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Research Article

Formulation and Evaluation of Pluronic -Lecithin Organogel Containing Natural Moisturizing Agent for Xerosis

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Abstract

Xerosis is a common skin condition as well as a key aspect of a number of diseases associated to hereditary and acquired conditions. The objective of this study was to formulate and evaluate the pluronic lecithin organogel containing natural moisturizing agents for topical application. Different formulations of pluronic lecithin organogels were prepared by using Pluronic F127, Lecithin, Vitamin E, Aloe vera, water, sorbic acid, and potassium sorbate. The gel containing different quantities of Polaxomer, soya lecithin and polyvinyl alcohol were characterized for their mechanical properties and moisturizing capabilities.The pH of the formulations was 6.89- 7.19 reflecting no risk of skin irritation. Pluronic enhances the stability of organogel by increasing the viscosity. The polymeric films, which were produced, were thin, flexible, resistant, and suitable for application on limbs and feet. Studies showed that the film was intact for longer period of time. The results obtained showed that the polymeric films formed from organogel containing vitamin E and Aloe vera could be an innovative therapeutic approach for enhancing the moisturization of skin.

Keywords: Organogel, film forming gel, dry skin, Aloe vera, Vitamin E, soya lecithin, Pluronic F127

1. INTRODUCTION:

Xerosis or dry skin is a common skin problem experienced by almost all the people at some stage of life and is associated with pathological and systemic conditions [1]. Normal, it is not a serious issue but sometimes the treatment is complicated. Xerosis gets aggravate in winter, when where both cold, dry air outside cause blood to be drawn away from the dermis and in dry, hot climates, where too much heat and air conditioning evaporate water from the skin[2]. The pervasiveness of xerosis increases with age as there seems to be changes in the process of keratinization and lipid content of the stratum corneum.The deficiency factors that contribute to xerosis, includes a deficiency in moisture-binding substances collectively known as the natural moisturizing factor (NMF)skin barrier lipids deficiency and ceramides.To effectively treat xerosis, each of the key factors that are important in modulating and maintaining skin hydration has to be consider[3]. Transdermal drug delivery system (TDDS) can provide some desirable performances over conventional pharmaceutical dosage formulations, such as improving drug bioavailability, reducing frequency. The current dosage formulations used for TDDS are mainly gels, ointments and creams [4].

The importance and need for topical delivery led to the search for novel carriers and contributed towards the noticeable expansion of the field. Organogel are clear, thermodynamically stable, and biocompatible gel like systems, mainly composed of hydrated phospholipids and appropriate organic liquid. It is a two phase system consisting of an oil (lipophilic) phase and a water (hydrophilic) phase. Recenlty organogels gained more popularity because of their structural and functional benefits. A number of therapeutic drug molecules have been incorporated into organogel for their facilitated transport through topical route [4]. Many researchers worked on formulation of pluronic lecithin organogel (PLO) to facilitate drug delivery across the epidermis after topical application due to their biocompatibility, their amphiphilic nature and permeation enhancing properties [5]. PLO gel is non-irritating to the skin, absorbs quickly, and is practically odorless.

MATERIAL AND METHODS:

Materials

Soya lecithin was obtained from Lipoid GmbH, Ludwighafen, Germany. Pluronic F127 was procured from Sigma Aldrich Chemie GmbH (Steinheim, Germany). Isopropyl palmitate, sorbic acid, and potassium sorbate were supplied by Loba Chemie (Mumbai, India). All other chemicals were of analytical grade and used as received.

Formulation of Pleuronic Lecithin Organogel

Organogel was prepared by slightly modified method [6]. Organogel was prepared by mixing the lecithin, oil phase, and aqueous phase in a ratio of 20:80 v/v. The oil phase was prepared by mixing lecithin, sorbic acid, and isopropyl

myristate and allowing the mixture to stand overnight at room temperature to ensure complete dissolution. The aqueous phase was prepared by adding pluronic F 127 / carbopol / HPMC to ice-cold water, the mixture was placed in a refrigerator and agitated to ensure complete dissolution. Sorbic acid was added as a preservative in the formulation. Vitamin E and Aloevera were dissolved in either ethyl alcohol or DMSO, and mixed with the prepared aqueous phase. The aqueous phase (80%) was slowly added drop-wise to the oil phase (20%) with continuous stirring (1,000 rpm using high-speed mechanical stirrer, Remi, India) for 1 minute at room temperature to form the Organogel. Different Organogel formulations were prepared as shown in Figure 1 and Table 1

