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STABILITY TESTING OCCURRED ON PIROXICAM CREAM PREPARATION BY USING STEARIC ACID AND TRIETHANOLAMINE AS EMULSIFYING AGENTS

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Abstract: Piroxicam is classified as a Class 2 product in the Biopharmaceutic Classification System due to its limited solubility in water. The cream preparations underwent optimisation of the stearic acid and triethanolamine concentrations. The optimisation results indicate that the most favourable amounts of stearic acid and triethanolamine (TEA) are 16% and 4% respectively. The physical attributes test yielded positive findings for the formula, indicating a successful cream formulation that satisfied the specified criteria. Purpose: The cream formulation is thereafter submitted to a stability assessment. The purpose of the stability test is to ascertain the long-lasting quality of the preparation when subjected to various storage circumstances. Procedure: Stability tests were conducted over 6 cycles at temperatures of 4° C and 40° C. During the testing phase, various characteristics of the cream preparation were assessed, including organoleptic properties, homogeneity, viscosity, adhesive power, spreadability, and pH. Result: The formulated solution successfully fulfils the criteria of the physical characteristics test, with the following parameter values: pH of 6.8, viscosity of 11010 Cps, spreading power of 6.8 cm, adhesive power of 2.6 seconds, and protective power of 6.5 seconds. Conclusion: The t-test findings conducted before and after assessing the stability of the preparation indicated a p-value greater than 0.05, indicating the absence of a significant difference.

Keywords: Stability test, Cream, Piroxicam

INTRODUCTION

Piroxicam is classified as a non-steroidal anti-inflammatory medication (NSAID). Piroxicam is used once daily to promote patient adherence due to its extended elimination half-life (Katzung, 2019). Piroxicam is classified as a Class 2 drug in the Biopharmaceutic Classification System (BCS), indicating that it has low solubility in water and high permeability in the intestines. This means that it is absorbed quickly, but its capacity to dissolve is weak (Islami et al., 2020). Oral administration of piroxicam can result in stomach irritation as a side effect (Lai et al., 2014). Studies have been conducted to enable the topical administration of piroxicam. A cream is one of the available dose forms.

Prior studies focused on optimising the use of stearic acid and TEA as agents to increase penetration. When comparing the concentrations of stearic acid and TEA at 16% and 4%, the results indicate that the physical characteristics testing meets the requirements and yields excellent outcomes. (Sonia and others, 2023). A stability test was conducted to determine the durability of the piroxicam cream formulation. The employed stability test is the cycle test method. The primary parameter in physical characteristics testing is the durability of the preparation. Stability tests are conducted to verify that the preparations retain their desired qualities during the storage period until they are delivered to the consumer. The study examined the organoleptic properties, homogeneity, viscosity, adhesive power, spreadability, and pH of the piroxicam cream preparation both before and after conducting the stability test. (Budianor et al., 2022).

METHODS

1. Formulation of piroxicam cream using stearic acid and TEA as emulsifiers

The process of preparing the cream starts with weighing the cup, followed by combining the oil phase by melting the specified quantity of stearic acid in a water bath. Then, 10 g of vaseline is added and stirred until a uniform mixture is achieved. The aqueous phase was prepared by dissolving methyl paraben in boiling distilled water, stirring until fully dissolved, and subsequently incorporating TEA while stirring until a uniform mixture was obtained. The cream base is prepared by gradually combining the oil phase with the water phase while stirring over a water bath until a uniform mixture is achieved. The emulsion of the oil phase and water phase is removed from the bath and agitated until it reaches a lower temperature and a uniform cream base is created. Propylene glycol is utilised as a wetting agent for piroxicam. The combination of active compounds is gradually incorporated into the cream base and agitated until a uniform consistency is achieved (Ika et al., 2022).

