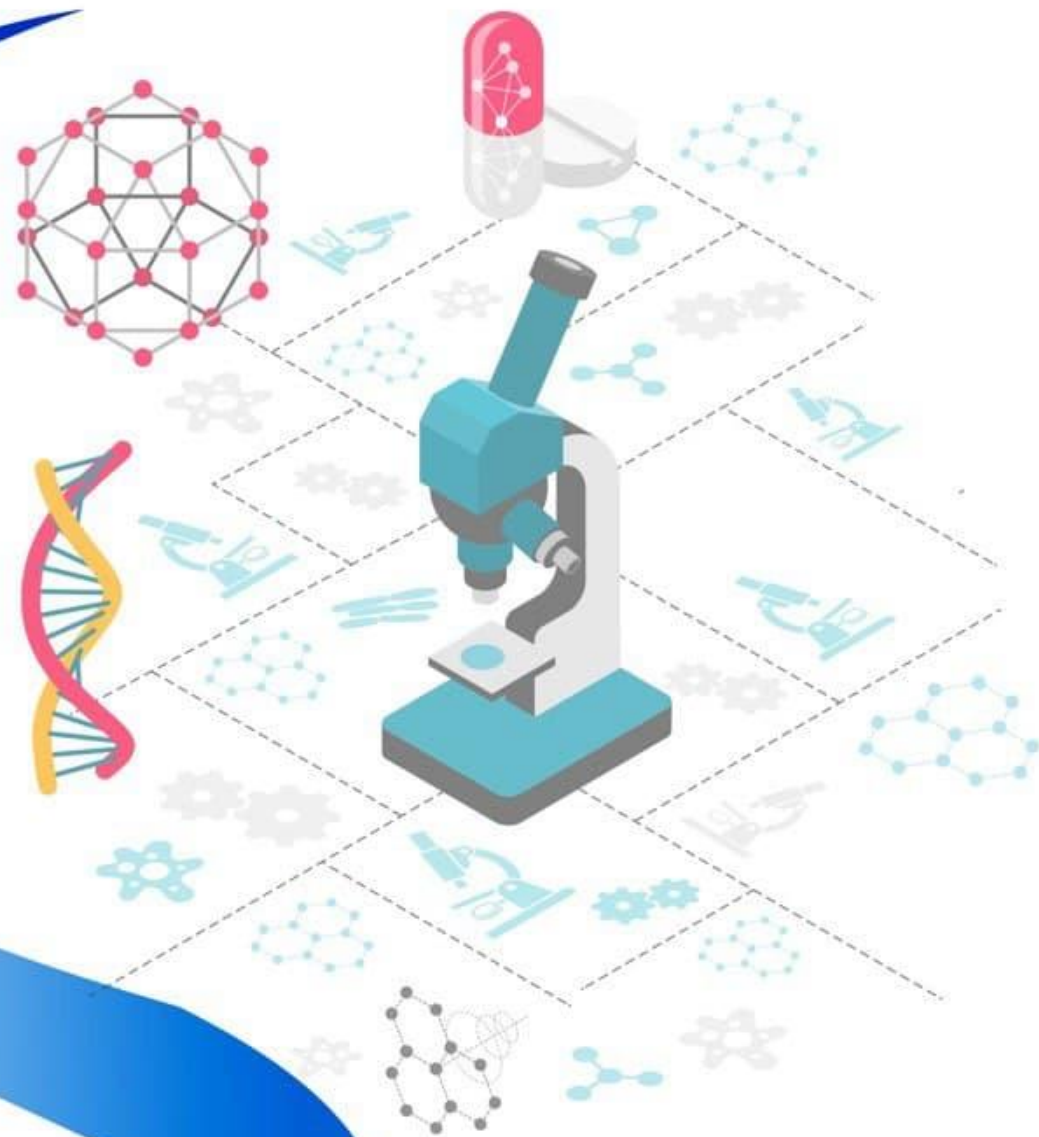


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SELECTION OF A BASE FOR A VENOM-BASED OINTMENT

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Abstract: Research has been conducted on selecting a base for an ointment formulation that provides effective pain relief and anti-inflammatory effects based on snake venom. Three different bases were selected and evaluated according to relevant regulatory documents.

