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检测
TESTING
CNAS L 10463

Test Report

Report Number: SZB24082509A-R1-EN

Sponsor: Changzhou Dreure Medical Material Co., LTD.

Factory: Changzhou Dreure Medical Material Co., LTD.

Sample Name: Single Use Powder Transfer Bag

Model/Specification: 25L-LDPE

Test Category: Entrusted Test

EPINTEK Suzhou Ltd.

苏州爱谱质量技术服务有限公司 检验检测专用章

Declaration

1. The report is invalid without the special stamp for test report of the test facility.
2. Partial copy is invalid without written approval of the test facility.
3. Any copy is invalid without the special stamp of of the test facility for test report.
4. The report is invalid without the signature of the authorized signtory.
5. The report is invalid once altered.
6. Any comment to the report should be submitted in writing to the test facility, otherwise it may not be accepted.
7. The results in this report are relevant only to the articles tested.
8. The sponsor is responsible for the authenticity of the sample and its information.

Institution name: EPINTEK Suzhou Ltd.

Address: No.558 Fenhu Avenue, Lili Town, Wujiang District, Suzhou, China

Web site: www.epintek.com

Telephone: 0512-63228100

Postal Code: 215211

EPINTEK Suzhou Ltd.
Test Report

Report Number: SZB24082509A-R1-EN

Sample Name	Single Use Powder Transfer Bag	Sample ID	SZB24082509A
Model/Specification	25L-LDPE		
Sponsor	Changzhou Dreure Medical Material Co., LTD.		
Address	No.502 Changting Road, Wujin Economic Development Zone, Changzhou		
Factory	Changzhou Dreure Medical Material Co., LTD.		
Test Facility	EPINTEK Suzhou Ltd.		
Test Category	Entrusted Test	Lot/Batch#	S202408067
Produced Date	2024-08-30	Sample Quantity	4 bags
Received Date	2024-09-13	Test Date(s)	2024-09-23 to 2024-10-02
Test Item(s)	Acute Systemic Toxicity Test, Intracutaneous Reactivity Test and Intramuscular Implantation Test		
Test Method(s)	USP <88>, Official as of 01-Aug-2013 - BIOLOGICAL REACTIVITY TESTS, IN VIVO		
Conclusion	The test results of the tested articles met the standard requirements. (Stamp for Test Report) Issued Date: 2024-10-29		
Note	"NA" means "not applicable", "/" means "blank"		

苏州爱品质量技术服务有限公司 检验检测专用章

Approved By: _____ Position: Authorized Signatory

Jack Fang

Report Number: SZB24082509A-R1-EN

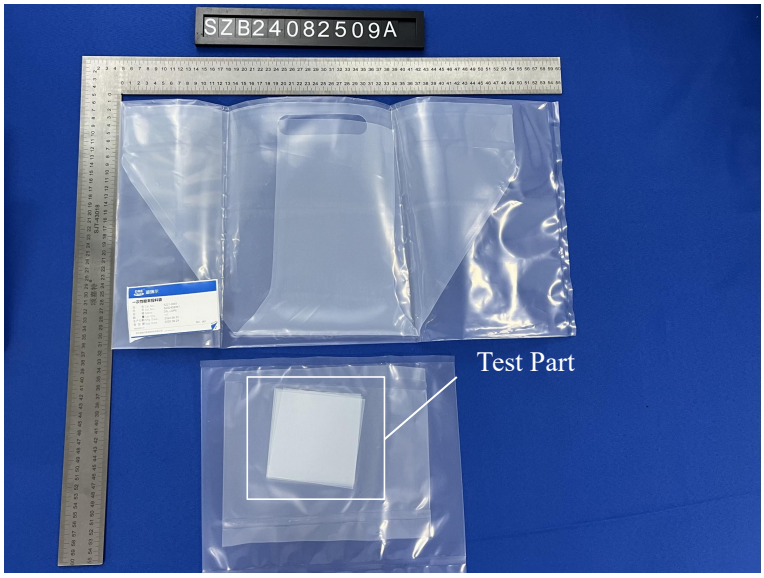
No.	Item	Standard Method	Acceptance Criteria	Test Result	Conclusion	Note
1	Acute Systemic Toxicity Test	USP <88>, Official as of 01-Aug-2013	During the observation period (72 h) of an acute systemic toxicity test none of the animals treated with the test sample showed a significantly greater biological reactivity than animals treated with the vehicle control, the sample met the requirements of this test.	All animals were not found any abnormal clinical symptoms. All animals were normal weight changed.	Met the Test Standard	Shown in Annex.1
2	Intracutaneous Reactivity Test	USP <88>, Official as of 01-Aug-2013	If the final score of the test sample is not greater than 1.0, the sample meets the requirements of this test.	The response of all anima's skin on testing sides were not exceed that on the control sides. The final irritation index of four groups were 0. All animals were not found abnormal clinical symptoms except skin reactions.	Met the Test Standard	Shown in Annex.2

Report Number: SZB24082509A-R1-EN

No.	Item	Standard Method	Acceptance Criteria	Test Result	Conclusion	Note
3	Intramuscular Implantation Test	USP <88>, Official as of 01-Aug-2013	If the difference between the test group and the control group in the final average score of cysts is not more than 1.0, the sample meets the requirements of this test.	During the whole clinical observation, no any abnormal reaction of the insertion point was observed. The differences between average scores for the test and control sites was 0.	Met the Test Standard	Shown in Annex.3
Following Blank						

苏州爱普质量技术服务有限公司 检验检测专用章

Report Number: SZB24082509A-R1-EN

Picture & Introduction

Description for Sample, Model/Specification
Initial State: Sterilized Irradiation sterilization (The information of sample hereby are provided by the sponsor.)
Misc
/

Test Report

Animal Test- Acute Systemic Toxicity Test

Sponsor: Changzhou Dreure Medical Material Co., LTD.

