Test Report

Date:2024.01.30
No.: DY24010292E

TEST FACILITY

STC (Guangdong) Company Limited
68 Fumin Nan Road,
Dalang, Dongguan, Guangdong,
China. (Zip code 523770)

SPONSOR

Ningbo BODI Seals Co., Ltd
1128 Building A, JiuWu Busi, No.598, JiangNan Road,
High-Tech, Ningbo, China

CONFIDENTIAL

STUDY TITLE

Intracutaneous Study in Rabbit of FFKM White USP Class VI using USP-NF 2022, General Chapter<88>, Biological Reactivity Tests, In Vivo Test Methods Intracutaneous Test, alcohol saline, polyethylene glycol 400, 0.9% sodium chloride injection and sesame oil extract

TEST SAMPLE NAME

FFKM White USP Class VI

TEST SAMPLE IDENTIFICATION

CP-MD-8709
CSD NO.: CL20240105830

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Summary

The test sample, FFKM White USP Class VI, was evaluated for intradermal reactivity in rabbit. in accordance with the USP-NF 2022, General Chapter<88>, Biological Reactivity Tests, In Vivo. The test sample was extracted in 0.9% sodium chloride injection (SC), alcohol saline (AS), polyethylene glycol 400 (PEG), and sesame oil (SO). A 0.2 mL dose of the appropriate test sample extract was injected intracutaneously into five separate sites on the left side of the back of each of two animals. Similarly, the negative control alone was injected on the right side of the back of each animal. 0.9% sodium chloride injection (SC) and Sesame oil (SO) were injected into one animal, while alcohol saline (AS) and polyethylene glycol 400 (PEG) were injected into the other. Note the appearance of each injection site immediately after injection and at (24 ± 2) h, (48 ± 2) h and (72 ± 2) h after injection.

There was no evidence of significant irritation from the extracts injected intracutaneously into rabbits. Each test sample extract met the USP Class VI respectively.

Authorized Signatory Approval: Emilly

Emilly Chen

1. Introduction

1.1 Purpose

The purpose of this study is to evaluate the local dermal irritation of a test sample extract following intracutaneous injection in rabbits.

1.2 Testing Guidelines

This study was based on the USP-NF 2022, General Chapter<88>, Biological Reactivity Tests, In Vivo.

1.3 Dates

Test Sample Received: 2024.01.16
Treatment Started: 2024.01.21
Observations Concluded: 2024.01.26

2. Identification of Test and Control Samples

The test sample provided by the sponsor was identified and handled as described below:

Table 1 - Test Sample

Name	FFKM White USP Class VI
Size	20*2
Thickness	N/A
CAS	N/A
Model	I
Lot	N/A
Initial State	N/A
Strength, Purity and Composition	FFKM White
Color	N/A

Physical Description of the Test Sample	Solid
Manufacture Date	N/A
Expiration Date	N/A

Table 2 - Negative Control Sample

Name	1 in 20 solution of alcohol in sodium chloride injection (AS) Polyethylene glycol 400 (PEG) 0.9% sodium chloride injection (SC) Sesame oil (SO)
Purity, Composition, and Other Characteristics	SC: Composition: 0.9% NaCl, pure water; sodium chloride CAS No.: 7647-14-5/water CAS No.: 7732-18-5 SO: CAS No.: 8008-74-0 AS: Composition: ethanol in saline 1:20; ethanol CAS:64-17-5/ sodium chloride CAS No.: 7647-14-5/water CAS No.: 7732-18-5 PEG: Identity: Matches infrared spectrum of polyethylene glycol 400 with average molecular weight of 380 to 420; CAS No.:25322-68-3

Table 3 - Reagents

Name	Brand	Lot
0.9% sodium chloride injection	Guangxiyuyan	H23103108
Sesame oil	HENRY LAMOTTE	8009773003
Alcohol	Xilongkexue	B2205261
Polyethylene glycol 400	aladdin	A22071062

3. Test System

3.1 Test System

Species:	Rabbit (Oryctolagus cuniculus)
Strain:	New Zealand White
Source:	Guangzhou huadu district huadongxinhua animal farm
Sex:	Male and Female (Females were nulliparous and nonpregnant)
Age:	Young adult
Acclimation Period:	Minimum 5 days
Number of Animals:	4
Identification Method:	Name card

3.2 Test System Management

The rabbit (animal) is specified as an appropriate animal model for evaluating potential intracutaneous injection test by the current USP testing standards. The rabbit is widely used for this purpose and relative ranking of intracutaneous injection scores can be determined.

4. Animal Management

4.1 Husbandry, Housing and Environment

Conditions conformed to STC Standard Operating Procedures. Animals were housed in groups in stainless steel or plastic suspended cages identified by a card indicating the animal numbers, test code, sex, animal code and date dosed.

The animal housing room is conventional system lab. Guangdong Science and Technology Department, certificate No.: SYXK (Guangdong province) 2023-0159. The animal housing room temperature and relative humidity were monitored daily. The temperature for the room was set to 18-26 °C and the relative humidity was set to 40-70 %. There were no significant temperature or relative humidity excursions that adversely affected the health of the animals.

The light cycle was controlled (12 hours light, 12 hours dark).

4.2 Food, Water and Contaminants

Food: Laboratory animal formula feed(rabbit). Shenyang Maohua Biotechnology Co., Ltd. was provided daily.

Water: The water quality met the "Sanitary standard for drinking water" (GB5749-2022)

Food and water meet animal welfare requirements. No contaminants present in the feed and water impacted the results of this study.

4.3 Personnel

Associates involved in this study were appropriately qualified and trained.

4.4 Veterinary Care

Standard veterinary medical care was provided in this study.

4.5 IACUC

This procedure has been approved by the STC Institutional Animal Care and Use Committee (IACUC), and is reviewed at least annually by the same committee.

4.6 Animals Selection

Only healthy, quarantined rabbits, animals free from irritation or other dermatological lesions that could interfere with the test were selected. If females, then nulliparous and nonpregnant.