2. Evaluation of the Physical Characteristics of Piroxicam Cream Preparations

a. Viscosity Test

The viscosity assessment of the piroxicam cream formulation was conducted with a Brookfield viscometer. The viscosity test commences with the installation of spindle number 64. The spindle speed is configured to rotate at a rate of 20 revolutions per minute (rpm). Viscosity measurements are conducted by affixing the sample, which is held in the beakerglass, to the viscometer until the spindle is fully immersed. The viscometer is activated until it displays the viscosity measurement in centipoise (cPs). The value that is both the longest and most frequently displayed on the viscometer screen is documented (Septiani et al, 2011).

b. Test for Spreadability

An experiment was conducted to assess the spreadability of the piroxicam cream preparation. The cream preparation, weighing 0.5 g, was placed on a glass scale. An initial load of 50 g was added and left for 1 minute. The test proceeded by adding additional loads of 50 g until the total load reached 150 g. Every additional load is left for a duration of 1 minute. The measurement of the diameter of spread is documented as spreading power data (Ika et al, 2022).

c. Adhesion Test

The adhesion strength testing procedure involves weighing a 0.5 g sample, laying it on a glass object, and then covering it with another glass object. Subsequently, a 50 g mass was applied to it for a duration of 5 minutes. The load is detached, and the end of the cover slide is linked to the bottom of the slide using a clamp on the adhesion test tool. Subsequently, the support lever is released. The duration is measured from the moment the load is released until the bond is released (Ika et al., 2022).

d. Organoleptic Evaluation

Ika et al. (2022) describe that organoleptic testing of piroxicam cream involves visually assessing the cream's odor, color, and shape when applied to the skin. Each formula was tested three times.

e. Test for homogeneity

The homogeneity test was conducted by measuring the weight of 0.5 g of piroxicam cream. The piroxicam cream was applied onto two glass slides and made even. Subsequently, the researchers utilized a magnifying glass to visually inspect the distribution of the preparation, assessing whether it was uniformly disseminated or not (Heather and Adam, 2012).

f. pH test

The pH test was conducted utilizing universal pH paper. The experiment involved the application of piroxicam cream preparation over universal pH paper, followed by the observation of any color change in the pH paper (Heather and Adam, 2012).

g. Cream Stability Test

This experiment employs the freeze-thaw technique, in which the sample is subjected to alternating temperatures of room temperature, 4° C, and 40° C for a total of 6 cycles. Each cycle lasts for 48 hours (Handayani et al, 2015).

h. Statistical examination and interpretation of data

The paired T test will be used to assess each test data in the physical attributes test. The paired T test is used to assess the impact of different storage conditions on the physical properties of piroxicam cream formulations.

RESULT AND DISCUSSION

The cream formulation was divided into 3 separate batches. Every batch underwent physical characteristic testing both before and after the stability test. Table 1 displays the outcomes of evaluating the physical attributes of the piroxicam cream formulation both before and after the stability test.

Table 1. Average Data Of Examinations Conducted On The Physical Characteristics Of Piroxicam Cream Formulations

	Before cycling test	After cycling test
Organoleptic	White, odorless	White, odorless
Homogenity	Homogen	Homogen
Adhesion	2.6 second	2.3 second
Spreadability	6.8 cm	6 cm
viscosity	11010 cps	11020 cps
pH	6.5	6.8

The cream formulation was produced in three separate batches. Every batch underwent physical characterization both before and after the stability test. The physical parameters of the piroxicam cream preparation were tested before and after the stability test, and the findings are presented in table 1.

1. Organoleptic evaluation

This organoleptic assessment is conducted to ascertain the form, hue, aroma, and flavor of the cream formulation when applied to the skin. The findings obtained are partially solid, possessing a whitish hue, and lacking any discernible odor. The color of the preparation is derived from both the active material and other supplementary substances. The resulting scent is devoid of any odor as there is no inclusion of corhigen odoris in the formulation.

Figure 1. Organoleptic Test Of Piroxicam Cream Formulation

2. Homogenity Test

The purpose of the homogeneity test is to assess the homogeneous distribution of particles in the cream mixture, ensuring optimal quality and performance when applied. The homogeneity of a substance can be affected by the manufacturing process, particularly when lowering particle size or combining substances based on their solubility to facilitate the mixing process. Using a homogenous preparation will yield optimal therapeutic efficacy. The findings from assessing the homogeneity of the optimal formula indicate that the preparation is homogeneous.