Sample Name: Single Use Powder Transfer Bag

Model/Specification: 25L-LDPE

Sample Amount for this test: 800 cm^2

Lot/Batch#: S202408067

EPINTEK Suzhou Ltd.

SUMMARY

1. Purpose

To evaluate the potential of the test article extraction to cause acute systemic toxicity in mouse.

2. Process Description

USP <88>, Official as of 01-Aug-2013 - BIOLOGICAL REACTIVITY TESTS, IN VIVO, CLASS VI was referenced in this test.

The test article was specified sampled. Extracted by 6 cm^2/mL, extraction condition was 50℃ 72h. Extraction solvents were 0.9% Sodium Chloride (SC), Corn Oil (CO), Alcohol solution (AL) and Polyethylene glycol 400 solution (PEG-400).

Took 40 male mice and divided them into eight groups. The mouse was injected the test article extracted by SC and AL or negative control into its caudal vein. The injection dosage was 50 mL/kg body weight.

The mouse was injected the test article extracted by CO and PEG-400 or negative control into its abdominal cavity. The injection dosage was 50 mL/kg body weight.

After administration, observed the instant response of the mouse. Furthermore, monitored and recorded the status of testing group and control group (e. g. toxicosis symptom) in immediately, 4 h, 24 h, 48 h and 72 h.

Body weight measurements were made immediately before dosing, daily for the first three days after dosing.

3. Result

All animals were not found any abnormal clinical symptoms.

All animals were normal weight changed.

4. Conclusion

Under the conditions of this study, the test article extracts met the requirements of the test.

Edited by: Colin Lu

Colin Lu

Checked by: Patryk Chen

Patryk Chen

1. STUDY SUMMARIES

1.1. Study Name (Study No.)

Single Use Powder Transfer Bag - Acute Systemic Toxicity Test (SZB24082509A-027)

1.2. Purpose

To evaluate the potential of the test article extraction to cause acute systemic toxicity in mouse.

1.3. Testing Facility

Name: EPINTEK Suzhou Ltd.

Address: No.558 Fenhu Avenue, Lili Town, Wujiang District, Suzhou, China

1.4. Sponsor

Name: Changzhou Dreure Medical Material Co., LTD.

Address: No.502 Changting Road, Wujin Economic Development Zone, Changzhou

ATTN: Wenqing Shi

Contact Information: +86 152 9518 5667 / wenqing.shi@dreure.com

1.5. Study Alteration Treatment

Before the study start, the study protocol was approved by Study Director and Sponsor. Any study alteration should be approved by Study Director.

1.6. Deviation(s) and Incident(s) Treatment

If any deviation or incident occurred during the test, the related information would be recorded timely and a deviation report should be submitted with the final report to interpretate the specific effect(s) on the final result caused by the deviation or incident.

1.7. Major Laboratory Personnel

Study Director: Patryk Chen

Main Operation Personnel: Bobi Ouyang, Qing Liu

1.8. Schedule of the Study

Protocol Effective Date: /

Test Start Date: 2024-09-23

Test Completion Date: 2024-09-29

Report Completion Date: 2024-10-25

2. CONTROL AND TEST SYSTEM CONFIRMATION

2.1. Negative Control

2.1.1. Negative control 1 (SC)

Name: 0.9% Sodium Chloride (SC)

Lot/ Batch#: D24041806

Physical State: Colorless Liquid

Manufacturer: Guizhou Kelun

2.1.2. Negative control 2 (CO)

Name: Corn Oil (CO)

Lot/ Batch#: C16262320

Physical State: Light yellow oily liquid

Manufacturer: Macklin

2.1.3. Negative control 3 (AL)

Name: Alcohol

Lot/ Batch#: 20220309

Physical State: Colorless liquid

Manufacturer: Sinopharm Chemical Reagent Co., Ltd.

Concentration: 1: 20 (Alcohol : Sodium chloride)

Date Prepared: 2024-09-23

2.1.4. Negative control 4 (PEG-400)

Name: Polyethylene Glycol 400

Lot/ Batch#: 20220812

Physical State: Colorless transparent viscous liquid

Manufacturer:	Sinopharm Chemical Reagent Co., Ltd.
Concentration:	200 mg/mL (Sodium chloride dilution)
Date Prepared:	2024-09-26

2.2. Animal

2.2.1. Animal information

Species:	ICR mouse
Microbial Levels:	SPF Grade
Number/Sex:	40/Male
Weight:	From 17 g to 23 g at the beginning of the test
Manufacturer:	SPF (Suzhou) Biotechnology Co., Ltd.
Production License#:	SCXK(Su)2022-0006
Quality Certificate#:	A202409200419

2.2.2. Animal feeding conditions

Breeding Density:	Five animals per cage
Cages:	Plastic cage
Animal Identification:	Stain with neutral magenta and identified by a cage card
Acclimation Period:	At least 3 days under the same conditions as for the actual test
Fodder:	Name: SPF Rat & Mouse Maintenance Formula Feed
	Manufacturer: KEAO XIELI FEED CO., LTD
	^{60}Co irradiation sterilization and free intake
Padding:	Name: Corn cob
	Manufacturer: KEAO XIELI FEED CO., LTD
	Autoclaved sterilization and periodic replacement
Water:	Barreled pure water
	Autoclaving and free intake

2.2.3. Animal room environmental conditions

Temperature:	20℃-26℃
Relative Humidity:	40%-70%RH

Differential Pressure: ≥10Pa

Ventilation Rate: ≥15/h

Lights: 12 hours light/dark cycle, full spectrum fluorescent lights

2.3. Main Instruments

Name	No.	Calibration Due Date
Electronic Balance	EPB-584	2025-05-20
Constant temperature vibrator	EPB-597	2025-07-17
Clean workbench	EPB-598	2025-07-17

2.4. Justification of the Test System

The species and number of animals used are recommended by standard guidelines.

