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IRRITABILITY IN SKIN WITH PRODUCTS WITH MENTHOL AND CAMPHOR. BASE TEST

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ABSTRACT

A study was conducted to determine the sensitizing effect of ointments and possible dermal irritability. The study was carried out in albino rabbits by the general method of irritability in skin analysis using the techniques described in the standardized work procedures established by the center of Health Sciences of the Autonomous University of Baja California. Evaluate local inflammatory reactions that are intact and abraded skin sensitizing effect of two ointments in skin of rabbits. Get values for erythema, formation of bedsores and formation of edema at 24 and 72 h well on intact skin as abraded skin. Irritation levels obtained in all cases allows products to be classified as non-irritating. It can be said to comply with the prerequisites for the acceptance of the product and its use in the pathology for which it was designed such formulation.

KEYWORDS: dermal irritability, sensitizing effect.

INTRODUCTION

Draize test is an acute toxicity test devised in 1944 by food and Drug (Administration FDA) toxicologists John H. Draize and Jacob M. Spines. Initially used for testing cosmetics, the procedure involves applying 0.5 mL or 0.5 g of a substance to the eyes or the skin of a sober and conscious animal and then leave it for the amount of time before you rinse it and record its effects.[21,22] animals are observed up to 14 days for signs of erythema and edema in the skin test as redness, edema, discharge, ulceration, bleeding, turbidity or blindness in the

tested eye. The test subject is commonly an albino rabbit, although other species are used too, including dogs.[23] animals are slaughtered after testing if the test represents an irreversible damage to the eyes or skin. Animals can be reused for testing Product A was constituted by: white solid Vaseline, paraffin white guayacol, oil of eucalyptus, natural menthol essence and synthetic camphor. Product B by: white vaseline, synthetic camphor, refined white paraffin. A study was conducted to determine the possible dermal irritability and sensitizing effect of ointments.

The study was conducted in albino rabbits through the general method of analysis of irritability in skin with the techniques described in the standard operating procedures of work established by the center of Sciences of the health of the Autonomous University of Baja California and the NORMA OFICIAL MEXICANA NOM-096-SSA1-1994.[24]

OBJECTIVE

Assess local inflammatory reactions that occur on intact and abraded skin as the effect of sensitizing of two ointments to skin of rabbits. Get the values for erythema and eschar formation and formation of edema at 24 and 72 h well on intact skin as abraded skin.

MATERIALS AND METHOD

12 albino rabbits were healthy adults with weight of 2 to 3.5 Kg, maintained to standards of vivarium conditions. A day before the test she was subjected in traps and dorsal area of each animal is shaved to one and other side of the backbone of the region, shoulder girdle to the lumbar. Avoided the mechanical irritation and withdrew the loose hair.

The day the test is delimited four areas of 4 cm per side, identified as A, B, C, and D. In two of them in interleaved A and D were to make an incision, taking care not to damage the dermis or cause bleeding, this was carried out through the use of a hypodermic needle of 22Gx14MM in scribing a line perpendicular to the spine in the ar EAS mentioned, that in every one of the rabbits. So that healthy skin B and C areas and two were eroded areas A and D.

Applied in the four areas 0.5 g of ointment in six rabbits and the other six applied 0.5 g of ointment B. Applied ointment with a spatula covering every area of application with a square patch of sterile gauze of 2.5 cm and two thick Monolayers, secured with adhesive fabric and is protected the edges to prevent leakage of the product.

Covered the trunk of the animal with waterproof material to hold the patch in place and retard evaporation.

After 24 hours of exposure, the patches were removed and evaluated the resulting reactions according to table A.

Table A: Evaluation of the presence of reactions based on the modified Daize method.

Skin reaction		**Value**
Erythema and eschar formation	No Erythema	0
	Very light Erythema	1
	Well defined Erythema	2
	Moderate to severe Erythema	3
	Severe Erythema	4
Formation of edema	No edema	0
	Very slight edema	1
	Slight oedema (edges and lifting	2
	Moderate edema, elevation	3
	Severe edema, higher elevation	4

Readings were performed again at 72 hours of application using the same table A Joined the values obtained in both readings for erythema and formation of bedsore for abraded skin both intact skin (areas B and C) (areas A and D). Similarly added the values for the formation of edema after 24 and 72 hours on intact skin (areas B and C) to abraded skin (areas A and D), using table A The total of the eight values were divided between four to get the value of irritation using table B.