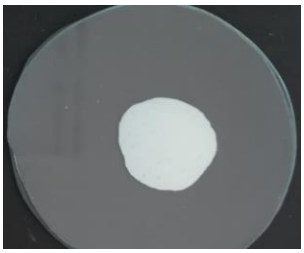

Figure 2. Homogeneity Test Conducted On The Piroxicam Cream Formulation

3. pH Test

The purpose of pH testing is to ascertain that the cream formulation does not cause skin irritation, by ensuring that its pH falls within the range of 4.5-7, which is consistent with the pH range of the skin. (Swastika et al., 2013). The pH of cream formulations can be affected by the pH of each item included in the formulation. The mean value obtained in pH testing was 6.7. An increase in stearic acid concentration leads to a decrease in pH due to the abundance of acid groups present in stearic acid. Conversely, a higher concentration of TEA results in an elevated pH due to the presence of basic groups in TEA (Astikah, 2015).

4. Viscosity Test

Viscosity testing is conducted to determine the viscosity of the cream formulation. The optimal viscosity range for cream formulations is 2000-50,000 cps, as stated by Erwiyani et al. in 2018. The viscosity of the optimal formula was tested three times, resulting in an average value of 11023.33 centipoise (cps). Spreadability testing is conducted to assess the cream's capacity to disperse evenly over the skin's surface. Greater dispersion of the cream formulation facilitates its application onto the skin. The mean outcome of the optimal formula is 7 cm.

5. Adhesion Test

The purpose of the adhesion test is to assess the cream preparation's capacity to stick to the skin surface upon application. The duration of cream adhesion to the skin directly correlates with the amount of active material that is absorbed. The mean outcome achieved in the adhesion test was 2.43 seconds. According to Ika et al. (2022), adhesion is considered satisfactory when it can maintain its stickiness for a duration of 2-300 seconds. A protective efficacy test was conducted to assess the preparation's capacity to shield the skin from external factors, such as dust, pollution, and sunshine. The mean outcome achieved was 6.2 seconds.

6. Stability Test

Stability tests are conducted to verify that the preparations retain their desired qualities throughout the storage procedure until they are delivered to the consumer. The presence of good stability in a cream preparation is indicated by the absence of physical alterations, such as the separation of water and oil components, changes in fragrance, alterations in color, solidification, or even liquefaction. The stability assessment involved conducting cycling tests before and after storing the sample at a low temperature of 4°C. The cycling tests consisted of 6 cycles in a refrigerator to simulate cold temperature conditions, and 6

cycles in an oven at 40°C to simulate hot temperature conditions. Each cycle was carefully observed and included an assessment of organoleptic properties, homogeneity, viscosity, stickiness, spreadability, and pH (Budianor et al., 2022).

Statistical analysis was conducted to assess the impact of storage conditions on the physical properties of piroxicam cream formulations. The data obtained from the viscosity, pH, spreadability, and adhesiveness tests in 6 stability test cycles did not show any significant differences ($p>0.05$). Table 2 displays the outcomes of statistical analysis piroxicam cream formulation both before and after the stability test.

Table 2. Presents The Results Of A Paired T Test Conducted On The Physical Characteristics Of Piroxicam Cream Preparations Before And After A Stability Test

Paired Samples Test	
	Sig. (2-tailed)
Uji Viskositas	.057
Uji pH	.205
Uji Daya Sebar	.058
Uji Daya Lekat	.126

CONCLUSION

According to the data analysis, the piroxicam cream prepared using the best formula remains stable while stored at temperatures of 4°C and 40°C. The p-values obtained from each physical attribute test are more than 0.05, indicating that the results are not statistically significant.

Stability tests can be conducted to assess chemical, physical, and microbiological properties. For additional storage testing, the accelerated fibre-stability test method might be employed for a duration of 3 months.

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