3. TEST DESIGN

3.1. Extract Preparation

3.1.1. Extraction process[1)]

Samples were taken under sterile conditions and prepared as follows.

Sampling Manner	Actual Sampling[2)]	Ratio	Solvent	Amount	Conditions
Specified	200 cm^2	6 cm^2/mL	SC	33.3 mL	50℃ 72h
	200 cm^2	6 cm^2/mL	CO	33.3 mL	50℃ 72h
	200 cm^2	6 cm^2/mL	AL	33.3 mL	50℃ 72h
	200 cm^2	6 cm^2/mL	PEG-400	33.3 mL	50℃ 72h

1) The vehicle (without the test article) was similarly prepared to serve as the negative control.

2) The surface area of the specified part of the sample is 200 cm^2 (provided by the sponsor).

3.1.2. Final extract[1,2)]

Final extract	Additional processing prior to the testing or Not	Presence of particles or Not	Color and Clear or Not
SC	Not	Not	Colorless and Clear
CO	Not	Not	Light yellow and Clear
AL	Not	Not	Colorless and Clear
PEG-400	Yes[3)]	Not	Colorless and Clear

1) Agitated extract vigorously prior to injection to ensure extracted matters well-distributed.
2) Used the extracts immediately when the extracts cooled to the room temperature.
3) The pH before dilution was 6.5, and the pH after dilution was 6.6.

3.2. Grouping

Took 40 mice and divided them into eight groups.

Group No.	Groups	Amount	Sex	Numbered list
1	Negative control (SC)	5	♂	1101~1105
2	Test group (SC)	5	♂	2106~2110
3	Negative control (CO)	5	♂	3111~3115
4	Test group (CO)	5	♂	4116~4120
5	Negative control (AL)	5	♂	5121~5125
6	Test group (AL)	5	♂	6126~6130
7	Negative control (PEG-400)	5	♂	7131~7135
8	Test group (PEG-400)	5	♂	8136~8140

3.3. Experimental Process

The mice of group 1~2 and 5~6 was injected the test article extract or negative control into its caudal vein. The injection dosage was 50 mL/kg body weight.

The mice of group 3~4 and 7~8 was injected the test article extract or negative control into its abdominal cavity. The injection dosage was 50 mL/kg body weight.

After administration, observed the instant response of the mouse. Furthermore, monitored and recorded the status of testing group and control group (e. g. toxicosis symptom) in immediately, 4 h, 24 h, 48 h and 72 h. Body weight measurements were made immediately before dosing, daily for the first three days after dosing.

4. EVALUATION CRITERION

1) If during the observation period (72 h) of an acute systemic toxicity test none of the animals treated with the test sample showed a significantly greater biological reactivity than animals treated with the vehicle control, the sample met the requirements of this test.
2) If two or more animals died, or if behavior such as convulsions or prostration occurs in two or more animals, or if a body weight loss greater than 2g occurs in three or more animals, the sample did not meet the requirements of the test.
3) If any animals treated with the sample showed only slight signs of biological reactivity, and not more than one animal shows gross symptoms of biological reactivity or dies, repeated the testing using groups of ten animals.
4) On the repeat test, if all ten animals treated with the sample showed no scientifically meaningful

biological reactivity above the vehicle control animals during the observation period, the sample met the requirements of this test.

5. ALTERATION AND DEVIATION

There were no changes and deviations of technical parameters that affect the experimental results.

6. RESULTS

All animals were normal weight changed.

See Attached Table 1-4.

All animals were not found any abnormal clinical symptoms.

See Attached Table 5-8.

7. CONCLUSION

Under the conditions of this study, the test article extracts met the requirements of the test.

8. ARCHIVING

All correspondence, including original copy of the protocol, original copy of the test report, and all raw data generated during the study (i.e., documentation forms as well as any other notes of raw data, printouts of instruments and computers) are stored in the archives room of the EPINTEK Suzhou Ltd.

9. ATTACHED TABLE

9.1. Attached Table 1 Results of Animal Body Weight and Dosage (SC)

Group	No.	Dosage (mL)	Weight (g)			
			0 h	24 h	48 h	72 h
Negative control (SC)	1101	1.0	19.69	21.48	22.66	23.87
	1102	0.96	18.82	19.52	21.08	22.23
	1103	1.0	19.93	20.44	22.36	23.39
	1104	1.1	21.13	22.42	23.18	23.84
	1105	1.1	20.88	21.23	23.10	23.83
Test group (SC)	2106	0.98	19.50	20.99	21.93	23.40
	2107	0.96	18.98	19.86	21.99	22.91
	2108	1.1	20.08	21.18	22.71	24.37
	2109	0.94	18.73	19.97	21.38	22.33
	2110	1.1	21.10	22.38	23.82	24.54

9.2. Attached Table 2 Results of Animal Body Weight and Dosage (CO)

Group	No.	Dosage (mL)	Weight (g)			
			0 h	24 h	48 h	72 h
Negative control (CO)	3111	1.0	19.84	20.43	21.73	23.00
	3112	1.0	19.67	21.06	22.44	24.23
	3113	1.0	19.90	21.45	22.86	24.25
	3114	1.1	20.52	20.67	21.71	22.37
	3115	1.1	20.40	22.26	21.90	22.80
Test group (CO)	4116	0.98	19.58	20.60	21.16	22.54
	4117	1.0	19.82	22.34	23.43	24.97
	4118	1.1	20.16	21.53	23.00	24.20
	4119	1.1	20.06	21.28	22.45	24.26
	4120	1.1	20.45	21.89	24.08	25.71