5. Method

5.1 Test and Control Sample Preparation

The test sample extracts and the negative vehicle control (extraction vehicle without the test sample) were prepared fresh for each phase of testing and subjected to the extraction conditions as described in Table 4. The extracts were continuously agitated during extraction.

Table4 - Extraction

Vehicle	Treatment Group	Extraction Ratio	Sample Amount	Volume of Vehicle	Extraction Condition
SC	Test	3 cm²/mL	28.574 cm²	9.5 mL	(50±2) ℃ for (72±2) h
	Control	N/A	N/A	20.0 mL	
SO	Test	3 cm²/mL	28.574 cm²	9.5 mL	
	Control	N/A	N/A	20.0 mL	
AS	Test	3 cm²/mL	28.574 cm²	9.5 mL	
	Control	N/A	N/A	20.0 mL	
PEG	Test	3 cm²/mL	28.574 cm²	9.5 mL	
	Control	N/A	N/A	20.0 mL	

The following table contains a description of the test and negative control sample extracts before and after extraction.

Table 5 - Condition of Extracts

Vehicle	Time Observed	Extract	Condition of Extracts		
			Color	Clarity	Particulates
SC	Before Extraction	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
	After Extraction	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
	Prior to Use	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
SO	Before Extraction	Test	Light yellow	Clear	None
		Control	Light yellow	Clear	None
	After Extraction	Test	Light yellow	Clear	None
		Control	Light yellow	Clear	None
	Prior to Use	Test	Light yellow	Clear	None
		Control	Light yellow	Clear	None

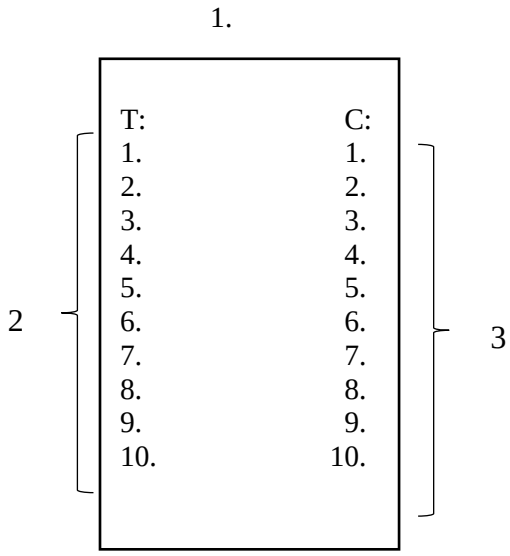
Vehicle	Time Observed	Extract	Condition of Extracts		
			Color	Clarity	Particulates
AS	Before Extraction	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
	After Extraction	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
	Prior to Use	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
PEG	Before Extraction	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
	After Extraction	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
	Prior to Use	Test	Colorless	Clear	None
		Control	Colorless	Clear	None

The extracts were tested immediately following extraction. The extracts were not centrifuged, filtered, or otherwise altered prior to dosing.

PEG test extract and negative control were diluted with saline to yield a 120 mg PEG/mL concentration before dosing the animal.

5.2 Test Procedure

Prior to treatment, each animal was identified and weighed. Within about 18 hours before treatment, each animal was clipped free of fur from the back and both sides of the spinal column to yield a sufficient injection area. One animal was prepared every two pair of extracts. 0.9% sodium chloride injection (SC) and Sesame oil (SO) were injected into one animal, while alcohol saline (AS) and polyethylene glycol 400 (PEG) were injected into the other. A 0.2 mL dose of the appropriate test sample extract was injected by the intracutaneous route into five separate sites on the left side of the back of each animal. Similarly, the corresponding negative control was injected on the right side of the back of each animal. Injections were spaced approximately 2 cm apart. As illustrated below in Figure 1.



1——Cranial
2——T1~T5 SC /AS; T6~T10 SO/PEG
3——C1~C5 SC /AS vehicle; C6~C10 SO/PEG vehicle
4——Caudal

Figure 1

The appearance of each injection site was noted immediately after injection. The animals were returned to their respective cages following the procedure.

Observations for erythema and edema were conducted at 24, 48, and 72 hours after injection. Reactions were scored on a 0 to 4 basis. Any reactions at the injection sites were also noted. The reactions were evaluated according to the following subjective rating scale:

Table 6 – Evaluation of Skin Reactions

Erythema and eschar Formation	Score		Edema Formation	Score
No erythema	0		No edema	0
Very slight erythema (barely perceptible)	1		Very slight edema (barely perceptible)	1
Well-defined erythema	2		Slight edema (edges of area well defined by definite raising)	2

Moderate to severe erythema	3		Moderate edema (raised approximately 1 mm)	3
Severe erythema (beet-redness) to slight eschar formation (injuries in depth)	4		Severe edema (raised more than 1 mm and extending beyond the area of exposure)	4

All times and temperatures reported herein are approximate and are within ranges established by the external standards described in the References section of this report and/or STC standard operating procedures.

6. Evaluation

The erythema and edema site scores for the test sample and negative control extracts for each animal at each scoring interval were calculated by adding the erythema and edema scores together (Only use observation data taken in 24-hours, 48-hours and 72-hours). The mean score of each individual animal (test and negative control) was calculated by totaling all of the individual site scores for each animal and dividing by 6 (3 scoring time points x 2 scoring categories). The overall mean for each test sample extract and negative control was calculated by adding the mean score for all two animals together and dividing by 2. The difference between the overall mean overall mean score for the negative control from the overall mean score for the test sample extract. If the overall mean score of the test sample extract was less than the overall mean score of the corresponding negative control, 0.0 was reported.

The requirements of the test were met if the difference between the test extract overall mean score and corresponding negative control overall mean score was 1.0 or less.

7. Results

All animals were clinically normal throughout the study. All animals survived the experiment without poisoning or abnormal symptoms. Results of erythema and edema scores for individual animals are presented in Appendix 1. All injection sites appeared normal immediately following injection.

