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Shenzhen Testing Center of Medical Devices

Test Report

Report No.:	WY20232385
Test Article:	PCL (Polycaprolactone)
Sponsor:	Shenzhen Esun Industrial Co., Ltd.
Manufacturer:	Shenzhen Jusing Biotechnology Co., Ltd.
Test Type:	Commission Test
Date of Issue:	Nov. 13,2023

扫码验证报告

提取码:176855

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Test Report

Report No.: WY20232385

Test Article	PCL (Polycaprolactone)		
Test Type	Commission Test	**Identification No./ Lot No.**	/
Trade Mark	esun	**Model / Type**	Viscosity-average Molecular Weight 60000 - 80000 g/mol
Date of Manufacturing	Aug. 11, 2023	**Accepting Date**	Aug. 29, 2023
Sponsor	Shenzhen Esun Industrial Co., Ltd.		
Applicant Address	Wuhan University Building A403-I and A901, No. 6 Yuexing 2 Road, Nanshan District, Shenzhen 518057		
Manufacturer	Shenzhen Jusing Biotechnology Co., Ltd.		
Production Address	Floor 3, No. 9, Yifenghua Innovation Industrial Park, Xinshi Community, Dalang Street, Longhua district, Shenzhen City		
Test Items	Animal irritation test by skin exposure		
Test in Accordance with	ISO 10993-23:2021 Biological evaluation of medical devices -Part 23: Tests for irritation		
Summary	The test article, PCL (Polycaprolactone), was extracted in 0.9% sodium chloride injection and sesame oil respectively at 37℃ for 72h. The resulting extract was evaluated animal irritation test by skin exposure in accordance with the requirements of ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation. A 2.5cm× 2.5cm patch of absorbent gauze, saturated with 500μL test article extract and positive control, was applied one patch on test side of rabbit. Similarly, the absorbent gauze saturated with negative control was patched on control site on the same rabbit. The animal was wrapped with a bandage for 4h and then removed. The treatment sites were washed with warm water and marked. Observations of erythema and oedema were recorded at 1h, 24h, 48h, and 72h after the patches were removed, and the Primary Irritation Index for the extracts was calculated. Under the conditions of this study, the 0.9% sodium chloride injection and sesame oil test article extract showed no evidence of causing skin irritation to rabbit. The Primary Irritation Index for 2 extracts was 0 and irritation responses were negligible. The positive control group howed obvious evidence of skin irritation to rabbits. The Primary Irritation Index for the positive control was 4.7 and irritation response was moderate.		
Comments	/		
Authorized Signatory	刘[illegible]	**Date Completed**	Nov.13,2023

深圳市医疗器械检验中心 检验检测专用章 4403055618

INTRODUCTION

The test article identified below was extracted and the extract was evaluated for animal irritation test by skin exposure in accordance with the guidelines of the ISO 10993-23:2021 *Biological evaluation of medical devices -Part 23: Tests for irritation.* An assessment is made of the potential of the article under test to produce dermal irritation in the rabbit. The test article was accepted on Aug. 29, 2023. The extraction was applied from Oct. 13, 2023 to Oct. 16, 2023. The treatment began on Oct. 16, 2023, and the observations were concluded Oct. 19, 2023.

MATERIALS

The sample provided by the sponsor was identified and disposed as follows:

Test Article:	PCL (Polycaprolactone)
Identification No.:	/
Storage Conditions:	Room temperature
Extract Vehicle:	Polar solvent: 0.9% sodium chloride injection ChP (SC) Non-polar solvent: sesame oil
Positive control:	20% (mass concentration) aqueous preparation of sodium lauryl sulphate
Preparation:	According to the requirements, under aseptic conditions, 3.00 g of the test article was covered with 15.00 mL SC based on a ratio of 0.2 g/mL. Another 3.00 g of test article was covered with 15.00 mL sesame oil in the same way. They were extracted at 37℃ for 72h. The extract vehicle without test article was similarly prepared to serve as the negative control. The extract was used immediately.