9.3. Attached Table 3 Results of Animal Body Weight and Dosage (AL)

Group	No.	Dosage (mL)	Weight (g)			
			0 h	24 h	48 h	72 h
Negative control (AL)	5121	0.98	19.54	20.94	22.74	23.57
	5122	0.94	18.60	19.81	21.69	23.44
	5123	0.94	18.62	20.14	21.20	22.44
	5124	0.98	19.45	20.66	22.29	23.05
	5125	1.1	20.15	20.86	22.87	23.61
Test group (AL)	6126	1.2	22.62	22.67	24.04	24.79
	6127	1.1	21.12	21.02	22.77	23.61
	6128	0.94	18.46	19.31	21.36	21.64
	6129	0.96	19.07	19.47	20.20	21.75
	6130	1.2	22.30	22.02	23.85	24.15

9.4. Attached Table 4 Results of Animal Body Weight and Dosage (PEG-400)

Group	No.	Dosage (mL)	Weight (g)			
			0 h	24 h	48 h	72 h
Negative control (PEG-400)	7131	1.1	21.27	21.20	22.92	24.99
	7132	0.98	19.36	20.38	22.26	24.56
	7133	1.1	21.45	22.94	24.34	25.32
	7134	0.94	18.59	19.32	21.05	21.85
	7135	1.1	20.02	21.20	22.62	24.26
Test group (PEG-400)	8136	1.00	19.82	20.00	22.71	25.63
	8137	1.1	21.23	22.17	23.61	23.82
	8138	1.1	21.13	22.54	23.13	24.17
	8139	1.1	22.00	22.09	22.97	23.69
	8140	1.1	20.98	21.73	22.98	23.84

9.5. Attached Table 5 Results of the Observed Signs (SC)

Group	No.	0 h	4 h	24 h	48 h	72 h
Negative control (SC)	1101	—	—	—	—	—
	1102	—	—	—	—	—
	1103	—	—	—	—	—
	1104	—	—	—	—	—
	1105	—	—	—	—	—
Test group (SC)	2106	—	—	—	—	—
	2107	—	—	—	—	—
	2108	—	—	—	—	—
	2109	—	—	—	—	—
	2110	—	—	—	—	—

Note: “—” means no abnormal reaction.

9.6. Attached Table 6 Results of the Observed Signs (CO)

Group	No.	0 h	4 h	24 h	48 h	72 h
Negative control (CO)	3111	—	—	—	—	—
	3112	—	—	—	—	—
	3113	—	—	—	—	—
	3114	—	—	—	—	—
	3115	—	—	—	—	—
Test group (CO)	4116	—	—	—	—	—
	4117	—	—	—	—	—
	4118	—	—	—	—	—
	4119	—	—	—	—	—
	4120	—	—	—	—	—

Note: “—” means no abnormal reaction.

9.7. Attached Table 7 Results of the Observed Signs (AL)

Group	No.	0 h	4 h	24 h	48 h	72 h
Negative control (AL)	5121	—	—	—	—	—
	5122	—	—	—	—	—
	5123	—	—	—	—	—
	5124	—	—	—	—	—
	5125	—	—	—	—	—
Test group (AL)	6126	—	—	—	—	—
	6127	—	—	—	—	—
	6128	—	—	—	—	—
	6129	—	—	—	—	—
	6130	—	—	—	—	—

Note: “—” means no abnormal reaction.

9.8. Attached Table 8 Results of the Observed Signs (PEG-400)

Group	No.	0 h	4 h	24 h	48 h	72 h
Negative control (PEG-400)	7131	—	—	—	—	—
	7132	—	—	—	—	—
	7133	—	—	—	—	—
	7134	—	—	—	—	—
	7135	—	—	—	—	—
Test group (PEG-400)	8136	—	—	—	—	—
	8137	—	—	—	—	—
	8138	—	—	—	—	—
	8139	—	—	—	—	—
	8140	—	—	—	—	—

Note: “—” means no abnormal reaction.

…… **End of Report**……

Test Report

Animal Test - Intracutaneous Reactivity Test

Sponsor: Changzhou Dreure Medical Material Co., LTD.

Sample Name: Single Use Powder Transfer Bag

Model/Specification: 25L-LDPE

Sample Amount for this test: 800 cm^2

Lot/Batch#: S202408067

EPINTEK Suzhou Ltd.

SUMMARY

1. Purpose

To determine the potential intracutaneous reactivity caused by intracutaneously inject the extract to rabbit.

2. Process Description

USP <88>, Official as of 01-Aug-2013 - BIOLOGICAL REACTIVITY TESTS, IN VIVO, CLASS VI was referenced in this test.

The test article was specified sampled. Extracted by 6 cm^2/mL, extraction condition was 50℃ 72h. Extraction solvents were 0.9% Sodium Chloride (SC), Corn Oil (CO), Alcohol solution (AL) and Polyethylene glycol 400 solution (PEG-400).

Took 8 female rabbits into four groups. Used the rabbits with healthy intact skin. Within 4 h to 18 h period before testing, closely clipped the fur on the back of the animals, allowed a sufficient distance on both sides of the spine for injection of the extracts.