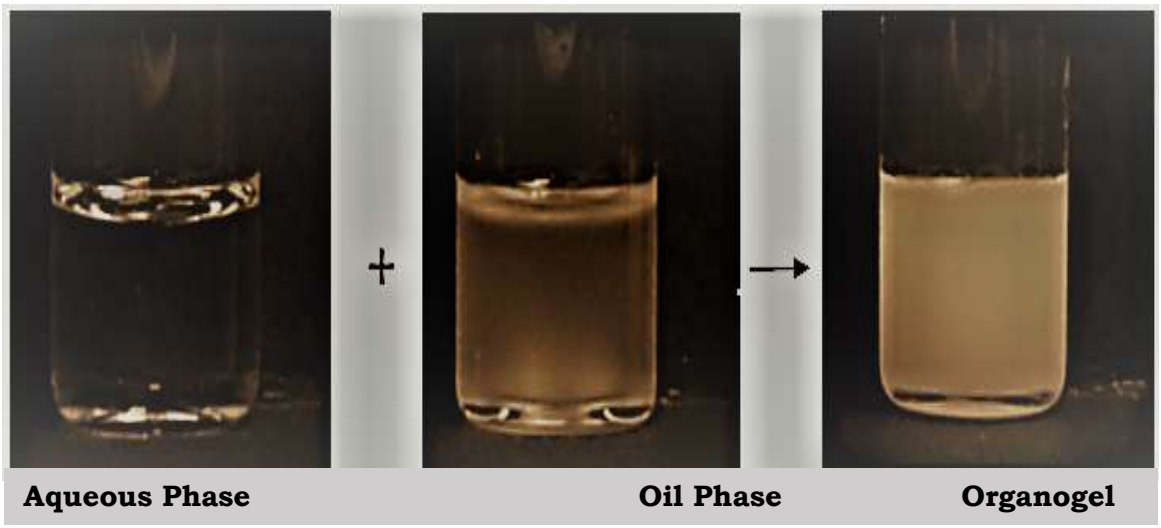

Fig 1: Formulation of Organogel

Table.1: Formulation of Organo Gel (%)

Ingredients/Formulation code	F1	F2	F3	F4	F5	F6	F7	F8	F9
Polaxomer PF-127 (gm)	10	20	30	10	20	30	10	20	30
Carbopol- 940 (gm)	10	-	-	-	10	-	-	-	10
HPMC (gm)	-	-	-	-	-	-	0.2	0.2	0.2
PVA (ml)	5	10	15	5	10	15	5	10	15
Potassium sorbate (gm)	-	-	-	0.2	0.2	0.2	-	-	-
Soya Lecithin (gm)	5	5	5	5	5	5	5	5	5
IPM (ml)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Aloe vera (ml)	1	2	3	1	2	3	1	2	3
Vitamin E acetate (ml)	1	2	3	1	2	3	1	2	3
Ascorbic Acid (gm)	0.2	0.2	0.2	-	-	-	0.2	0.2	0.2
Distilled Water (ml)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

PREFORMULATION STUDIES

Organoleptic Characteristics

Each formulation was tested for color, odor, texture, and phase separation as well as feels upon application (stiffness, grittiness, greasiness, and tackiness).

Homogeneity Test

About 100 mg of gel was tested for the homogeneity as per the procedure in order to determine the consistency of formulation and presence of any that any coarse particles.

Washability

A small quantity (100 mg) of gel was rubbed on the skin of the back of the hand, than patch was washed with water and observed weather it is washable or not.

pH Determination

A solution containing 1 g of gel in 30 ml of neutralized distilled water (pH 7) was prepared and subjected to pH measurement by using a pH meter (Systronic µ pH system 361).

Rheological Studies

Rheological studies were performed with a thermostaticallycontrolled Brook field viscometer(Model LV Brookfield viscometer) by using spindle LV-6 4 at 100 rpm and at temperature 25°C [7].

Spreadability:

One of the criteria for the gels to ideal qualities is that it should possess good spreadability. Spreadability was determined by modified wooden block and glass slide apparatus. For determination of spreadability, a measured amount of gel was placed on fixed glass slide, the movable glass slide with a pan attached to it and was placed over the fixed glass slide, such that gel was sandwiched between the two slides for 5 min. The weight was continuously removed. Spreadability was determined using the following formula: S=M/T, where S is the spreadability in g/s, M is the mass in grams, and T is the time in seconds [8].

Drying Time:

For the assessment of the drying time the formulation was applied to the inner sides of the forearm of a volunteer, who participated in the study on informed consent basis. After 2 minutes a glass slide was placed on the film without pressure. If no remains of liquid were visible on the glass slide after removal, the film was considered dry. If remains of liquid were visible on the glass slide the experiment was repeated until the film was found to be completely dry.

