NCC	**	E	NG	ES
		F5	5.3	*	NCC	*	E	NG	ES

CONCLUSION

A vitamin E enriched cold cream is well formulated with almond oil as an internal phase by using fusion method. The overall research concluded that the formulation batch **F4** shows the best result and it provide the nourishing, antioxidant and moisturizing property of Sweet almond oil and Vitamin E oil to the skin.

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