Used the smallest needle appropriate to the viscosity of the test material for the intradermal injection. Injected intracutaneously 0.2 mL of the test extracts at five sites on left side of each rabbit. Similarly, injected 0.2 mL of blank solvent control at five sites on the contralateral side of each rabbit.

Described and scored the skin reaction for erythema and oedema according to the scoring system for each injection site immediately after injection and at 24 h, 48 h and 72 h after injection.

3. Result

According to what observed:

The response of all anima's skin on testing sides were not exceed that on the control sides.

The final irritation index of four groups were 0.

All animals were not found abnormal clinical symptoms except skin reactions.

4. Conclusion

Under the conditions of this study, the test article extracts met the requirements of the test.

Edited by: Colin Lu

Colin Lu

Checked by: Patryk Chen

Patryk Chen

1. STUDY SUMMARIES

1.1. Study Name (Study No.)

Single Use Powder Transfer Bag - Intracutaneous Reactivity Test (SZB24082509A-011)

1.2. Purpose

To determine the potential intracutaneous reactivity caused by intracutaneously inject the extract to rabbit.

1.3. Testing Facility

Name: EPINTEK Suzhou Ltd.

Address: No.558 Fenhu Avenue, Lili Town, Wujiang District, Suzhou, China.

1.4. Sponsor

Name: Changzhou Dreure Medical Material Co., LTD.

Address: No.502 Changting Road, Wujin Economic Development Zone, Changzhou

ATTN: Wenqing Shi

Contact Information: +86 152 9518 5667 / wenqing.shi@dreure.com

1.5. Study Alteration Treatment

Before the study start, the study protocol was approved by Study Director and Sponsor. Any study alteration should be approved by Study Director.

1.6. Deviation(s) and Incident(s) Treatment

If any deviation or incident occurred during the test, the related information would be recorded timely and a deviation report should be submitted with the final report to interpretate the specific effect(s) on the final result caused by the deviation or incident.

1.7. Major Laboratory Personnel

Study Director: Patryk Chen

Main Operation Personnel: Lark Sun, Betty Liu

1.8. Schedule of the Study

Protocol Effective Date: /

Test Start Date: 2024-09-23

Test Completion Date: 2024-09-29

Report Completion Date: 2024-10-25

2. CONTROL AND TEST SYSTEM CONFIRMATION

2.1. Negative Control

2.1.1. Negative control 1 (SC)

Name: 0.9% Sodium Chloride (SC)

Lot/ Batch#: D24041806

Physical State: Colorless Liquid

Manufacturer: Guizhou Kelun

2.1.2. Negative control 2 (CO)

Name: Corn Oil (CO)

Lot/ Batch#: C16262320

Physical State: Light yellow oily liquid

Manufacturer: Macklin

2.1.3. Negative control 3 (AL)

Name: Alcohol

Lot No.: 20220309

Physical State: Colorless liquid

Manufacturer: Sinopharm Chemical Reagent Co., Ltd.

Concentration: 1: 20 (Alcohol: Sodium chloride)

Date Prepared: 2024-09-23

2.1.4. Negative control 4 (PEG-400)

Name: Polyethylene Glycol 400

Lot No.: 20220812

Physical State: Colorless transparent viscous liquid

Manufacturer:	Sinopharm Chemical Reagent Co., Ltd.
Concentration:	120 mg/mL (Sodium chloride dilution)
Date Prepared:	2024-09-26

2.2. Animal

2.2.1. Animal information

Species:	New Zealand white rabbit
Microbial Levels:	Conventional
Number/Sex:	8/Female（nulliparous and non-pregnant）
Weight:	More than 2 kg at the beginning of the test
Manufacturer:	FMC Laboratory Animals Inc.
Production License#:	SCXK(Zhe)2023-0009
Quality Certificate#:	20240913Ceeee0600000951

2.2.2. Animal feeding conditions

Breeding Density:	One animal per cage
Cages:	Suspended stainless steel
Animal Identification:	Marked the ID in animal's right ear and identified by a card
Acclimation Period:	At least 7 days under the same conditions before the actual test
Fodder:	Name: Rabbit Maintenance Formula Feed
	Manufacturer: KEAO XIELI FEED CO., LTD
	Daily 75 g quantitative uptake per animal
Water:	Automatic drinking device
	Free intake

2.2.3. Animal room environmental conditions

Temperature:	16°C-26°C
Relative Humidity:	40%-70%RH
Ventilation Rate:	≥8/h
Lights:	12 hours light/dark cycle, full spectrum fluorescent lights

2.3. Main Instruments

Name	No.	Calibration Due Date
Electronic Balance	EPB-302	2025-06-12
Electronic Balance	EPB-004	2025-07-24
Constant temperature vibrator	EPB-597	2025-07-17
Clean workbench	EPB-598	2025-07-17

2.4. Justification of the Test System

The rabbit is specified as an appropriate animal model for evaluating potential intracutaneous irritants by the current testing standards.

3. TEST DESIGN

3.1. Extract Preparation

3.1.1. Extraction process[1)]

Samples were taken under sterile conditions and prepared as follows.

Sampling Manner	Actual Sampling[2)]	Ratio	Solvent	Amount	Conditions
Specified	200 cm^2	6 cm^2/mL	SC	33.3 mL	50°C 72h
	200 cm^2	6 cm^2/mL	CO	33.3 mL	50°C 72h
	200 cm^2	6 cm^2/mL	AL	33.3 mL	50°C 72h
	200 cm^2	6 cm^2/mL	PEG-400	33.3 mL	50°C 72h

1) The vehicle (without the test article) was similarly prepared to serve as the negative control.

2) The surface area of the specified part of the sample is 200 cm^2 (provided by the sponsor).

