



中国认可
国际互认
检测
TESTING
CNAS L0317



Test Report

Report No.:YL202500007472

Client: Anhui Meirunkang Packaging Co., LTD

Manufacturer: Anhui Meirunkang Packaging Co., LTD

Sample Name: Single-use sterile medical device packaging pouch

Types and specifications: 180*120*0.10

Categories of tests: Registration supplementary inspection ()

Other inspection (✓) Commissioned inspection

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Test Institution: Ningbo Customs District Technology Center

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Sample name	Single-use sterile medical device packaging pouch		Sample No.	25M04661
	Send sample (√)	Sampling ()		
Brand	/		Model Size	180*120*0.10
Customer	Anhui Meirunkang Packaging Co., LTD		Categories of tests	Commissioned inspection
Address	B9, SME Incubation center ,Laofeng Town, Yingjiang District, Anqing City, Anhui Province		Lot /Batch	Mr-kang2509026
Manufacturer	Anhui Meirunkang Packaging Co., LTD		Sample sheet number	—
Unit under inspection	—		Production Date	2025.9.29
Sampling unit	—		Sample quantity	1 pcs
Sampling locations	—		Sampling base	—
Sampling date	—		Inspection location	Block C, Meigang Building, Meishan Subdistrict, Beilun District, Ningbo, Zhejiang, China
Sample receipt date	2025.11.12		Inspection date	2025.11.12-2025.12.17
Inspection items	Acute systemic toxicity test			
Inspection basis	ISO 10993.11-2017			
Inspection conclusion	Under the conditions of this study, the test sample was prepared in polar extraction sodium chloride injection, or in the non-polar extraction sesame oil did not cause any acute systemic toxicity. The sample has no acute systemic toxicity. (Special seal for inspection report or official seal of inspection unit) Issue date: 2026.01.06			
Remarks	1) The "—" in the report indicates that this item does not apply, and the "/" in the report indicates the blank.			

Approver: 邵白串 Checker: 孙运 Inspector: 陈雪君 梁雁芹 秦柏芳

Position: Authorized signatory

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No.	Testing Item	Technical requirement clause	Technical requirements	Results	Single conclusion	Remarks
1	Acute systemic toxicity test	/	/	Under the conditions of this study, the test sample was prepared in polar extraction sodium chloride injection, or in the non-polar extraction sesame oil did not cause any acute systemic toxicity. The sample has no acute systemic toxicity.	/	/
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Acute systemic toxicity test

1. Summary

Objective: To evaluate the potential of sample to cause acute systemic toxicity in mice according to *ISO 10993-11:2017 "Biological evaluation of medical devices — Part 11: Tests for systemic toxicity"*.

Methods: The sodium chloride injection and sesame oil were used as extraction vehicle to prepared the sample. The extract of sodium chloride injection was administrated by intravenous injection, controls were administrated in same way with sodium chloride injection. The extract of sesame oil was administrated by intraperitoneal injection, controls were administrated in same way with sesame oil. The status of all animals and the number of dead animals were observed and recorded at 1 h, 4 h, 24 h, 48 h and 72 h after infection. The animal's body weight was measured immediately before dosing, daily for the first three days after dosing.

Results: During the experiment, all the experimental mice had no toxic symptoms, no death, and no abnormal changes in body weight, and the reaction of the experimental group was not greater than that of the control group.

Conclusion: Under the conditions of this study, the test sample was prepared in polar extraction sodium chloride injection, or in the non-polar extraction sesame oil did not cause any acute systemic toxicity. The sample has no acute systemic toxicity.

Test Personnel: Chen Xuejun, Liang Yanning, Qin Yangfen.

Test Date: 2025.11.12 ~ 2025.12.17.

2. Test Materials

2.1 Test sample

Sample description: Unsterilized packaging, solid

Intended use: Primary packaging for medical devices, sterile barrier, post-sterilization residue analysis.

Storage conditions: Room temperature.

2.2 Extraction vehicle:

Polar extraction vehicle: sodium chloride injection (Manufacturers: Cisen Pharmaceutical Co.,

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Ltd., Lot No.:825061856).

Non-polar extraction vehicle: Sesame oil (Manufacturers: Tianjin Convinced & Condar Pharmaceutical Co., Ltd.; Specification: 500 g/bottle Lot No.: C016240601).

2.3 Preparation of test product: The test sample was sterilized in an ultra-clean table to prepare the extracted sample. The surface area is 432 cm²/pcs (surface area provided by customer). Taken the original test sample and divided it evenly into two parts. According to customer requirements, the test samples were sterilized with EO and analyzed for one week before leaching. Based on the ratio of 6 cm²/mL, the test sample was covered with extraction vehicle for preparing the test extraction at condition (37±1) °C for (24±2)h. Freshly prepared extracts were preferred. The sample and extraction vehicle volume are as follows:

Extraction vehicle	Group	Samples (cm ²)	Extraction vehicle volume (mL)
Sodium chloride injection	Test group	216.0	36.0
	Control group	/	20.0
Sesame oil	Test group	216.0	36.0
	Control group	/	20.0

2.4 Control group: The same batch of extraction vehicle, preparation process refers to sample preparation.

2.5 Status of extracts:

Extraction vehicle	Treated group	Control group
Sodium chloride injection	clear	clear
Sesame oil	clear	clear

3. Experimental animals

3.1 Species/Strain and microbial status: SPF ICR mice.

3.2 Animal source: Shanghai jie si jie laboratory animal CO., LTD., Certificate No.: SCXK (Hu) , and the qualification certificate number is 20230004029817.