Table 7 - Mean Erythema and Edema Scores

Extract	Test Group Mean	Negative Control Group Mean	Mean Difference (Test - Negative Control)
SC	0.0	0.0	0.0
SO	0.0	0.0	0.0
AS	0.0	0.0	0.0
PEG	0.0	0.0	0.0

8. Conclusion

There was no evidence of significant irritation from the extracts injected intracutaneously into rabbits. Each test sample extract met the USP Class VI respectively.
Results and conclusions apply only to the test sample tested. Any extrapolation of these data to other samples is the sponsor's responsibility.

9. Records

All raw data pertaining to this study and a copy of the final report are retained in designated STC archive files in accordance with STC SOPs. All the files were storage in DGSTC MD Archiving room.

10. ISO Compliance

All procedures were compliance to ISO 17025.

11. References

International Organization for Standardization (ISO) 10993-1, Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process (2018).
International Organization for Standardization (ISO) 10993-2, Biological evaluation of medical devices -Part 2: Animal welfare requirements (2022).
International Organization for Standardization (ISO) 10993-12, Biological evaluation of medical devices -Part 12: Sample preparation and reference materials (2021).

International Organization for Standardization/International Electrotechnical Commission (ISO/IEC)17025, General requirements for the competence of testing and calibration laboratories (2017).

USP-NF 2022, General Chapter<88>, Biological Reactivity Tests, In Vivo

Appendix 1– USP Intracutaneous Observations

Animal number	Body weight (g)	Extract		Scoring Interval (ER/ED)			
				Immediately after injection	24h	48h	72h
2023112307	3029.5	SC	Test	0/0	0/0	0/0	0/0
			Control	0/0	0/0	0/0	0/0
		SO	Test	0/0	0/0	0/0	0/0
			Control	0/0	0/0	0/0	0/0
2023110209	4062.4	SC	Test	0/0	0/0	0/0	0/0
			Control	0/0	0/0	0/0	0/0
		SO	Test	0/0	0/0	0/0	0/0
			Control	0/0	0/0	0/0	0/0
2023121404	3355.1	AS	Test	0/0	0/0	0/0	0/0
			Control	0/0	0/0	0/0	0/0
		PEG	Test	0/0	0/0	0/0	0/0
			Control	0/0	0/0	0/0	0/0
2023110207	3100.7	AS	Test	0/0	0/0	0/0	0/0
			Control	0/0	0/0	0/0	0/0
		PEG	Test	0/0	0/0	0/0	0/0
			Control	0/0	0/0	0/0	0/0

Appendix 2 - Periodic Positive Control Study for the intracutaneous reactivity Test

What was tested:

Positive control:

A 20% sodium dodecyl sulfate solution (SDS) was prepared with sodium lauryl sulfate and purified water at a 1:8 basis for pretreatment.

Brand: Macklin, Lot:C14657847

Negative Control:

0.9% sodium chloride injection (Brand: Guangxi Yuyuan，Lot：H23081005)

Sesame oil (Brand: HENRY LAMOTTE, Lot:8009773003)

PEG400 (Brand: Xilongkexue，Lot：B2205261)

1 in 20 solution of alcohol in sodium chloride injection (AS) (Brand: Aladdin，Lot：A22071062)

Dates:

Treatment Started: 2023.10.30

Observations Concluded: 2023.11.02

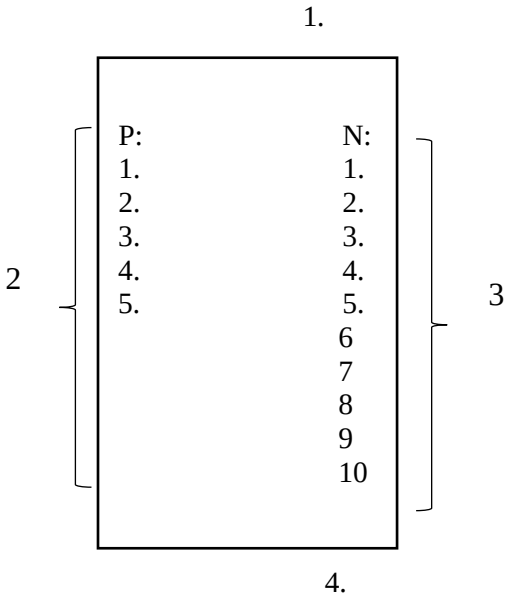
Purpose:

A periodic positive control study was conducted for the intracutaneous test to meet the following objectives: 1) confirm the methodology in USP-NF 2022, General Chapter<88>, Biological Reactivity Tests, In Vivo, 2) substantiate the potential of SDS in an attempt to induce intradermal reaction, 3) verify proper training of the technicians performing these studies, and 4) substantiate the susceptibility of the New Zealand white rabbit strain to dermal intradermal reaction.

Methods:

New Zealand rabbits provided by Huadong Xinhua Experimental Animal Farm in Huadu district, Guangzhou were used in this experiment Medical Laboratory Animal Center. The weight at study initiation were more than 2 kilograms. Four animals（two per group） were prepared. Within about 4 to 18 hours before treatment, each animal was clipped free of fur from the back and both sides of the spinal column to yield a sufficient injection area. Two animals were prepared every two pair of negative controls. 0.9% sodium chloride injection and sesame oil were injected into one of group, while alcohol saline (AS) and polyethylene glycol 400 (PEG400) were injected into the other. A 0.2 mL dose of the appropriate 20% SDS was injected by the intracutaneous route into five separate sites on the left side of the back of each animal. Similarly, the corresponding negative control was

injected on the right side of the back of each animal. Injections were spaced approximately 1~2 cm apart. As illustrated below in Fig 1.