3.1.2. Final extract[1,2)]

Final Extract	Additional Processing prior to the Testing or Not	Presence of Particles or Not	Color and Clear or Not
SC	Not	Not	Colorless and Clear
CO	Not	Not	Light yellow and Clear
AL	Not	Not	Colorless and Clear
PEG-400	Yes[3)]	Not	Colorless and Clear

1) Agitated extract vigorously prior to injection to ensure extracted matters well-distributed.

2) Used the extracts immediately when the extracts cooled to the room temperature.

3) The pH before dilution was 6.6, and the pH after dilution was 6.8.

3.2. Grouping

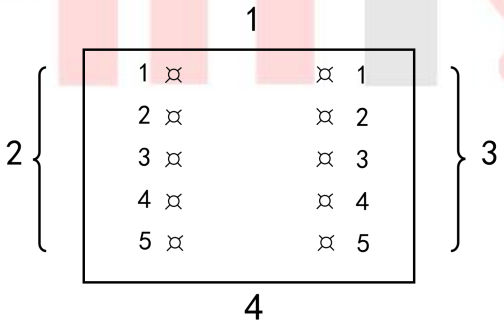
Took 8 female rabbits into 4 groups.

Group No.	Group Name	Amount	Sex	Numbered list
1	Test group (SC)	2	♀	1201~1202
2	Test group (CO)	2	♀	2203~2204
3	Test group (AL)	2	♀	3205~3206
4	Test group (PEG-400)	2	♀	4207~4208

3.3. Experimental Process

3.3.1. Dosing process

Used the rabbits with healthy intact skin. On the day of test, closely clipped the fur on the back of the animals, allowed a sufficient distance on both sides of the spine for injection of the extracts. Used the smallest needle appropriate to the viscosity of the test material for the intradermal injection. Injected intracutaneously 0.2 mL of the test extracts at five sites on left side of each rabbit. Similarly, injected 0.2 mL of solvent control at five sites on the contralateral side of each rabbit. (**See Figure 1**).



1 -cranial end, 2- 0.2 mL injections of test extract, 3 -0.2 mL injections of solvent control, 4 -caudal end

Figure 1 Arrangement of the Injection Site

3.3.2. Observation of animals

Described and scored the skin reaction for erythema and oedema according to the scoring system given in **Table 1** for each injection site at each time interval. Recorded the appearance of each injection site immediately after injection and at 24 h, 48 h and 72 h after injection.

Table 1 Classification System for Skin Reaction

Erythema and Eschar Formation	score
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**

3.3.3. Other observed endpoints

Clinical symptoms except dermal reactions were observed every day.

4. EVALUATION CRITERION

1) The average erythema and edema scores for Sample and Blank sites were determined at every scoring interval (24, 48, and 72 hours) for each rabbit.
2) After the 72 hours scoring, all erythema scores plus edema scores were totalled separately for each Sample and Blank.
3) Divided each of the totals by 12 (2 animals × 3 scoring periods × 2 scoring categories) to determine the overall mean score for each Sample versus each corresponding Blank.
4) The final irritation index was obtained by subtracting the score of the blank from the test sample score.
5) The requirements of the test were met if the final irritation index was 1.0 or less.
6) If at any observation period the average reaction to the Sample was questionably greater than the average reaction to the Blank, repeated the test used three additional rabbits.

5. ALTERATION AND DEVIATION

There were no changes and deviations of technical parameters that affect the experimental results.

6. RESULTS

According to what observed:

The response of all animal's skin on testing sides were not exceed that on the control sides.

The final irritation index of four groups were 0.

All animals were not found abnormal clinical symptoms except skin reactions.

See Attached Table1-2.

7. CONCLUSION

Under the conditions of this study, the test article extracts met the requirements of the test.

8. ARCHIVING

All correspondence, including original copy of the protocol, original copy of the test report, and all raw data generated during the study (i.e., documentation forms as well as any other notes of raw data, printouts of instruments and computers) are stored in the archives room of the EPINTEK Suzhou Ltd.

9. ATTACHED TABLE

9.1. Attached Table 1 Body Weight Change and Clinical Observation

Animal No.	Body Weight (g)		Clinical Observation Except Dermal Reactions
	Before	End	
1201	2043	2094	Normal
1202	2341	2392	Normal
2203	2302	2356	Normal
2204	2198	2244	Normal
3205	2204	2257	Normal
3206	2158	2207	Normal
4207	2098	2145	Normal
4208	2102	2157	Normal

9.2. Attached Table 2 Dermal Observations of Test Groups

Extract	Rabbit No.	Injection Site	Reaction	24 h	48 h	72 h
SC	1201	Test Article	Erythema	0	0	0
			Oedema	0	0	0
		Blank Control	Erythema	0	0	0
			Oedema	0	0	0
	1202	Test Article	Erythema	0	0	0
			Oedema	0	0	0
		Blank Control	Erythema	0	0	0
			Oedema	0	0	0
Final irritation index: 0						
CO	2203	Test Article	Erythema	0	0	0
			Oedema	0	0	0
		Blank Control	Erythema	0	0	0
			Oedema	0	0	0
	2204	Test Article	Erythema	0	0	0
			Oedema	0	0	0
		Blank Control	Erythema	0	0	0
			Oedema	0	0	0
Final irritation index: 0						
AL	3205	Test Article	Erythema	0	0	0
			Oedema	0	0	0
		Blank Control	Erythema	0	0	0
			Oedema	0	0	0
	3206	Test Article	Erythema	0	0	0
			Oedema	0	0	0
		Blank Control	Erythema	0	0	0
			Oedema	0	0	0
Final irritation index: 0						
PEG-400	4207	Test Article	Erythema	0	0	0
			Oedema	0	0	0
		Blank Control	Erythema	0	0	0
			Oedema	0	0	0
	4208	Test Article	Erythema	0	0	0
			Oedema	0	0	0
		Blank Control	Erythema	0	0	0
			Oedema	0	0	0
Final irritation index: 0						

…… **End of Report**……

Test Report

Animal Test - Intramuscular Implantation Test

Sponsor: Changzhou Dreure Medical Material Co., LTD.

