

**Stability Studies of Moisturizing Creams Containing Rice Bran Wax**

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ABSTRACT

The aim of the present work is to study long term stability of moisturizing creams as per ICH guidelines in order to verify their shelf life. For this purpose we analyzed the sample for various physico-chemical parameters like pH, particle size, spreadability, rheological measurement and *in vitro* occlusivity. The results showed that there was no change in pH, particle size, spreadability, rheological measurement and *in vitro* occlusivity of moisturizing creams during 12 months of its storage at $25^{\circ}\text{C} \pm 2^{\circ}\text{C}/60\% \text{RH} \pm 5\% \text{RH}$. Therefore, we concluded that the prepared moisturizing cream formulation is stable for one year.

Key Words: Moisturizing cream, Occlusivity, Spreadability, Stability.

INTRODUCTION

The purpose of stability testing is to provide evidence on how the quality of a drug substance or pharmaceutical product varies with time under the influence of a variety of environmental factors such as temperature, humidity, light and to establish a re-test period for the drug substance or a shelf life for the pharmaceutical product and recommended storage conditions¹. The design of the formal stability studies for the drug product should be based on knowledge of the behavior and properties of the drug substance and from stability studies on the drug substance and on experience gained from clinical formulation studies². In the present work stability study was performed on two optimized formulations of moisturizing cream as per ICH stability guidelines for 12 months and analyzed the product after every 3 months time interval for physico-chemical parameters such as pH, particle size, spreadability, rheological measurement and *in vitro* occlusivity.

MATERIALS AND METHODS**Materials**

The Rice bran wax (RBW) was obtained as a gift sample from Space lab, Nasik in flakes form; stearic acid, lanoline, glycerin, sorbitol etc were obtained as a gift sample from Aquatic Remedies Mumbai.

Formula of Optimized Moisturizing Cream

Formulations of various proportion of RBW were prepared and on the basis of physico-chemical parameters such as pH, particle size, spreadability, rheological measurements and *in-vitro* occlusivity the successful formulations were optimized whose compositions are as follows:

Table-1: Composition of optimized moisturizing cream formulations A and B

Ingredients	Cream A	Cream B
Phase A		
Rice Bran Wax	7.5	15
Stearic Acid	1.75	3.5
Lanolin	2	2
Liquid Paraffin	5	5
Cetostearyl Alcohol	2	2
Glyceryl Monostearate	3	3
Phase B		
Triethanolamine	0.8	1.6
Glycerin	7.5	7.5
Sorbitol	2.5	2.5
Propylene Glycol	5	5
Methyl Paraben	0.18	0.18
Propyl Paraben	0.02	0.02
Water	q.s. to 100g	q.s. to 100g

Method of Preparation*Preparation of Aqueous Phase*

To the water in a glass beaker, other water-soluble materials like Triethanolamine, Glycerin and Sorbitol were added and the solution heated until it attained a temperature of about 70°C .

Preparation of Oil Phase

For the oil phase, Rice Bran Wax, Glyceryl Monostearate, Cetostearyl Alcohol, Stearic Acid, Lanolin and Liquid Paraffin were added as the temperature was increased to about 70°C .

Preparation of Cream Formulation

The aqueous phase was then transferred to the oil phase maintained at 70°C. The mixture was stirred manually with a glass stirring rod until the phases were homogeneous. The temperature of the mixture was allowed to cool to 50°C while stirring manually, and a separate solution of Methyl and Propyl Paraben in Propylene Glycol was added. The creams were then stirred until a smooth consistency was obtained, after which they were packed into 25 g ointment jars and stored at room temperature (25°C) until required for further analysis.

Stability Conditions

Moisturizing cream A and B were prepared and kept in humidity chamber at 25°C ± 2°C/60% RH ± 5% RH for 12 months^{3,4} and samples were withdrawn after every 3 months and evaluated for its physico-chemical properties such as pH, particle size, spreadability, rheological measurement and *in vitro* occlusivity.

Table-2: Storage conditions for optimized moisturizing cream formulations.

Study	Storage condition	Minimum time period covered by data at submission	Time interval
Long term stability teating	25°C ± 2°C/60% RH ± 5% RH	12 months	Every 3 months

RESULTS AND DISCUSSION

The results obtained for various physicochemical parameters at different time interval are summarised in table-3 and 4. Both the samples of moisturizing cream (Formulation A and B) showed consistent results up to 12 months.

Table-3: Characterization of cream A at different time intervals

Evaluation parameters	Stability testing time interval				
	0 month	3 month	6 month	9 month	12 month
Viscosity at 5 rpm (m Pa s)	2.4 x 10 ⁶	3.4 x 10 ⁶	2.5 x 10 ⁶	2.7 x 10 ⁶	2.8 x 10 ⁶
In-vitro Occlusivity test	better occlusivity	better occlusivity	better occlusivity	better occlusivity	better occlusivity
pH	8.20±0.195	8.30±0.197	8.21±0.155	7.80±0.194	8.70±0.295
Spreadability (cm)	6.4±0.08	6.7±0.08	6.5±0.18	5.9±0.18	6.8±0.02

Table-4: Characterization of cream B at different time intervals

Evaluation parameters	Stability testing time interval				
	0 month	3 month	6 month	9 month	12 month
Viscosity at 5 rpm (mPa s)	10.8 x 10 ⁶	11.8 x 10 ⁶	10.9 x 10 ⁶	11.1 x 10 ⁶	10.7 x 10 ⁶
In-vitro Occlusivity test	Better occlusivity	Better occlusivity	Better occlusivity	Better occlusivity	Better occlusivity
pH	8.31±0.244	8.41±0.344	7.61±0.284	8.44±0.344	8.81±0.454
Spreadability (cm)	6.1±0.08	6.2±0.18	6.4±0.09	5.9±0.07	6.5±0.01

CONCLUSION

On the basis of results obtained from stability studies of moisturizing cream A and B containing Rice bran wax, it can be concluded that the optimized formulations A and B are stable up to one year.

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