METHODS

Test System:	
Species:	Conventional rabbit
Breed:	New Zealand White
Source:	Guangdong Animal Center of Medical Experimental
Sex:	Females, they should be nulliparous and not pregnant
Body Weight Range:	2.6 kg～2.8 kg
Age:	Young adult
Acclimation:	7 days
Number of Animals:	9
Animal Management:	
Husbandry:	Conditions conformed to ISO 10993-2 Animal welfare requirements.
Food:	General rabbit diet was provided daily.
Water:	Urban domestic water was provided.
Contamination:	Reasonably expected contaminants in food or water supplies did not have the potential to influence the outcome of this test.
Environmental:	The room temperature and humidity were daily monitored. The temperature of the room was controlled within 20℃～26℃. The humidity of the room was controlled within 40%～70%.
Facility:	Shenzhen testing center of Medical Devices is a CNAS accredited facility.
Personnel:	Associates involved were appropriately qualified and trained.
Selection:	Only healthy and previously unused animals were selected.

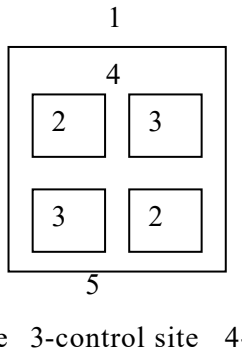
Experimental Procedure:

Nine rabbits were randomly divided into polar, non-polar and positive control groups, each group was included 3 rabbits.

Fur is generally clipped within 24h of testing on the backs of the animals, a sufficient distance on both sides of the spine for application and observation of all test sites (approximately 10cm×15cm).

Before the treatment, each rabbit was weighed. Each 2.5cm×2.5cm patch of absorbent gauze was saturated with 500μL test article extract and was applied on the test site of rabbit as illustrated in Fig. 1. Similarly, the absorbent gauze saturated with negative control was patched on the control site of the same rabbit.

Each 2.5cm×2.5cm patch of absorbent gauze was saturated with 500μL positive control and was applied one patch on test site of rabbit as illustrated in Fig. 1. Similarly, the gauze saturated with polar control was patched on control site on the same rabbit.



1-cranial end 2-test site 3-control site 4-clipped dorsal region 5-caudal end

Fig. 1 Location of skin application sites

Each animal was wrapped with a bandage for 4h, then removed the bandage. The treatment sites were washed with warm water to remove residual reagents and marked.

Observations of erythema and oedema were recorded at 1h, 24h, 48h, and 72h respectively after the patches were removed. The reactions were evaluated according to Table 1.

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-define 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.	

After the 72h grading, all erythema grades plus oedema grades 24h, 48h and 72h are totalled separately for each test article extract, negative control and positive control for each animal. The primary irritation

score for an animal is calculated by dividing the sum of all the scores by 6 (two test/observation sites, three time points).

To obtain the primary irritation index(PII) for the test sample add all the primary irritation scores of the individual animals and divide by the number of animals (generally three). Calculate the primary irritation score for the negative control and subtract that score from the score using the test article extract to obtain the primary irritation score. The PII is characterized by score and response category in Table 2.

Table 2- Primary or cumulative irritation index categories in rabbit

Mean score	Response category
0 to 0.4	Negligible
0.5 to 1.9	Slight
2 to 4.9	Moderate
5 to 8	Severe

RESULTS

The test article and the negative control showed no obvious evidence of skin irritation to rabbits. The positive control group showed obvious evidence of skin irritation to rabbits. Results of scores for individual rabbits appear in Table 3.

Table 3-Skin Irritation Observations

Rabbit No.	Weigh (kg)	Group	Scoring Interval								Mean Score	Irritation Score
			1 h (ER/OE)		24 h (ER/OE)		48 h (ER/OE)		72 h (ER/OE)			
1#	2.7	Polar extracts	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0	0
		Polar negative control	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0	
2#	2.7	Polar extracts	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0	0
		Polar negative control	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0	
3#	2.6	Polar extracts	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0	0
		Polar negative control	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0	
4#	2.8	Non-polar extracts	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0	0
		Non-polar negative control	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0	
5#	2.6	Non-polar extracts	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0	0
		Non-polar negative control	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0	