Table. B: Format for evaluation of values.

Skin reaction		**Values**		
		24 hr	72 hr	Total
Erythema and eschar formation	Intact skin			
	Abraded skin			
Formation of edema	Intact skin			
	Abraded skin			

Based on the values obtained from irritation samples were classified into the following categories according to tables C and D.

Table. C: Classification of values.

Area	Value	Interpretation
Intact skin	0-0.9	Non-irritant
	1.0-1.9	Slightly irritant
	2.0-4.0	Very irritating (avoided)
Abraded skin	0-0.9	Non-toxic
	1.0-1.9	Slightly toxic
	2.0-4.0	Very toxic (avoided)

Tabla. D. Interpretation.

Intact skin	Abraded skin	interpretation
0.0 - 0.9	0.0 - 0.9 1.0 - 1.9 2.0 - 4.0	Non irritant Non irritant For intact skin could be innocuous For abraded skin could require protective measures Irritant for intact skin. Avoid contact with skin
1.0 - 1.9	0.0 - 0.9 1.0 - 1.9	Could be innocuous for intact and abraded skin It requires protective measures Could be innocuous for intact skin. It requires protective measures. Avoid use in abraded skin
2.0 -4.0	2.0 -4.0	Very irritant for intact and abraded skin. Avoid use

RESULTS

The results obtained are shown in table E and F. Using the statistical package SPSS v17.0 to obtain descriptive statistics.

Table. E. Results

Ointment A					
	Erythema		**Edema**		**Value of irritation**
	Irritated skin	**Abraded skin**	**Irritated skin**	**Abraded skin**	
Rabbit 1	Slightly irritant	Slightly toxic	Reqs. protective measures	Avoid use	1
Rabbit 2	Non irritant	Non toxic	Non irritant	Reqs.protective measures	0.5
Rabbit 3	Non irritant	Non toxic	Non irritant	Reqs.protective measures	0.25
Rabbit 4	Non irritant	Non toxic	Non irritant	Reqs.protective measures	0.25
Rabbit 5	Non irritant	Non Toxic	Non irritant	Reqs.protective measures	0
Rabbit 6	Non irritant	Non toxic	Non irritant	Reqs.protective measures	0

Table. F. Results.

Ointment B					
Erythema			**Edema**		**Value of irritation**
	Irritated skin	**Abraded skin**	**Irritated skin**	**Abraded skin**	
Rabbit 7	Non irritant	Non toxic	Non irritant	Reqs.protective measures	0.5
Rabbit 8	Non irritant	Non toxic	Non irritant	Reqs.protective measures	0
Rabbit 9	Non irritant	Non toxic	Non irritant	Reqs.protective measures	0.5
Rabbit 10	Non irritant	Non toxic	Non irritant	Reqs.protective measures	0
Rabbit 11	Very irritant	Very Toxic	Very irritant	Avoid use	2.5
Rabbit 12	Slightly irritant	Slightly toxic	Reqs.protective measures	Avoid use	1

These are based on the value obtained from irritation, they oscillate between 0 which indicates no irritant for intact skin and non-toxic to eroded skin to a value of 2.5 which indicates very irritating to intact skin and very toxic to abraded skin, and indicates prevention of their use.

The following graphic shows the frequency of the obtained level of irritation when applying the ointment to skin.