Keywords: pain reliever, snake venom, excipients, hydrophilic base, hydrophobic base, colloid stability, thermal stability, pH, melting temperature.

INTRODUCTION

Joint pain, back pain, and osteoarthritis have become significant issues affecting a large portion of the global population today. The high prevalence of back pain (affecting 17.6% of the U.S.A workforce) and its economic impact (exceeding \$50 billion) pose significant challenges to society. Statistics indicate that 80% of people start their day with pain.

According to a 2016 survey by the U.S.A Department of Health and Human Services, 50 million American adults live with chronic pain, making it the most common reason adults seek medical attention.

Today, the global pharmaceutical market offers a wide range of pain-relieving drugs. Recent studies show that topical pain relief formulations have several advantages, such as self-administration by patients without the need for medical professionals, no gastrointestinal issues as seen with oral medications, rapid action, and no adverse effects on the cardiovascular system.

In developing a high-quality, safe, and effective drug, the excipients used, along with the active ingredients, packaging, dosage form, and storage conditions, play a critical role. Excipients not only make up the bulk of the drug but also assist in delivering the desired pharmacological effect, masking the organoleptic properties in some formulations, and ensuring the drug's overall or localized action. Therefore, selecting suitable excipients for each dosage form and product is a key task for pharmaceutical technologists.

Topical dosage forms, such as ointments, are ancient and are still widely used in medicine today. Excipients play an essential role in ensuring the therapeutic efficacy of ointments. They form the base of the ointment and are selected according to the nature of the ointment, the area of application, and the physicochemical properties of the active ingredient. Excipients must help deliver the desired pharmacological effect,

prevent microbial growth, be easy to apply, and align with therapeutic recommendations. A well-chosen ointment base improves skin condition, facilitates the penetration of the active ingredient through the skin, and ensures an active mechanism of action. Given these considerations, we conducted research on selecting and developing the technology for a snake venom-based ointment with pain-relieving and anti-inflammatory properties.

Materials and methods of research Three different ointment bases were selected as research objects by studying the bases mentioned in scientific literature and those available in the global pharmaceutical market for snake venom-based ointments. The properties of the bases were analyzed according to relevant regulatory documents, including:

Appearance (color, odor, taste) was assessed visually.

Homogeneity was visually inspected to ensure no small particles were present in the tested bases.

The pH value was determined potentiometrically according to relevant regulatory documents. The pH indicates the concentration of hydrogen ions in a solution, expressed as the negative logarithm of hydrogen ion activity. The pH value for ointments intended for application to the skin should ideally be between 5.60-6.90.

The melting point of the ointment bases was determined using an open capillary method. The temperature at which the substance in the capillary begins to move upwards was recorded as the melting point. The experiment was repeated five times, and the arithmetic mean of the five values was recorded as the melting point, ensuring the difference between values did not exceed 1°C .

The colloidal stability of the ointment bases was tested by checking for separation into emulsion and water layers. The tested bases should not separate into layers according to the regulatory document.

The thermal stability of the ointment bases was determined using the method described in the regulatory document with a thermostat device.

Three different bases were selected for the snake venom-based ointment with anti-inflammatory and pain-relieving properties based on literature reviews and the study of existing pharmaceutical ointments.

№1 Hydrophilic base 40.0 gr

Gelatin - 1.2 gr

Glycerin- 10 gr

Purified water - 28.8 gr

Technology: gelatin is divided into pieces, placed in a porcelain bowl, and purified water is poured over it and left for 3-4 hours. Then put glycerin on it and heat it in a water bath until it forms a homogeneous liquid. The mixture is left for a certain time until a mass of soft consistency is formed.

№2 Hydrophobic base 40.0 gr

Beeswax - 3.6 gr

Vaseline - 28.8 gr

Lanolin - 7.6 gr

Technology: beeswax is placed in a porcelain mortar and melted in a water bath. After it melts, add vaseline and continue mixing in a water bath. After the mixture cools down a little, add lanolin and thoroughly emulsify it. Mixing is continued until a yellow uniform mass is formed.