6#	2.7	Non-polar extracts	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0	0
		Non-polar negative control	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0	
7#	2.6	Positive control	1/1	1/1	1/2	2/2	2/2	3/3	3/3	3/3	4.8	4.8
		Polar negative control	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0	
8#	2.6	Positive control	1/1	1/0	2/1	2/1	3/2	3/3	3/2	3/2	4.5	4.5
		Polar negative control	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0	
9#	2.8	Positive control	1/1	1/0	2/1	2/2	2/2	3/2	3/3	3/3	4.7	4.7
		Polar negative control	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0	
Primary Irritation Index (Polar extracts)			0									
Irritation Response (Polar extracts)			Negligible									
Primary Irritation Index (Non-polar extracts)			0									
Irritation Response (Non-polar extracts)			Negligible									
Primary Irritation Index (Positive control)			4.7									
Irritation Response (Positive control)			Moderate									
ER/OE=Erythema/Oedema												
Remarks: Use only 24h, 48h and 72h observations for calculations.												

CONCLUSION

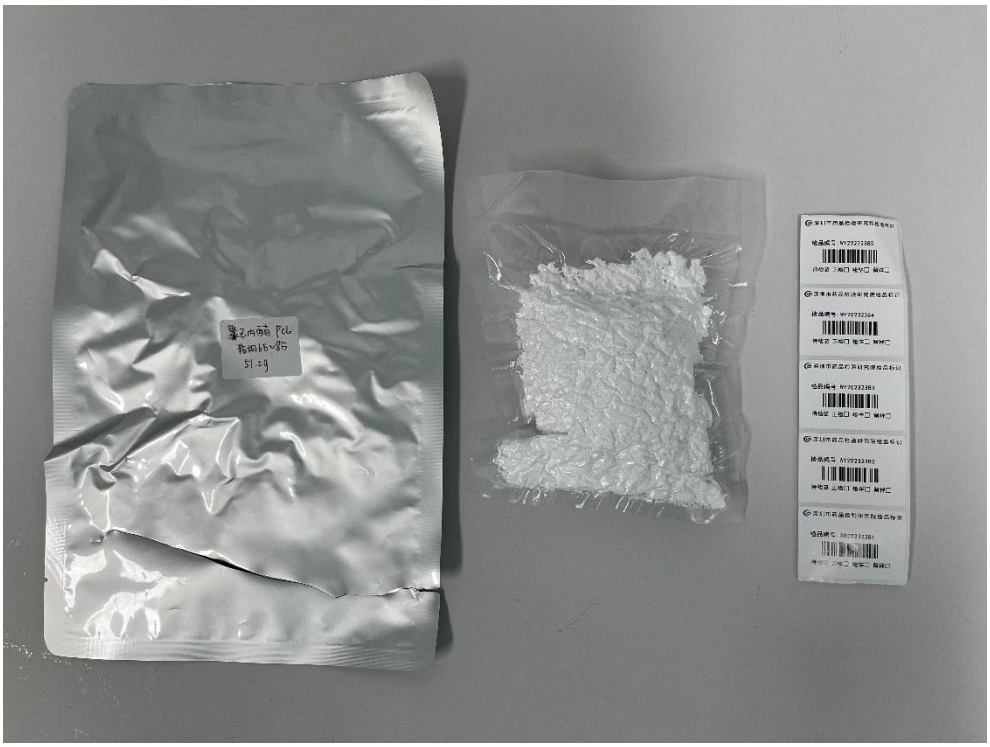
Under the conditions of this study, the 0.9% sodium chloride injection and sesame oil test article extract showed no evidence of causing skin irritation to rabbits. The Primary Irritation Index for 2 extracts was 0 and irritation responses were negligible. The positive control group showed obvious evidence of skin irritation to rabbits. The Primary Irritation Index for the positive control was 4.7 and irritation response was moderate.

Results and conclusions apply only to the test article tested. No further evaluation of these results is made by our testing center. Any extrapolation of these data to other samples is the responsibility of the sponsor. All procedures were conducted in conformance with ISO 17025.

RECORD STORAGE

All raw data pertaining to this study and a copy of the final report are to be retained in designated archive files in our testing center.

Test Report

Test Article
 Fig. 2 Test Article
Sample Specification
/
Model / Type
/

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