3.3 Number and sex: 20 females were nulliparous and non-pregnant.

3.4 Weight range at the beginning of the test: 18.2 g~22.0 g.

3.5 Marking method: Staining mark on the different part of body.

3.6 Acclimatization: 7 days.

3.7 Animal selection: Healthy, unused animals can be tested after passing the quarantine.

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3.8 Reasons for selection of test animals: mouse is used to evaluate the systemic toxicity response in accordance with ISO standards and national standards. It has been confirmed that the test samples can effectively evaluate the potential risk of systemic toxicity under test conditions.

3.9 Animal feeding management

3.9.1 Environmental Conditions

Breeding room: Animal house in barrier environment. Laboratory animal use license No. SYXK(ZHE)2021-0032.

Temperature and humidity: The room temperature and humidity were monitored daily. Temperature 21.9°C~22.6°C; Relative humidity 41.9%~49.5%.

Illumination: Use an automatic timer to control 12 hours of light and 12 hours of darkness.

3.9.2 Feed

Name: Irradiated Lab Rat and Mouse Maintenance Formula Diet.

Production unit: Jiangsu Xietong Pharmaceutical Bio-engineering Co., Ltd.

Production License Number: Jiangsu Feed Certificate (2024) 01008.

Quality Certificate No.: 25-SM251029061.

Specification: 2.5 kg / bag, 8 bags / box.

Batch No.: 2510010102.

Production date: 2025.10.03.

Shelf life: 6 months under normal temperature.

Feeding method: free feeding.

3.9.3 Water

Type: First-grade RO ultra-filtered water, after chlorination treatment, the free chlorine content of water is controlled at 0.3 mg/L~2 mg/L.

Water supply method: water intake ad libitum through automatic water supply system.

Analysis and testing: The heavy metal content, microorganism and free chlorine content of the tested drinking water meet the requirements of GB 5749-2022 "Standards for drinking water quality".

3.10 Personnel: All participants in the trial have been trained and have obtained the corresponding

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qualifications.

3.11 Animal ethics: This test was approved by the animal ethics committee of this unit, and during the test, the relevant documents formulated by the animal ethics committee were strictly implemented to maintain animal welfare.

4. Equipment

Weighing Balance (Instrument ID: 201200001653), Constant temperature incubator(Instrument ID:31S4120251000010), EO (2022JWJ002) ,Syringe (specification: 2 mL, Lot No.: 20241221, expiration date: 20271220, production date: 20241221, specification: 50 mL, Lot No.: 20250421A, expiration date: 20280420, production date: 20250421, source: Chengdu Xinjin Shifeng medical device Co., Ltd.), Transfusion needle (Manufacturer: Zhejiang Kangdelai medical device Co., Ltd., Batch No: C20240319,expiration date:20270318, production date: 20240319).

5. Methods

5.1 Test Preparations: 20 mice were selected, randomly divided to 4 sets, 5 animals per set. The animals were marked and weighed.

5.2 Test Procedure:

Set I, the extract of sodium chloride injection was administrated by intravenous injection using syringe to treated group, the control group was administrated in same way with sodium chloride injection correspondingly. (Dose volume 50 mL/kg).

Set II, the extract of sesame oil was administrated by intraperitoneal injection using syringe to treated group, the control group was administrated in same way with sesame oil correspondingly. (Dose volume 50 mL/kg).

5.3 Observation:observation of the animals was individually after dosing during the first 1 h. Signs of toxicity including mortality,time course of onset, severity and duration of effects were recorded 4 h, 24 h, 48 h and 72 h after test. The animal's body weight was measured immediately before dosing, daily for the first three days after dosing.After the experiment, all the animals showed no obvious symptoms .Full histopathology is not carried out on organs and tissues .

6. Results

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6.1 Clinical signs: No signs of toxicity were observed in Set I and Set II till scheduled termination.

All animals feeding and activity are normal. The Clinical signs data was given in Table 1.

6.2 Mortality: No mortality was observed in experiment period. The mortality data was given in Table 1.

6.3 Body Weight: All the surviving animals exhibited a progressive increase in body weight throughout the study period, and the body weight was normal after administration. The body weight was given in Table 2.

7. Conclusion

Under the conditions of this study, the test sample was prepared in polar extraction sodium chloride injection, or in the non-polar extraction sesame oil did not cause any acute systemic toxicity. The sample has no acute systemic toxicity.

