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Shenzhen Testing Center of Medical Devices

Test Report

Report No.:	WY20240159
Test Article:	PLLA polymer
Sponsor:	Shenzhen Esun Industrial Co., Ltd.
Manufacturer:	Shenzhen Jusing Biotechnology Co. , Ltd.
Test Type:	Commission Test
Date of Issue:	Apr. 19,2024

扫码验证报告

提取码:664474

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Test Report

Report No.: WY20240159

Test Article	PLLA polymer		
Test Type	Commission Test	**Identification No./ Lot No.**	/
Trade Mark	esun	**Model / Type**	Viscosity average Molecular Weight sixty thousand to eighty thousand
Date of Manufacturing	Dec. 12, 2023	**Accepting Date**	Jan. 22, 2024
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	Skin sensitization tests		
Test in Accordance with	ISO 10993-10:2021 *Biological evaluation of medical devices - Part 10: Tests for skin sensitization*		
Summary	The test article, PLLA polymer, was extracted in 0.9% sodium chloride injection and cottonseed oil respectively at 37℃ for 72h. The resulting extract was evaluated the potential for skin sensitization tests in accordance with the guinea pig maximization test requirements of ISO 10993-10:2021 *Biological evaluation of medical devices - Part 10: Tests for skin sensitization.* The test article extract was intradermally injected and occlusively patched to ten test guinea pigs in an attempt to induce sensitization. The positive control and the solvent control were similarly injected and occlusively patched to ten control guinea pigs respectively. Following a recovery period, the test and control animals received a challenge patch of the appropriate test article extract, solvent control and positive control. All sites were scored at 24h and 48h after patch removal. Under the conditions of this study, the 0.9% sodium chloride injection and cottonseed oil test article extracts showed no evidence of causing skin sensitization in the guinea pig.		
Comments	"/" in the report indicates that this item is blank.		
Authorized Signatory		**Date Completed**	Apr.19,2024

深圳市医疗器械检验中心 检验检测专用章 4403055618

INTRODUCTION

A guinea pig maximization test of the test article identified below was conducted to evaluate the potential to cause skin sensitization. This study was conducted based on the guinea pig maximization test requirements of the ISO 10993-10:2021 *Biological evaluation of medical devices - Part 10: Tests for skin sensitization.* The test article was accepted on Jan. 22, 2024. The extraction was applied from Feb. 26, 2024 to Feb. 29, 2024. The treatment began on Feb. 29, 2024, and the observations were concluded on Mar. 25, 2024.

MATERIALS

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

Test Article:	PLLA polymer
Identification No.:	/
Storage Conditions:	Room temperature
Extract Vehicle:	Polar solvent: 0.9% sodium chloride injection ChP (SC) Non-polar solvent: Cottonseed oil
Positive control:	0.1% 1-chloro-2,4-dinitrobenzene
Freund's Complete Adjuvant:	FCA, SIGMA
Preparation:	Prior to use, according to the requirements, under aseptic conditions, a quantity of the test article was covered with SC based on a ratio of 0.2 g/mL, a quantity of other test article was covered with cottonseed oil based on a ratio of 0.1 g/mL after saturation with cottonseed oil. They were extracted at 37℃ for 72h. The extract vehicle without test article was similarly prepared to serve as the solvent control. The extract was used immediately.

METHODS

Test System:

Species:	Conventional guinea pig
Breed	Albino
Source:	Guangdong Animal Center of Medical Experimental
Sex:	Males and nonpregnant nulliparous Females
Body Weight Range:	300g to 400g
Age:	Young adult
Acclimation:	3 days
Number of Animals:	50

Animal Management:

Husbandry:	Conditions conformed to ISO 10993-2 Animal welfare requirements.
Food:	General Guinea pig 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 range for the room was controlled within 20℃～26℃. The humidity range for 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.

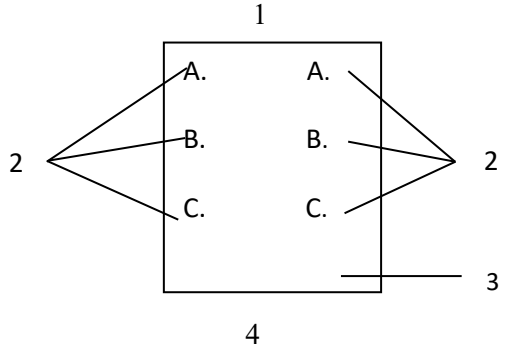
Selection: Only healthy and previously unused animals were selected.

