ACTO PHARMA HİJYEN SAN. TİC. A.Ş.

Akcaburgaz Mahallesi 3038 Sokak No: 11
34522 Esenyurt / ISTANBUL
TÜRKİYE

Münster, 28.04.2014

Sertifika

Kozmetik ürün:

Actolind® W Solution

2014 yılında insanlar üzerinde yapılan dermatolojik test

Dermatolojik uzmanların kontrolü altında ürününüz üzerinde yaptığımız dermatolojik test, bu ürün için

"çok iyi" olarak geçmiştir.

Bu ürün, uluslararası yönergelere uygun olarak yapılan alerji testlerinde toksik-tahriş edici intolerans reaksiyonlarına yol açmamıştır. Dolayısı ile preparat dermatolojik olarak test edilmiş olarak açıklanabilir.

İmza
Dr. Gerrit Schlippe
Dermatoloji, venereoloji, alergoloji

Smap

ARGEDS-2015/85A

SKIN IRRITATION TEST REPORT

GENERAL INFORMATION

Test Name Skin Irritation

Guidelines
This study followed the procedures indicated by the following internationally accepted guidelines:

ISO 10993: Biological evaluation of medical devices
- ISO 10993-1:2014 - Evaluation and testing within a risk management process
- ISO 10993-10:2014 - Tests for irritation and skin sensitization
- ISO 10993-12:2013 - Sample preparation and reference materials

Testing Facility : Hacettepe University
Faculty of Pharmacy
Department of Pharmacology 06100 ANKARA

Test Sample : Actolind W Solution*
Lot No : 15091174
Quantity : 3 pieces

* As the request of the supplier, this report does not include the supplier's company information.

Arrival of the test sample : 08.12.2015

Start of Experiment : 22.12.2015

End of Experiment : 25.12.2015

Date of Report : 30.12.2015

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EXPERIMENTAL PROCEDURE

Blank sample: Physiological saline (0.9 % (m/v) NaCl)

Test procedure: Three healthy adult albino rabbits (either sex, 2-3 kg) was used.

On the day before the test, the fur on the back of the animals was shaved. A sufficient distance was kept on both sides of the spine for the application and observation of all test sites. The test material (0.5 ml) and a blank sample (0.5 ml) immersed in four-ply gauze patches were applied directly to the skin on both sides in two different areas of the rabbit. The application sites were covered with a 2,5x2,5 cm gauze patch and were wrapped with a semi-occlusive bandage for 4 h. At the end of the contact time the patches and dressings were removed and the position of the sites were marked by permanent ink.

OBSERVATION & CALCULATION

Application sites are observed for erythema and oedema at 1st, 24th, 48th, and 72nd hours following the removal of the patches. Only 24th, 48th, and 72nd hours observations are used for calculations. Irritation was scored by using ISO 10993-10, "Scoring system for skin reaction". Irritation grades are presented as mean of two application sites of either test or blank sample. The primary irritation score for each animal is calculated by dividing the sum of all the irritation scores by six (two test/observation sites, three time points). Primary irritation index is calculated by subtracting the sum of primary irritation scores for the blank sample from the sum of primary irritation scores for the test samples and then dividing this difference by the total number of animals (three). According to the calculated primary irritation index values, the results are presented as the appropriate response category which is given below.

TABLE 1: SCORING SYSTEM FOR SKIN REACTION

Reaction	Irritation score
Erythema and eschar formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet-redness) to eschar formation preventing grading of erythema	4
Oedema formation	
No oedema	0
Very slight oedema (barely perceptible)	1
Well-defined oedema (edges of area well-defined by definite raising)	2
Moderate oedema (raised approximately 1 mm)	3
Severe oedema (raised more than 1 mm and extending beyond exposure area)	4
Maximal possible score for irritation	8
Other adverse changes at the skin sites shall be recorded and reported.	

RESULT

TABLE 2: MEAN IRRITATION SCORES OF TWO APPLICATION SITES AT 24 th, 48th,72th HOURS

Observation time points (hours)	1st rabbit		2nd rabbit		3rd rabbit	
	Control site	Test site	Control site	Test site	Control site	Test site
24th	0	0	0	0	0	0
48th	0	0	0	0	0	0
72nd	0	0	0	0	0	0
Primary irritation score	**0**	**0**	**0**	**0**	**0**	**0**

Primary irritation index: 0

Primary irritation index	Response category
0 to 0.4	Negligible
0.5 to 1.9	Slight
2 to 4.9	Moderate
5 to 8	Severe

Response category: Negligible

CONCLUSION

This result indicates that the test sample "**Actolind W Solution** (Lot 15091174) " **does not cause any skin irritation.**

Study Director

Professor Pelin Kelicen Uğur

Coordinator

Professor Serdar Uma