1——Cranial
2——P1~P5 Positive control SDS injection sites
3——N1~N5 Negative control 0.9% sodium chloride /AS injection sites
N6~N10 Native control sesame oil /PEG400 injection sites
4——Caudal

Fig 1

Note the appearance of each injection site immediately after injection and at (24 ± 2) h, (48 ± 2) h and (72 ± 2) h after injection. Reactions were scored on a 0 to 4 basis. Any reactions at the injection sites were also noted. The reactions were evaluated according to the following subjective rating scale:

Table 1 – Evaluation of Skin Reactions

Erythema and eschar Formation	Score		Edema Formation	Score
No erythema	0		No edema	0
Very slight erythema (barely perceptible)	1		Very slight edema (barely perceptible)	1

Well-defined erythema	2		Slight edema (edges of area well defined by definite raising)	2
Moderate to severe erythema	3		Moderate edema (raised approximately 1 mm)	3
Severe erythema (beet-redness) to slight eschar formation (injuries in depth)	4		Severe edema (raised more than 1 mm and extending beyond the area of exposure)	4
Maximal possible score for irritation				8
Other adverse changes at the injection sites shall be recorded and reported				

Evaluation:

The erythema and edema site scores for the positive and negative control for each animal at each scoring interval were calculated by adding the erythema and edema scores together (Only use observation data taken in 24-hours, 48-hours and 72-hours). The mean score of each individual animal (positive and negative control) was calculated by totaling all of the individual site scores for each animal and dividing by 6 (3 scoring time points x 2 scoring categories). The overall mean for each positive and negative control was calculated by adding the mean score for all two animals together and dividing by 2. The difference between the overall mean overall mean score for the negative control from the overall mean score for the positive control. If the overall mean score of the positive control was less than the overall mean score of the corresponding negative control, 0.0 was reported.

The requirements of the test were met if the difference between the positive control overall mean score and corresponding negative control overall mean score was 1.0 or less.

Results:

Under the experimental conditions, the overall mean score of the positive control group was 8, and the overall mean score of the negative control was 0; the overall mean score difference between the positive control group and the negative control was greater than 1.0, and the positive control solution produced an intradermal reaction. That is, two animals in the positive control had a positive intradermal reaction to the known allergen SDS. The animals in the negative control group did not produce intradermal reactions. The table below showed the total average score of each group at each time stage. The specific results are shown below:

Animal number	Body weight (g)	**Group**	Scoring Interval (ER/ED)			
			Immediately after injection	**24h**	**48h**	**72h**
2023080322	3870.1	SDS	0/0	4/4	4/4	4/4
		0.9% sodium chloride injection	0/0	0/0	0/0	0/0
		Sesame oil	0/0	0/0	0/0	0/0
2023072023	3691.4	SDS	0/0	4/4	4/4	4/4
		0.9% sodium chloride injection	0/0	0/0	0/0	0/0
		Sesame oil	0/0	0/0	0/0	0/0
2023082413	3857.1	SDS	0/0	4/4	4/4	4/4
		AS	0/0	0/0	0/0	0/0
		PEG400	0/0	0/0	0/0	0/0
2023072031	4217.8	SDS	0/0	4/4	4/4	4/4
		AS	0/0	0/0	0/0	0/0
		PEG400	0/0	0/0	0/0	0/0

Conclusion：

The known sensitizer SDS produced evidence of causing intradermal reaction in the rabbits. Therefore, the following objectives were met: 1) the methodology in USP-NF 2022, General Chapter<88>, Biological Reactivity Tests, In Vivo was confirmed, 2) the potential for SDS to cause intradermal reaction was substantiated, 3) proper training of the technicians performing this study design was verified and 4) the susceptibility of the rabbit strain to intradermal reaction was substantiated.

Appendix 3– Photograph(s) of Test Samples

******* END OF TEST REPORT *******

Conditions of Issuance of Test Reports

1. All samples and goods are accepted by The STC (Guangdong) Company Limited (the "Company") solely for testing and reporting in accordance with the following terms and conditions. The Company provides its services on the basis that such terms and conditions constitute express agreement between the Company and any person, firm or company requesting its services (the "Clients").

2. Any report issued by the Company as a result of this application for testing service (the "Report") shall be issued in confidence to the Clients and the Report will be strictly treated as such by the Company. It may not be reproduced either in its entirety or in part and it may not be used for advertising or other unauthorized purposes without the written consent of the Company. The Clients to whom the Report is issued may, however, show or send it, or a certified copy thereof prepared by the Company to his customer, supplier or other persons directly concerned. Subject to clause 3, the Company will not, without the consent of the Clients, enter into any discussion or correspondence with any third party concerning the contents of the Report, unless required by the relevant governmental authorities, laws or court orders.

3. The Company shall be at liberty to disclose the testing-related documents and/or files anytime to any third-party accreditation and/or recognition bodies for audit or other related purposes. No liabilities whatsoever shall attach to the Company's act of disclosure.

4. The Company shall not be called or be liable to be called to give evidence or testimony on the Report in a court of law without its prior written consent, unless required by the relevant governmental authorities, laws or court orders.

5. The results in the Report apply only to the sample as received and do not apply to the bulk, unless the sampling has been carried out by the Company and is stated as such in the Report. The Clients provide the sample's relevant information, and the Company will not be liable for or accept responsibility for the truth of the sample information.

6. When a statement of conformity to a specification or standard is provided, the ILAC-G8 Guidance document (and/or IEC Guide 115 in the electrotechnical sector) with 95% coverage probability will be adopted as a decision rule for the determination of conformity unless it is inherent in the requested specification or standard, or otherwise specified in the Report.

7. In the event of the improper use the report as determined by the Company, the Company reserves the right to withdraw it, and to adopt any other additional remedies which may be appropriate.

8. Sample submitted for testing are accepted on the understanding that the Report issued cannot form the basis of, or be the instrument for, any legal action against the Company.

9. The Company will not be liable for or accept responsibility for any loss or damage howsoever arising from the use of information contained in any of its Reports or in any communication whatsoever about its said tests or investigations.