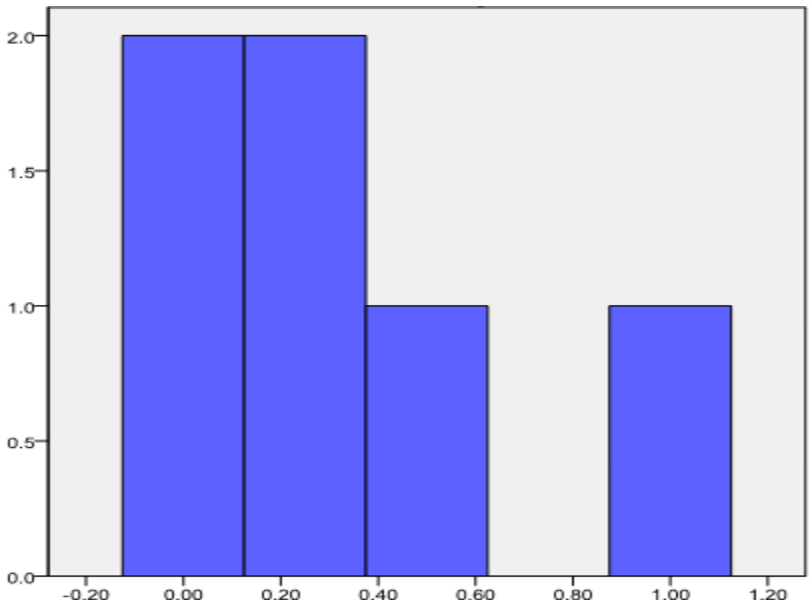

Figure. 1. A Ointment.

N = 6, Typical deviation= 0.376, Mean = 0.33

In the graph figure 1 the mean value obtained for irritation was 0.33, with a typical deviation of 0.376 which is in the category range of non-irritant.

For the Group of rabbits that were applied with ointment B, we obtained a mean value of irritation of 0.75 with a standard deviation of 0.935. The following graph shows the frequency of the obtained level of irritation when applying ointment B as shown in figure 2.

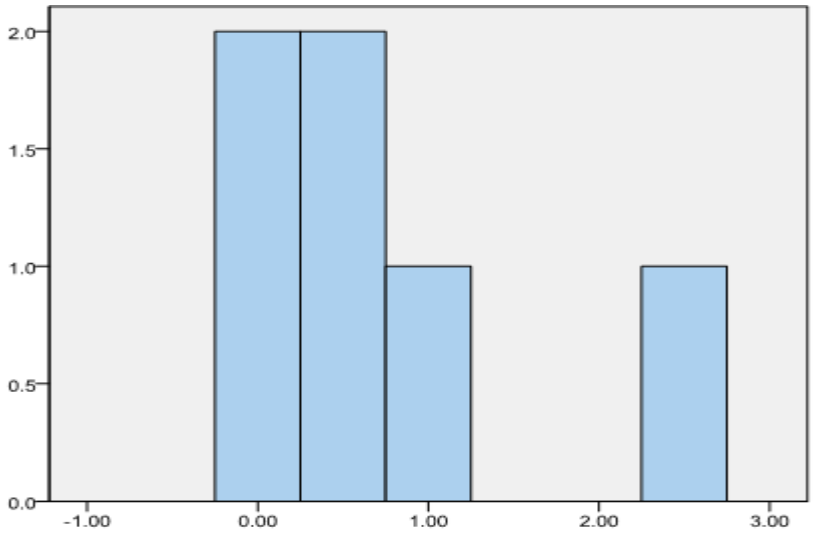

Figure. 2. B Ointment.

N = 6, Typical deviation = 0.935, Mean = 0.75

33% of sample rabbits presented an irritation value of 0, of this percentage 50% corresponds to ointment A. Value of irritation sign averaged 0.50, this corresponds to table C of interpretation to a result of non-irritant to skin intact or eroded, non-toxic to the composite you abraded skin. The table D this value indicates harmless to intact and abraded skin. Protection measures are required for their use.

No rabbit presented edema after 24 and 72 hours of application of ointments. 25% of the sample has a value of 0.5, 16.6% irritation presents a value of 0.25, another 16.6% present value of 1 table-based irritation C this indicates slightly irritating to intact skin, requires protective measures during use, for abraded skin slightly toxic requires protection measures for its use. The table D this value indicates non-irritant may be harmless to intact skin for abraded skin protection measures required during use. Avoid use on abraded skin. The 8.33% presents a value of 2.5 irritation in the table C this value indicates very irritating to intact skin, very toxic for abraded skin, prevent their use. D this same value reported in table very irritating for skin intact and abraded skin, to prevent their use.

CONCLUSION

Evaluated formulations met with the requirements established for this type of preparation and presented physical and chemical stability during the study time in storage environmental temperature plastic jars. Based on this we can conclude that pH does not influence the chemical stability of ointments. Irritation levels obtained in all cases allows to classify products as non-irritating. It can be said to comply with the prerequisites for the acceptance of the product and its use in the pathology for which the formulation was designed.

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