Sample Name: Single Use Powder Transfer Bag

Model/Specification: 25L-LDPE

Sample Amount for this test: (1 cm×0.1 cm)×8

Lot/Batch#: S202408067

EPINTEK Suzhou Ltd.

SUMMARY

1. Purpose

The test was designed to evaluate the potential of the test article to cause local stimulation following muscle implantation to rabbit.

2. Process Description

USP <88>, Official as of 01-Aug-2013 - BIOLOGICAL REACTIVITY TESTS, IN VIVO, CLASS VI was referenced in this test.

The sample and negative control were prepared into strips of about 1 cm×0.1 cm under aseptic conditions. The prepared negative control was autoclave sterilized at 121℃ for 30min.

Took 2 female rabbits into one group. The rabbits were restrained and the fur clipped on the area over the paravertebral muscles to expose about 10 cm×20 cm area. The rabbits were anesthetized with Zoletil-50 combined with Xylazine (15/5 mg/kg， IM.). Then wiped the exposed skin with 75% alcohol and iodophor. Four test article sections were implanted in the left paravertebral muscle of each rabbit. (2.5~5) cm from the midline and parallel to the spinal column, and about 2.5 cm apart from each other. Two negative control sections were similarly implanted in the opposite muscle.

Observed and recorded every day after implantation, especially the insertion point of the skin was evaluated to measure abnormal responses such as bleeding, red swelling, necrosis and injection site discharge. The rabbits were euthanatized and dissected after 1 week. Examined macroscopically the area of the tissue surrounding the center portion of each implant strip. Used a magnifying lens and auxiliary light source. Observed the test article and negative control implant sites for hemorrhage, necrosis, discolorations, and infections, and record the observations. Measured and scored encapsulation, then calculated the differences between average scores for the test article and negative control sites.

3. Result

According to what observed:

During the whole clinical observation, no any abnormal reaction of the insertion point was observed.

The differences between average scores for the test and control sites was 0.

4. Conclusion

Under the conditions of this study, the test article met the requirements of the test.

Edited by: Colin lu

Colin Lu

Checked by: Patryk Chen

Patryk Chen

1. STUDY SUMMARIES

1.1. Study Name (Study No.)

Single Use Powder Transfer Bag-Intramuscular Implantation Test (SZB24082509A-017)

1.2. Purpose

The test was designed to evaluate the potential of a test article to cause local stimulation following muscle implantation to rabbit.

1.3. Testing Facility

Name: EPINTEK Suzhou Ltd.

Address: No.558 Fenhu Avenue, Lili Town, Wujiang District, Suzhou, China.

1.4. Sponsor

Name: Changzhou Dreure Medical Material Co., LTD.

Address: No.502 Changting Road, Wujin Economic Development Zone, Changzhou

ATTN: Wenqing Shi

Contact Information: +86 152 9518 5667 / wenqing.shi@dreure.com

1.5. Study Alteration Treatment

Before the study start, the study protocol was approved by Study Director and Sponsor. Any study alteration should be approved by Study Director.

1.6. Deviation(s) and Incident(s) Treatment

If any deviation or incident occurred during the test, the related information would be recorded timely and a deviation report should be submitted with the final report to interpretate the specific effect(s) on the final result caused by the deviation or incident.

1.7. Major Laboratory Personnel

Study Director: Patryk Chen

Main Operation Personnel: Lark Sun, Betty Liu

1.8. Schedule of the Study

Protocol Effective Date: /

Test Start Date:	2024-09-25
Test Completion Date:	2024-10-02
Report Completion Date:	2024-10-25

2. CONTROL AND TEST SYSTEM CONFIRMATION

2.1. Negative Control

Name:	High-density polyethylene
Lot/ Batch#:	D-181
Color:	White
Manufacturer:	Hatano Research Institute, FDSC

2.2. Animal

2.2.1. Animal information

Species:	New Zealand white rabbit
Microbial Levels:	Conventional
Number/Sex:	2/Female (nulliparous and non-pregnant)
Weight:	More than 2.5 kg at the beginning of the test
Manufacturer:	FMC Laboratory Animals Inc.
Production License#:	SCXK(Zhe)2023-0009
Quality Certificate#:	20240911Ceeee0600000584

2.2.2. Animal feeding conditions

Breeding Density:	One animal per cage
Cages:	Suspended stainless steel
Animal Identification:	Marked the ID in animal's right ear and identified by a card
Acclimation Period:	At least 7 days under the same conditions before the actual test
Fodder:	Name: Rabbit Maintenance Formula Feed Manufacturer: KEAO XIELI FEED CO., LTD Daily 75 g quantitative uptake per animal
Water:	Automatic drinking device

Free intake

2.2.3. Animal room environmental conditions

Temperature: 16℃-26℃

Relative Humidity: 40%-70%RH

Ventilation Rate: ≥8/h

Lights: 12 hours light/dark cycle, full spectrum fluorescent lights

2.3. Main Instruments and Reagents

2.3.1. Main instruments

Name	No.	Calibration Due Date
Electronic Balance	EPB-303	2025-06-12
Clean Bench	EPB-314	2025-06-13

2.3.2. Reagents

Name	Lot #	Manufacturer
Zoletil-50	998L	VIRBAC
Xylazine	20231015	Shengda Animal
Sterile Water for Injection	998LA	VIRBAC
Tissue Fixation Solution	240513	YULU EXPERIMENT EQUIPMENT

2.4. Justification of the Test System

The rabbit is a suitable animal model for evaluating biological materials according to nowadays test Standards. Muscle tissue is traditionally used because it is easy to grade and compare with known negative control for its implantation reaction.