10. Clients wishing to use the Report in court proceedings or arbitration shall inform the Company to that effect prior to submitting the sample for testing.

11. Subject to the variable length of retention time for test data and report stored hereinto as to otherwise specifically required by individual accreditation authorities, the Company will only keep the supporting test data and information of this test report for a period of six years. The data and information will be disposed of after the aforementioned retention period has elapsed. Under no circumstances shall we provide any data and information which has been disposed of after the retention period. Under no circumstances shall we be liable for damages of any kind, including (but not limited to) compensatory damages, lost profits, lost data, or any form of special, incidental, indirect, consequential or punitive damages of any kind, whether based on breach of contract of warranty, tort (including negligence), product liability or otherwise, even if we are informed in advance of the possibility of such damages.

12. Issuance records of the Report are available on the internet at www.gdstc.group. Further enquiry of validity or verification of the Reports should be addressed to the Company.

Test Report

Date : 2024.02.28
No. : DY24010293E

TEST FACILITY

STC(Guangdong) Company Limited.
No.68, Fumin South Road, Dalang, Dongguan, Guangdong, China. Zip Code: 523770

SPONSOR

Ningbo BODI Seals Co., Ltd
1128 Building A, JiuWu Busi, No.598, JiangNan Road, High-Tech, Ningbo, China

CONFIDENTIAL

STUDY TITLE

Systemic Toxicity Injection Test in mice of FFKM White USP Class VI using USP-NF 2022, General Chapter <88>, Biological Reactivity Tests, In Vivo Systemic Injection Test, alcohol saline, polyethylene glycol 400, 0.9% sodium chloride injection and sesame oil extract

TEST SAMPLE NAME

FFKM White USP Class VI

TEST SAMPLE IDENTIFICATION

CP-MD-8709
CSD NO.: CL20240105830

Test Report

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Test Report

Summary

The test sample, FFKM White USP Class VI, was evaluated for systemic toxicity in mice. in accordance with the USP-NF 2022, General Chapter <88>, Biological Reactivity Tests, In Vivo. The test sample was extracted in 1 in 20 solution of alcohol in saline (AS), polyethylene glycol 400(PEG), 0.9% sodium chloride injection (SC) and sesame oil (SO). A single dose of the appropriate test sample extract was injected into a group of five animals. Similarly, a separate group of five animals was dosed with each corresponding extraction vehicle alone (control). The animals were observed for signs of systemic toxicity immediately after injection and at 4, 24, 48 and 72 hours after injection. Body weights were recorded prior to dosing and on days 1, 2 and 3.

There was no mortality or evidence of systemic toxicity from the extracts injected into mice. Each test sample extract met the USP 88 Class VI requirements of the study.

Authorized Signatory Approval: Emilly

Emilly Chen

1. Introduction

1.1 Purpose

The purpose of this study is to evaluate the acute systemic toxicity of a test sample extract following injection in mice.

1.2 Testing Guidelines

This study was based on the USP-NF 2022, General Chapter<88>, Biological Reactivity Tests, In Vivo.

1.3 Dates

Test Sample Received:	2024.01.16
Test conducted:	2024.02.17
Observations Concluded:	2024.02.23

2. Identification of Test and Control Samples

The test sample provided by the sponsor was identified and handled as described below:

Table 1 - Test Sample

Name	FFKM White USP Class VI
Size	20*2
Thickness	N/A
CAS	N/A
Model	I
Lot	N/A
Initial State	N/A
Strength, Purity and Composition	FFKM White
Color	N/A

Physical Description of the Test Sample	Solid
Manufacture Date	N/A
Expiration Date	N/A
Intended Clinical Use of Test Sample	N/A

Table 2 - Negative Control Sample

Name	1 in 20 solution of alcohol in sodium chloride injection (AS) Polyethylene glycol (PEG) 0.9%Sodium chloride injection (SC) Sesame Oil (SO)
Purity, Composition, and Other Characteristics	SC: Composition: 0.9% NaCl, balance is water; sodium chloride CAS No.: 7647-14-5/water CAS No.: 7732-18-5 SO: CAS No.: 8008-74-0 AS: Composition: ethanol in saline 1:20; ethanol CAS:64-17-5/ sodium chloride CAS No.: 7647-14-5/water CAS No.: 7732-18-5 PEG: Identity: Matches infrared spectrum of polyethylene glycol 400 with average molecular weight of 380 to 420; Composition: Neat: CAS:25322-68-3

Table 3 - Reagents

Name	Brand	Lot
0.9% Sodium chloride injection	Guangxiyuyuan	H23103108
Sesame oil	HENRY LAMOTTE	1000021737
Alcohol	Xilongkexue	B2205261
PEG400	aladdin	A22071062

3. Test System

3.1 Test System

Species :	Mouse
Breed:	KM
Level:	SPF
Source:	Guangzhou Ruige Biotechnology Co., Ltd.
Sex:	Male and Female（Females were nulliparous and nonpregnant）
Number of Animal:	40
Acclimation Period:	Minimum 5 day
Identification Method:	Name card, Ear tag, Picric acid marking

3.2 Justification of Test System

Mice have historically been used to evaluate potential toxicity of test samples. The use of mice injected with a single intravenous (i.v.) or intraperitoneal (i.p.) dose of test sample extract or control sample is specified in the current USP standard for evaluation of medical plastics.

4. Animal Management

4.1 Husbandry, Housing and Environment

Conditions conformed to STC Standard Operating Procedures. Animals are housed in groups in plastic suspended cages identified by ear tag, picric acid marking and a card indicating the animal numbers, test code, sex, animal code and date dosed.

The animal housing room is barrier system lab. The animal use license issued by Guangdong Science and Technology Department, certificate No.: SYXK (Guangdong province) 2023-0159. The animal housing room temperature and relative humidity were monitored daily. The temperature for the room was set to 20-25℃ and the relative humidity was set to 40-70%. There were no significant temperature or relative humidity excursions that adversely affected the health of the animals.