Experimental Procedure:

4h prior to treatment, each animal was weighed, identified and clipped free of fur over the dorsoscapular region.

Intradermal Induction:

The test animals were injected with the test article extract and the control animals were injected with the control. Intradermal injections were given to each animal within an approximate 4cm×6cm boundary of the fur clipped area as illustrated below:



1- Cranial end
2- 0.1mL intradermal injections
3- Clipped intrascapular region
4- Caudal end
A, B, C injection sites

Fig.1 Location of intradermal injection sites

Solvent Control Animal:

A. 0.1 mL of 50:50 (v/v) mixture of FCA and the solvent
B. 0.1 mL of the solvent
C. 0.1 mL of an emulsion of the blank liquid with adjuvant

Test Animal:

A. 0.1 mL of 50:50 (v/v) mixture of FCA and the solvent
B. 0.1 mL of test extract
C. 0.1 mL of a 1:1 mixture of the 50:50 (v/v) solvent / FCA mixture and the test extract

Positive Control Animal:

A. 0.1 mL of 50:50 (v/v) mixture of FCA and the solvent
B. 0.1 mL of 0.1% 1-chloro-2, 4-dinitrobenzene
C. 0.1 mL of a 1:1 mixture of the 50:50 (v/v) solvent / FCA mixture and 0.1% 1-chloro-2, 4-dinitrobenzene

Topical Induction:

6 days after the injections, the same area used during intradermal induction was clipped free of fur and treated with 10 % sodium dodecyl sulfate suspension in petrolatum. The suspension was massaged into the skin over the injection site to provoke a mild acute inflammation. The area was left uncovered for 24h. Then 8cm^2 section of medical gauze, saturated with the test article extract, was applied to the previously injected sites of the test animals. The control animals were similarly patched with the appropriate control. Secure the patches with an occlusive dressing. Remove the dressings and patches after 48h.

Challenge:

At 13 days after the removal of the topical induction patch, 8cm^2 section of medical gauze, saturated with the test article extract or control. All patches were applied to upper flank areas. Secure with an occlusive dressing. Remove the dressings and patches after 24h.

Observation:

Observe the appearance of the challenge skin sites of the test and control animals at 24h and 48h after removal of the dressings. Describe and grade the skin reactions for erythema and oedema according to the Magnusson and Kligman grading given in Table 1 for each challenge site and at each time interval.

Table 1-Magnusson and Kligman scale

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and/or swelling	3

Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in solvent control animals. If grades of 1 or greater are noted in the solvent control animals, then the reactions of test animals which exceed the most severe reaction in solvent control animals are presumed to be due to sensitization.

RESULTS

Individual body observations are presented in Table 2.

The solvent control group and the test article group was a grade 0 during observation period. The positive control group was a grade 2 to 3 during observation period.

Table 2-Individual observations

Polar solvent control	Animal No.	1	2	3	4	5	6	7	8	9	10
	weight(g)	371	356	345	384	349	373	361	330	359	371
	24h	0	0	0	0	0	0	0	0	0	0
	48h	0	0	0	0	0	0	0	0	0	0
Polar extracts	Animal No.	11	12	13	14	15	16	17	18	19	20
	weight(g)	379	340	361	341	350	378	368	366	368	374
	24h	0	0	0	0	0	0	0	0	0	0
	48h	0	0	0	0	0	0	0	0	0	0
Non-polar solvent control	Animal No.	21	22	23	24	25	26	27	28	29	30
	weight(g)	372	348	386	358	332	342	366	370	357	357
	24h	0	0	0	0	0	0	0	0	0	0
	48h	0	0	0	0	0	0	0	0	0	0
Non-polar extracts	Animal No.	31	32	33	34	35	36	37	38	39	40
	weight(g)	368	371	343	388	371	351	354	338	370	345
	24h	0	0	0	0	0	0	0	0	0	0
	48h	0	0	0	0	0	0	0	0	0	0
Positive control	Animal No.	41	42	43	44	45	46	47	48	49	50
	weight(g)	389	359	384	330	361	368	336	382	332	346
	24h	2	2	2	2	2	2	2	2	2	2
	48h	2	3	3	2	3	2	3	3	2	3

CONCLUSION

Under the conditions of this study, the 0.9% sodium chloride injection and cottonseed oil test article extracts showed no evidence of causing skin sensitization in the guinea pig.