3. TEST DESIGN

3.1. Sample Preparation

The sample and negative control were prepared into strips of about 1 cm×0.1 cm under aseptic conditions. The prepared negative control was autoclave sterilized at 121℃ for 30min.

3.2. Grouping

Took 2 female rabbits into 1 group.

Group No.	Group Name	Amount	Sex	Numbered list
1	Test group	2	♀	1201~1202

3.3. Experimental Process

3.3.1. Implantation process

The rabbits were restrained and the fur clipped on the area over the paravertebral muscles to expose about 10 cm×20 cm area. The rabbits were anesthetized with Zoletil-50 combined with Xylazine (15/5 mg/kg， IM.). Then wiped the exposed skin with 75% alcohol and iodophor. Four test article sections were implanted in the left paravertebral muscle of each rabbit. (2.5~5) cm from the midline and parallel to the spinal column, and about 2.5 cm apart from each other. Two negative control sections were similarly implanted in the opposite muscle.

3.3.2. Clinical observation

Observed and recorded every day after implantation, especially the insertion point of the skin was evaluated to measure abnormal responses such as bleeding, red swelling, necrosis and injection site discharge.

3.3.3. Anatomical observation

The rabbits were euthanatized through air embolism and dissected after 1 week. Allowed sufficient time to elapse for the tissue to be cut without bleeding. Examined macroscopically the area of the tissue surrounding the center portion of each implant strip. Used a magnifying lens and auxiliary light source. Observed the sample and control implant sites for hemorrhage, necrosis, discolorations, and infections, and recorded the observations. Measured encapsulation, if present, by recording the width of the capsule (from the periphery of the space occupied by the implant the test article and negative control to the periphery of the capsule) rounded to the nearest 0.1 mm. Scored encapsulation according to Table 1.

Table 1 Evaluation of Encapsulation in the Implantation Test

Capsule Width	Score
None	0
Up to 0.5 mm	1
0.6–1.0 mm	2
1.1–2.0 mm	3
Greater than 2.0 mm	4

4. EVALUATION CRITERION

1) Calculate the differences between average scores for the test article and negative control sites.
2) Sample average points - control average points.
3) The requirements of the test met if the difference did not exceed 1.0.
4) If the difference between the test article and negative control mean scores for more than one of the four implant sites did not exceed 1 for any implanted animal.

5. ALTERATION AND DEVIATION

There were no changes and deviations of technical parameters that affect the experimental results.

6. RESULTS

According to what observed:

During the whole clinical observation, no any abnormal reaction of the insertion point was observed.

The differences between average scores for the test and control sites was 0.

See Attached Table 1-3.

7. CONCLUSION

Under the conditions of this study, the test article met the requirements of the test.

8. ARCHIVING

All correspondence, including original copy of the protocol, original copy of the test report, and all raw data generated during the study (i.e., documentation forms as well as any other notes of raw data, printouts of instruments and computers) are stored in the archives room of the EPINTEK Suzhou Ltd.

9. ATTACHED TABLE

9.1. Attached Table 1 Clinical Observation-Test Group

Animal No.	Implant sites	Symptom				
		Bleeding	Red swelling	Necrosis	Injection site discharge	Others
1201	Test article 1	—	—	—	—	—
	Test article 2	—	—	—	—	—
	Test article 3	—	—	—	—	—
	Test article 4	—	—	—	—	—
	Negative control 1	—	—	—	—	—
	Negative control 2	—	—	—	—	—
1202	Test article 5	—	—	—	—	—
	Test article 6	—	—	—	—	—
	Test article 7	—	—	—	—	—
	Test article 8	—	—	—	—	—
	Negative control 3	—	—	—	—	—
	Negative control 4	—	—	—	—	—

Note:“—”means no abnormal reaction.

9.2. Attached Table 2 Anatomical Observation-Test Group

Animal No.	Implant sites	Symptom				
		Hemorrhage	Necrosis	Discolorations	Infections	Others
1201	Test article 1	—	—	—	—	—
	Test article 2	—	—	—	—	—
	Test article 3	—	—	—	—	—
	Test article 4	—	—	—	—	—
	Negative control 1	—	—	—	—	—
	Negative control 2	—	—	—	—	—
1202	Test article 5	—	—	—	—	—
	Test article 6	—	—	—	—	—
	Test article 7	—	—	—	—	—
	Test article 8	—	—	—	—	—
	Negative control 3	—	—	—	—	—
	Negative control 4	—	—	—	—	—

Note:“—”means no abnormal reaction.

9.3. Attached Table 3 Evaluation of Encapsulation -Test Group

Implantation Time	1 Week											
Group	Test Control								Control			
Animal No.	1201				1202				1201		1202	
Implantation Sites	T1	T2	T3	T4	T5	T6	T7	T8	C1	C2	C3	C4
Encapsulation Score	0	0	0	0	0	0	0	0	0	0	0	0
Score of Individual Animal	0				0				0		0	
Average Scores	0								0			
Test (0) – Control (0) =0												

9.4. Attached Table 4 Body Weight Change and Clinical Observation

Animal No.	Body Weight (g)		Clinical Observation Except Dermal Reactions
	Before	End	
1201	2678	2815	Normal
1202	2594	2748	Normal

End of the Report