The light cycle was controlled (12 hours light, 12 hours dark).

4.2 Food, Water and Contaminants

Food: SPF Rat & Mouse Maintenance Feed, Shenyang Maohua Biotechnology Co., Ltd. was provided daily.

Water: The water quality met the "Sanitary standard for drinking water" (GB5749-2022) Food and water were sterile. No contaminants present in the feed and water impacted the results of this study.

4.3 Personnel

Associates involved were appropriately qualified and trained.

4.4 Sedation, Analgesia or Anesthesia

It had been determined that the used of sedation, analgesia or anesthesia was not necessary during the routine course of this procedure.

4.5 Veterinary Care

All anesthetics, analgesics, and other medications may be given or altered at the discretion of the attending veterinarian in accordance with standard veterinary practice and the study objectives. This applies to specific medication, dose, and dosing intervals. In the unlikely event that an animal should become injured, ill, or moribund, care was conducted in accordance with current veterinary medical practice. If warranted for humane reasons, euthanasia was conducted in accordance with the current report of the American Veterinary Medical Association's Guidelines on Euthanasia. The objective of the study is given due consideration in any decision and the study sponsor was advised.

4.6 IACUC

This procedure has been approved by the STC Institutional Animal Care and Use Committee (IACUC), and is reviewed at least annually by the same committee.

4.7 Selection

Healthy young adult animals of commonly used laboratory strains should be employed. Females were nulliparous and non-pregnant. Each animal, at the commencement of its dosing, was between 8 and 12 weeks old and its weight, fell in an interval within ±20% of the mean weight of any previously dosed animals.

5. Method

5.1 Test and Control Sample Preparation

The test sample and the control sample (extraction vehicle without the test sample) were subjected to the extraction conditions as described below. The extracts were continuously agitated during extraction.

Table 4 - Extraction

Vehicle	Treatment Group	Extraction Ratio	Sample Amount	Volume of Vehicle	Extraction Condition
SC	Test	3 cm²/mL	39.564 cm²	13.2 mL	（50±2） ℃ for（72±2）h
	Control	N/A	N/A	20 mL	
SO	Test	3 cm²/mL	39.564 cm²	13.2 mL	
	Control	N/A	N/A	20 mL	
AS	Test	3 cm²/mL	39.564 cm²	13.2 mL	
	Control	N/A	N/A	20 mL	
PEG400	Test	3 cm²/mL	39.564 cm²	13.2 mL	
	Control	N/A	N/A	20 mL	

The following table contains a description of the test and control sample extracts before and after extraction.

Table 5 - Condition of Extracts

Vehicle	Time Observed	Extract	Condition of Extracts		
			Color	Clarity	Particulates
SC	Before Extraction	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
	After Extraction	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
	Prior to Use	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
SO	Before Extraction	Test	Light yellow	Clear	None
		Control	Light yellow	Clear	None
	After Extraction	Test	Light yellow	Clear	None
		Control	Light yellow	Clear	None
	Prior to Use	Test	Light yellow	Clear	None
		Control	Light yellow	Clear	None
AS	Before Extraction	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
	After Extraction	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
	Prior to Use	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
PEG	Before Extraction	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
	After Extraction	Test	Colorless	Clear	None
		Control	Colorless	Clear	None
	Prior to Use	Test	Colorless	Clear	None
		Control	Colorless	Clear	None

The extracts were tested immediately following extraction. The extracts were not centrifuged, filtered, or otherwise altered prior to dosing.

PEG400 test extract of the sample prepared with Polyethylene Glycol 400, and the corresponding Blank, with 4.1 volumes of sodium chloride injection to obtain a solution having a concentration of about 200 mg of polyethylene glycol per mL concentration before dosing the animal.

5.2 Test Procedure

Prior to dosing, the animals were individually identified, weighed and arbitrarily assigned to a treatment group as shown below

Table 6 - Treatment Group Assignment

Extract	Treatment Group	Number of Animals	Sex	Dose	Route of Administration
SC	Test	5	Male	50 mL/kg	Intravenous
	Control	5	Male	50 mL/kg	Intravenous
SO	Test	5	Female	50 mL/kg	Intraperitoneal
	Control	5	Female	50 mL/kg	Intraperitoneal
AS	Test	5	Male	50 mL/kg	Intravenous
	Control	5	Male	50 mL/kg	Intravenous
PEG	Test	5	Female	10 g/kg	Intraperitoneal
	Control	5	Female	10 g/kg	Intraperitoneal

A single dose of each test sample extract was injected into each animal in the test group. Each control blank was similarly injected into each animal in the control group. Dosing occurred on day 0. Animals were observed for any adverse clinical reactions immediately after injection. The animals were then returned to their cages. The animals were observed for signs of systemic reactions at 4, 24, 48 and 72 hours after injection. The animals were weighed daily for three days after dosing. After the test was

completed, all animals were euthanized according to an IACUC approved STC procedure.

All times and temperatures reported herein are approximate and are within ranges established by the external standards described in the References section of this report and/or STC standard operating procedures.

6. Evaluation

If during the observation period, none of the animals treated with the individual test extract exhibited a significantly greater reaction than the control animals, the test sample met the requirements of the standard. If two or more mice die, or if abnormal behavior such as convulsions or prostration occurs in two or more mice, or if a body weight loss greater than 2 g occurs in three or more mice, the test sample did not meet the test requirements.

7. Results

7.1 Mortality Data

The mortality data are presented in Appendix Table 1 in the appendices.

7.2 Clinical Observations

All animals were clinically normal throughout the study, the AS leaching animals in a coma after subjects, then wake up in 4 hours, and after the has been no abnormal, the rest of the animals in the clinical observation were normal in the test. The clinical observations are presented in Appendix Table 2 in the appendices.

7.3 Body Weight

All animals gained weight throughout the study. The clinical observations are presented in Appendix Table 3 in the appendices.