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

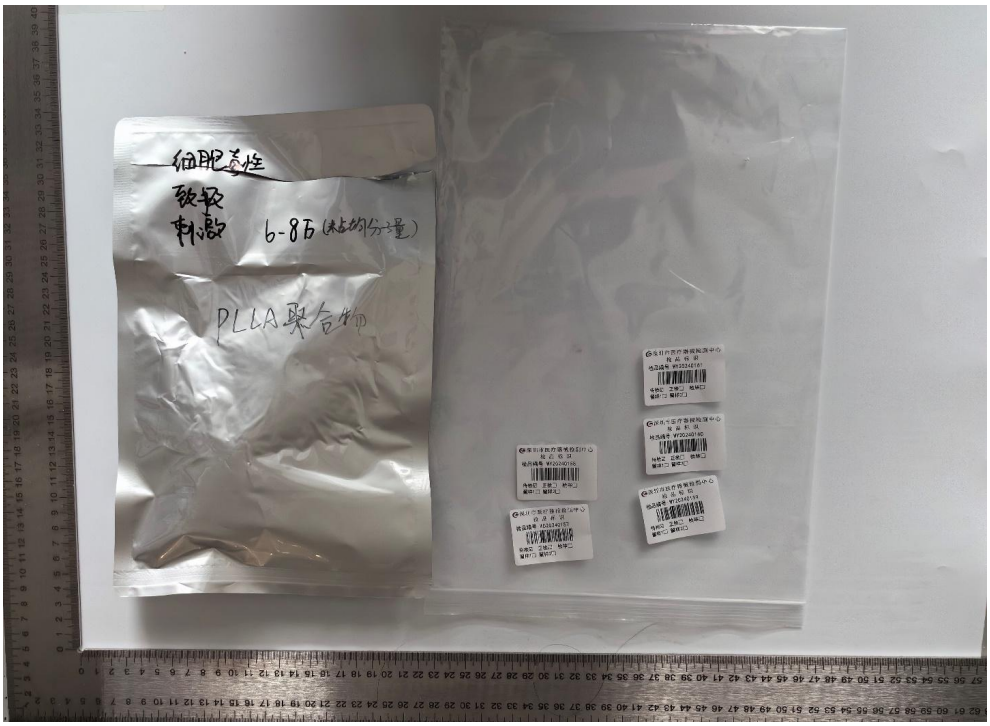


Fig. 2 Test Article 1

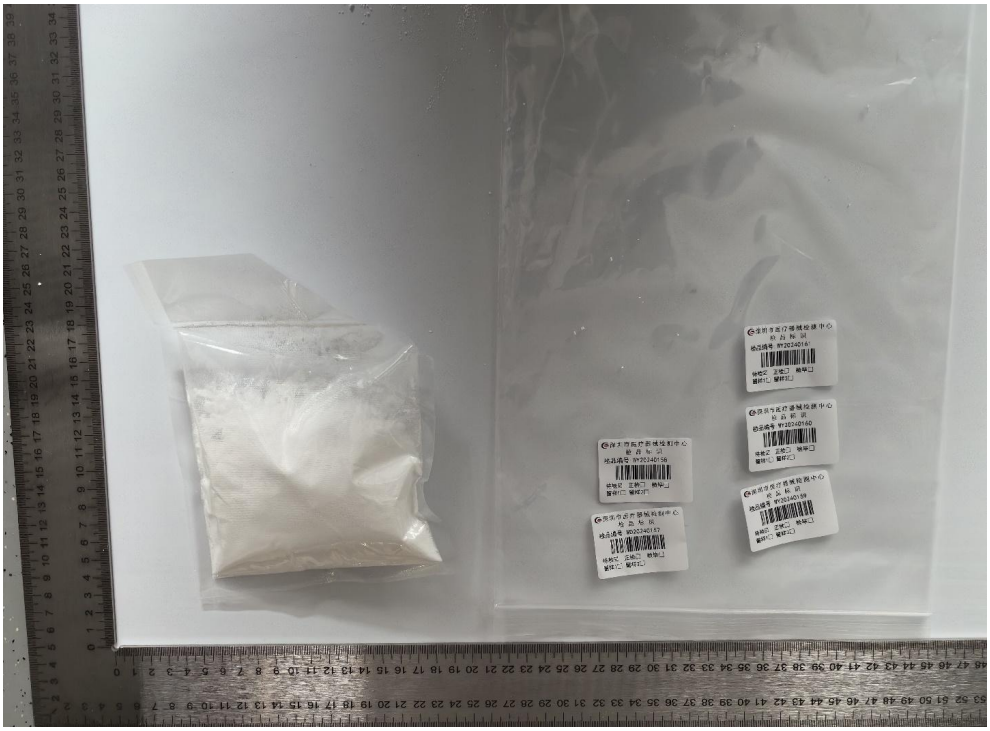


Fig. 3 Test Article 2

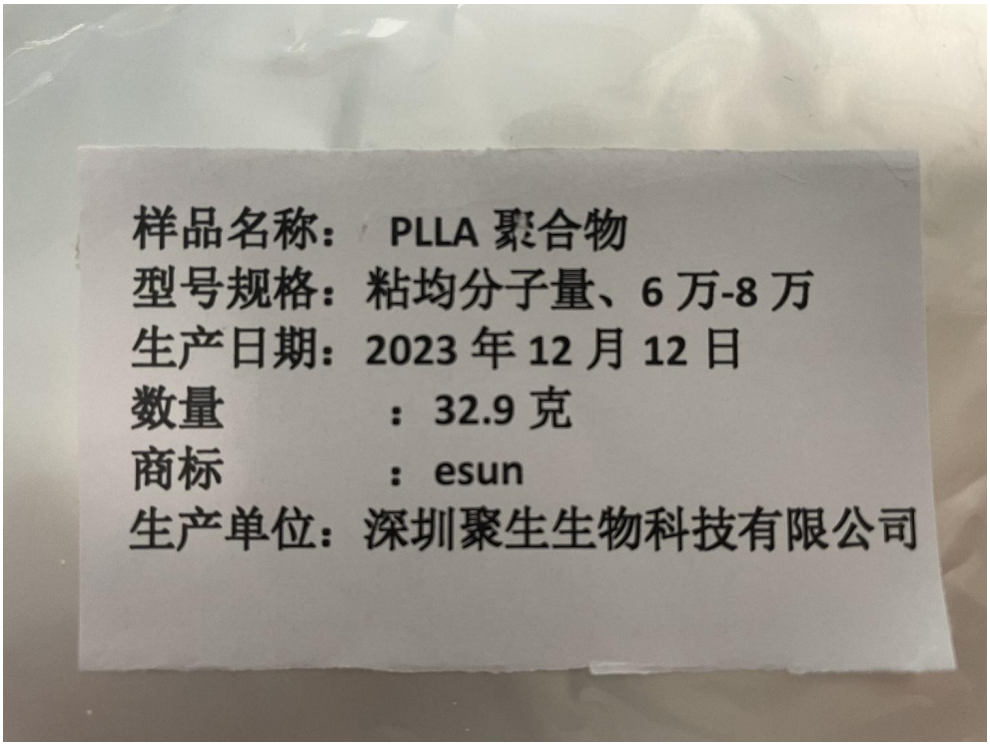


Fig. 4 Test Label

Sample Specification

浸提液制备说明

Instructions for preparation of leaching solution

PLLA 聚合物产品是吸油不吸水的，所以浸提比例极性的按 0.2g/mL，非极性按饱和后 0.1g/mL 来浸提

PLLA polymer products absorb oil but not water, so the leaching ratio is 0.2g/mL for polar and 0.1g/mL for nonpolar.

深圳光华伟业股份有限公司

Shenzhen Esun Industrial CO.,Ltd.

2024 年 03 月 27 日

March 27, 2024

Fig. 5 Sample Specification

Model / Type

/

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