Film intactness:

The formulation was applied to the inner surface of forearm of a volunteer as described for the assessment of the drying time. The dry film was then worn for few hours by the test subject. After every hour the test area was examined visually for completeness of the film, appearance of cracks or flaking.

Skin Irritation Study:

The hairs were removed from the back of the mice with the help of hair removing cream and an area of 2 cm^2 was marked on both the sides. One side served as control while the other as test and animals were used after 24 h of depilation. The formulation was applied once a day for 7 days and sight was covered with cotton bandage[10]. The mice were observed for sensitivity and the reaction if any and were graded as shown in Table 2. The resulting reactions were compared against control group (n=3) and scored according to table 2

Table 2: Score rating for skin irritation study

Score	Grading
0	No reaction
1	Slight, patchy erythema
2	Moderate erythema
3	Severe erythema

RESULTS

Formulation and Characterization of Pluronic Organogel Formulations

Precipitation occurs in some of the batches (F4, F6, F7, F8 andF9) of polymer based organogel which could be due to the incompatibility in the system. Hence, these batches were discarded and remaining batches (F1, F2, F3 and F5) were considered for further study shown in fig. 2

Figure 2: Formulated PLO Organogel

Organoleptic properties

The samples were found to be a slight yellowish in color and the odour was aromatic due to the presence of soya-lecithin.

pH Measurement:

The pH of the formulation was determined by using pH meter and observations are shown in the table 3.

Rheological Parameter:

The viscosity of the formulations is shown in the table 3.

Spreadability:

The spreadability of formulations was found to be 15.26 ± 3.01 to 21.58 ± 0.62 gcm/s (Table I), respectively.

Table 3: PH, Viscosity, Spreadability and Skin Irritation test of Organogel

Formulation Code	PH	Spreadability (Gm.cm/sec)	Viscosity (cps)	Skin Irritation study (0-4)
F1	6.89 ± 0.27	15.26 ± 3.01	254 ± 11.26	0
F2	7.15 ± 0.19	19.74 ± 2.23	273 ± 4.19	0
F3	6.93 ± 0.14	17.68 ± 2.59	221 ± 28.96	0
F5	6.95 ± 0.23	21.58 ± 0.62	194 ± 16.88	0

Drying Time and Film Intactness:

The formulation was applied to the inner surface of forearm of a volunteer as described for the assessment of the drying time. The dry film was then worn for few hours by the test subject. The observations are as shown in the figure 3.

Figure 3: Application of Organogels after specific interval of time

Skin Irritation Study:

The optimized formulations showed no sign of skin irritancy in mice indicating the compatibility of formulations with skin.

DISCUSSION

Precipitation occurs in some of the batches (F4, F6, F7, F8 andF9) of polymer based organogel which could be due to the incompatibility in the system. Hence, these batches were discarded and remaining batches (F1, F2, F3 and F5) were considered for further study.

As the concentration of the organogelator was increased, the consistency of the products increased. All the samples were found to be oily to touch and were having gritty nature and did not show any phase separation. The pH of the formulations was found to be suitability for the application on the skin, because pH was found to be in the range of skin pH and was compatible.

The viscosity of formulation (F5) was found to be highest and viscosity of F1 was found to be least. The increase in viscosity might be due to formation of complex network, as in the case of gel, the consistency depends on percentage of solids in relation to liquid. In case of pluronic lecithin organogel, consistency was increased, which could due to combination of pluronic and lecithin present in formulation. The spreadability offormulations was found to be 15.26 ± 3.01 to 21.58 ± 0.62 gcm/s (Table I), respectively, which revealed that the presence of pluronic increases the spreadability of formulation. The optimized formulations showed no sign of skin irritancy in mice indicating the compatibility of formulations with skin.

CONCLUSION

Organogels offers improved topical applications as compared to hydrogels. The prepared organogel was a yellowish, transparent, jelly-like substance with good flexibility and adhesive property, which was easy to be coated on the skin surface and in situ forms a very thin and comfortable film with an aesthetical appearance but without any greasy feeling. In addition, the results showed that the gel has good film-forming properties and aloevera and vitamin E also added to enhance the moisturization of skin. The findings of the present study suggest that the prepared organogels containing lecithin and pluronic were observed to be safe, stable, and cost-effective topical delivery system.

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Conflict of Interest

The authors declare no conflict of interest, financial or otherwise.

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Authors' contributions:

KW and RT conceived and designed the experiments; SS and US performed the experiments, analyzed the data and wrote the manuscript; MU and YA performed the statistical analysis of the study. All authors contributed to critical revision of the manuscript.

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