№3 Hydrophobic base 40.0 gr

Enziphobe base

(Patent No. IAP 05976)

Beef fat

Sunflower oil

Lipase solution

Phosphate buffer

The selected bases were evaluated according to the mentioned regulatory documents, and the results are presented in the table (Table 2):

Appearance (color, odor, taste) was assessed visually.

The homogeneity of the ointment base samples was visually inspected by placing 0.02 g of each base sample on a glass slide, covering it with another slide, and pressing until a spot with a diameter of about 2 cm was formed. Then, the sample was examined with the naked eye from a distance of 30 cm to check for the presence of small particles.

The pH value was determined potentiometrically using a "Five Easy FE20" pH meter. For this, 3.0 g of each base was mixed with 30 ml of deionized water, heated in a water bath at 50-60°C while stirring, and the pH of the aqueous layer was measured.

The liquefaction temperature in the glass so that there was a distance of 1 cm between the bottom of the glass and the thermometer ball. Water was poured into the glass at a layer height of 5 cm and the temperature was raised at a rate of 10 C per minute. The above of the base samples was determined by the open capillary method. For the experiment, open-ended glass capillary, 80 mm long, outer diameter 1.4-1.5 mm, inner diameter 1.0-1.2 mm, heated magnetic stirrer, value up to 0.10 C A liquid glass thermometer was obtained. The bases were placed in sufficient quantity to form a column approximately 10 mm high in each of the 5 capillaries and left for a specified time. One of the capillaries was placed in the thermometer with the substance near the bulb of the thermometer. Then this thermometer was placed

process was repeated with the remaining 4 capillaries. At the end of the experiment, the average arithmetic value (four) of the 5 (t_1, t_2, t_3, t_4, t_5) values obtained was calculated and determined as the liquefaction temperature (Table 1)

Table 1**Melting Point Measurement Results**

Base Type	t_1	t_2	t_3	t_4	t_5	$t_{o'rt}$
Hydrophilic	36,9	36,9	37,2	37,0	37,0	37
Hydrophobic	37,7	37,9	38,2	38,0	38,2	38
Enzyphobic	37,7	37,3	37,4	37,5	37,6	37,5

The colloidal stability of the bases was tested using a ЦЖМН Р 10-01-ЭЛЕКОН centrifuge. Three samples of each base were centrifuged at 1500 rpm for 5 minutes. No separation into layers was observed in any of the tested bases.

The thermal stability was tested by placing five test tubes with base samples in a thermostat at $40 \pm 2^\circ\text{C}$ for 24 hours. After 24 hours, the samples were removed and stored at $10 \pm 2^\circ\text{C}$ in a refrigerator for 24 hours. No separation into layers was observed.

Table 2**Base Analysis Results**

№	Measured Parameters	Base Samples		
		№1	№2	№3
1	Color	Clear, colorless, transparent	Yellow	White
2	Odor and Taste	Odorless, tasteless	Mild vaseline odor	Odorless, slightly greasy taste
3	Homogeneity	Meets standards	Meets standards	Meets standards
4	Consistency at 15-20°C	Liquid	Thick, ointment-like	Thick, ointment-like
5	pH	5,74	6,0	6,7
6	Melting Point, °C	37	38	37,5
7	Thermal Stability	No separation	No separation	No separation
8	Colloidal Stability	No separation	No separation	No separation

CONCLUSION:

1. Scientific literature and ointments containing snake venom in the domestic and foreign pharmaceutical market were studied, and based on the obtained data, 3 different base compositions were selected for the ointment.

2. Selected basic contents were prepared and quality analyzes were conducted based on regulatory documents.

3. Based on the results of the analysis, the consistency of the hydrophilic base (gelatin-glycerin) was liquid and did not meet the microbiological stability index when stored at room temperature. The second and third base samples met all the quality indicators specified in the regulatory documents.

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