8. Attached table

Table 1 mortality and Clinical signs

Extraction vehicle	Group	Mortality / Total number of animals	Observation				
			1h	4h	24h	48h	72h
Sodium chloride	Control group	0/5	Normal	Normal	Normal	Normal	Normal
	Test group	0/5	Normal	Normal	Normal	Normal	Normal
Sesame oil	Control group	0/5	Normal	Normal	Normal	Normal	Normal
	Test group	0/5	Normal	Normal	Normal	Normal	Normal

Table 2 Body Weight(g)

Extraction vehicle	Group	Sex	Number of animals	Body Weight ($\bar{X} \pm SD$) (g)				
				0 day	1 day	2 day	3 day	3 days Body Weight gain
Sodium chloride	Control group	♀	5	21.1±1.04	21.6±1.19	22.1±1.33	22.5±1.54	1.4±1.04
	Test group	♀	5	20.9±0.80	21.3±0.72	21.9±0.76	22.6±0.94	1.7±0.61
Sesame oil	Control group	♀	5	19.9±1.20	20.2±1.09	21.0±1.17	21.8±1.11	1.9±0.77
	Test group	♀	5	20.4±1.17	20.5±1.29	21.3±1.28	22.3±1.66	1.9±0.70

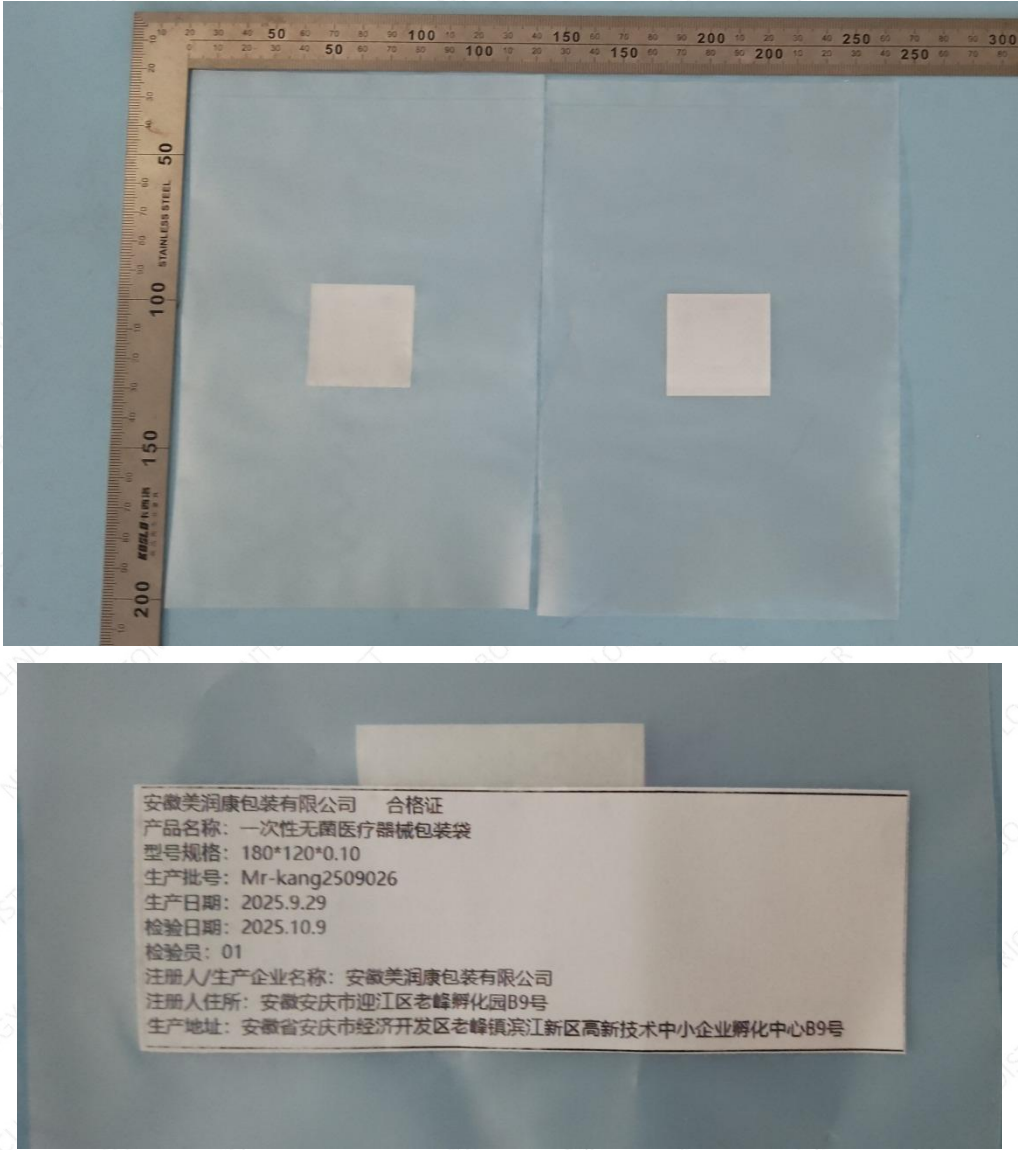
The End

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Photos and descriptions	
	
Sample description	
Unsterilized packaging, solid	
Sample model or other descriptions	
180*120*0.10	

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