8. Conclusion

There was no mortality or evidence of systemic toxicity from the extracts injected into mice. Each test sample extract met the USP 88 Class VI requirements of the study.

Results and conclusions apply only to the test sample tested. Any extrapolation of these data to other samples is the sponsor's responsibility.

9. Records

All raw data pertaining to this study and a copy of the final report are retained in designated STC archive files in accordance with STC SOPs.

10. ISO Compliance

All procedures were compliance to ISO 17025.

11. References

International Organization for Standardization (ISO) 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (2018).

International Organization for Standardization (ISO) 10993-2, Biological evaluation of medical devices - Part 2: Animal welfare requirements (2022).

International Organization for Standardization (ISO) 10993-11, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (2017).

International Organization for Standardization (ISO) 10993-12, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (2021).

International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025, General requirements for the competence of testing and calibration laboratories (2017).

USP-NF 2022, General Chapter <88>, Biological Reactivity Tests, In Vivo

Appendix 1 – SC Extract

Table 1 - Mortality Data

Treatment Group	Number Dead/Number Tested
Test	0/5
Control	0/5

Table 2 - Clinical Observations

Treatment Group	Animal Number	Observation				
		Immediate	4 hours	Day 1	Day 2	Day 3
Test	ST1	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	ST2	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	ST3	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	ST4	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	ST5	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
Control	SC1	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	SC2	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	SC3	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	SC4	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	SC5	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal

Table 3 - Body Weight Data

Treatment Group	Animal Number	Body Weight(g)									
		Day 0	Day 1	Change	Change rate	Day 2	Change	Change rate	Day 3	Change	Change rate
Test	ST1	18.86	19.89	+1.03	5.46%	22.08	+2.19	11.01%	24.02	+1.94	8.79%
	ST2	18.94	20.74	+1.80	9.50%	22.47	+1.73	8.34%	23.61	+1.14	5.07%
	ST3	20.20	22.04	+1.84	9.11%	24.78	+2.74	12.43%	25.94	+1.16	4.68%
	ST4	21.38	21.85	+0.47	2.20%	24.53	+2.68	12.27%	26.61	+2.08	8.48%
	ST5	22.59	24.65	+2.06	9.12%	27.41	+2.76	11.20%	29.64	+2.23	8.14%
Control	SC1	18.00	19.54	+1.54	8.56%	21.08	+1.54	7.88%	22.90	+1.82	8.63%
	SC2	18.96	21.39	+2.43	12.82%	22.65	+1.26	5.89%	23.93	+1.28	5.65%
	SC3	21.13	22.53	+1.40	6.63%	23.79	+1.26	5.59%	24.89	+1.10	4.62%
	SC4	21.94	23.59	+1.65	7.52%	24.75	+1.16	4.92%	26.54	+1.79	7.23%
	SC5	22.54	24.74	+2.20	9.76%	25.83	+1.09	4.41%	27.51	+1.68	6.50%

Appendix 2 – SO Extract

Table 1 - Mortality Data

Treatment Group	Number Dead/Number Tested
Test	0/5
Control	0/5

Table 2 - Clinical Observations

Treatment Group	Animal Number	Observation				
		Immediate	4 hours	Day 1	Day 2	Day 3
Test	OT1	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	OT2	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	OT3	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	OT4	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	OT5	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
Control	OC1	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	OC2	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	OC3	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	OC4	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	OC5	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal

Test Report

Table 3 - Body Weight Data

Treatment Group	Animal Number	Body Weight(g)									
		Day 0	Day 1	Change	Change rate	Day 2	Change	Change rate	Day 3	Change	Change rate
Test	OT1	17.21	17.21	+0.00	0.00%	19.20	+1.99	11.56%	20.72	+1.52	7.92%
	OT2	17.89	18.68	+0.79	4.42%	20.63	+1.95	10.44%	21.91	+1.28	6.20%
	OT3	19.08	19.94	+0.86	4.51%	22.30	+2.36	11.84%	23.14	+0.84	3.77%
	OT4	20.16	21.62	+1.46	7.24%	22.81	+1.19	5.50%	24.43	+1.62	7.10%
	OT5	21.03	21.61	+0.58	2.76%	23.13	+1.52	7.03%	24.70	+1.57	6.79%
Control	OC1	17.25	18.04	+0.79	4.58%	19.32	+1.28	7.10%	21.14	+1.82	9.42%
	OC2	18.05	18.48	+0.43	2.38%	19.68	+1.20	6.49%	21.69	+2.01	10.21%
	OC3	18.81	19.66	+0.85	4.52%	21.41	+1.75	8.90%	22.66	+1.25	5.84%
	OC4	19.94	20.59	+0.65	3.26%	22.02	+1.43	6.95%	23.58	+1.56	7.08%
	OC5	20.53	20.85	+0.32	1.56%	22.75	+1.90	9.11%	24.53	+1.78	7.82%

Appendix 3 – AS Extract

Table 1 - Mortality Data

Treatment Group	Number Dead/Number Tested
Test	0/5
Control	0/5

Table 2 - Clinical Observations

Treatment Group	Animal Number	Observation				
		Immediate	4 hours	Day 1	Day 2	Day 3
Test	AST1	Fall asleep, and then wake up	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	AST2	Fall asleep, and then wake up	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	AST3	Fall asleep, and then wake up	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	AST4	Fall asleep, and then wake up	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	AST5	Fall asleep, and then wake up	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
Control	ASC1	Fall asleep, and then wake up	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	ASC2	Fall asleep, and then wake up	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	ASC3	Fall asleep, and then wake up	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	ASC4	Fall asleep, and then wake up	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	ASC5	Fall asleep, and then wake up	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal

Test Report

Table 3 - Body Weight Data

Treatment Group	Animal Number	Body Weight(g)									
		Day 0	Day 1	Change	Change rate	Day 2	Change	Change rate	Day 3	Change	Change rate
Test	AST1	18.47	19.37	+0.90	4.87%	21.40	+2.03	10.48%	23.53	+2.13	9.95%
	AST2	19.73	20.82	+1.09	5.52%	23.17	+2.35	11.29%	24.98	+1.81	7.81%
	AST3	20.93	22.28	+1.35	6.45%	23.49	+1.21	5.43%	25.89	+2.40	10.22%
	AST4	21.50	22.30	+0.80	3.72%	24.48	+2.18	9.78%	26.12	+1.64	6.70%
	AST5	22.58	23.58	+1.00	4.43%	25.29	+1.71	7.25%	26.67	+1.38	5.46%
Control	ASC1	18.12	20.03	+1.91	10.54%	21.84	+1.81	9.04%	22.92	+1.08	4.95%
	ASC2	19.66	20.73	+1.07	5.44%	22.21	+1.48	7.14%	23.33	+1.12	5.04%
	ASC3	20.81	21.78	+0.97	4.66%	23.76	+1.98	9.09%	26.03	+2.27	9.55%
	ASC4	21.35	21.67	+0.32	1.50%	24.71	+3.04	14.03%	26.07	+1.36	5.50%
	ASC5	22.59	24.55	+1.96	8.68%	26.47	+1.92	7.82%	28.42	+1.95	7.37%

Appendix 4 – PEG Extract

Table 1 - Mortality Data

Treatment Group	Number Dead/Number Tested
Test	0/5
Control	0/5

Table 2 - Clinical Observations

Treatment Group	Animal Number	Observation				
		Immediate	4 hours	Day 1	Day 2	Day 3
Test	PEGT1	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	PEGT2	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	PEGT3	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	PEGT4	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	PEGT5	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
Control	PEGC1	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	PEGC2	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	PEGC3	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	PEGC4	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	PEGC5	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal

Test Report

Table 3 - Body Weight Data

Treatment Group	Animal Number	Body weight(g)									
		Day 0	Day 1	Change	Change rate	Day 2	Change	Change rate	Day 3	Change	Change rate
Test	PEGT1	17.02	17.99	+0.97	5.70%	19.54	+1.55	8.62%	21.17	+1.63	8.34%
	PEGT2	18.40	19.18	+0.78	4.24%	20.33	+1.15	6.00%	21.93	+1.60	7.87%
	PEGT3	18.86	19.29	+0.43	2.28%	20.83	+1.54	7.98%	22.68	+1.85	8.88%
	PEGT4	20.36	21.58	+1.22	5.99%	22.98	+1.40	6.49%	24.93	+1.95	8.49%
	PEGT5	21.38	21.77	+0.39	1.82%	23.36	+1.59	7.30%	24.84	+1.48	6.34%
Control	PEGC1	17.18	18.04	+0.86	5.01%	19.27	+1.23	6.82%	20.47	+1.20	6.23%
	PEGC2	17.79	18.24	+0.45	2.53%	19.58	+1.34	7.35%	20.97	+1.39	7.10%
	PEGC3	18.85	20.51	+1.66	8.81%	21.59	+1.08	5.27%	22.47	+0.88	4.08%
	PEGC4	20.37	20.95	+0.58	2.85%	22.13	+1.18	5.63%	23.47	+1.34	6.06%
	PEGC5	20.58	22.19	+1.61	7.82%	23.59	+1.40	6.31%	24.25	+0.66	2.80%

Appendix 5 – Photograph(s) of Test Samples

******* END OF STUDY REPORT *******

Conditions of Issuance of Test Reports

1. All samples and goods are accepted by The STC (Guangdong) Company Limited (the "Company") solely for testing and reporting in accordance with the following terms and conditions. The Company provides its services on the basis that such terms and conditions constitute express agreement between the Company and any person, firm or company requesting its services (the "Clients").

2. Any report issued by the Company as a result of this application for testing service (the "Report") shall be issued in confidence to the Clients and the Report will be strictly treated as such by the Company. It may not be reproduced either in its entirety or in part and it may not be used for advertising or other unauthorized purposes without the written consent of the Company. The Clients to whom the Report is issued may, however, show or send it, or a certified copy thereof prepared by the Company to his customer, supplier or other persons directly concerned. Subject to clause 3, the Company will not, without the consent of the Clients, enter into any discussion or correspondence with any third party concerning the contents of the Report, unless required by the relevant governmental authorities, laws or court orders.

3. The Company shall be at liberty to disclose the testing-related documents and/or files anytime to any third-party accreditation and/or recognition bodies for audit or other related purposes. No liabilities whatsoever shall attach to the Company's act of disclosure.

4. The Company shall not be called or be liable to be called to give evidence or testimony on the Report in a court of law without its prior written consent, unless required by the relevant governmental authorities, laws or court orders.

5. The results in the Report apply only to the sample as received and do not apply to the bulk, unless the sampling has been carried out by the Company and is stated as such in the Report. The Clients provide the sample's relevant information, and the Company will not be liable for or accept responsibility for the truth of the sample information.

6. When a statement of conformity to a specification or standard is provided, the ILAC-G8 Guidance document (and/or IEC Guide 115 in the electrotechnical sector) with 95% coverage probability will be adopted as a decision rule for the determination of conformity unless it is inherent in the requested specification or standard, or otherwise specified in the Report.

7. In the event of the improper use the report as determined by the Company, the Company reserves the right to withdraw it, and to adopt any other additional remedies which may be appropriate.

8. Sample submitted for testing are accepted on the understanding that the Report issued cannot form the basis of, or be the instrument for, any legal action against the Company.

9. The Company will not be liable for or accept responsibility for any loss or damage howsoever arising from the use of information contained in any of its Reports or in any communication whatsoever about its said tests or investigations.

10. Clients wishing to use the Report in court proceedings or arbitration shall inform the Company to that effect prior to submitting the sample for testing.

11. Subject to the variable length of retention time for test data and report stored hereinto as to otherwise specifically required by individual accreditation authorities, the Company will only keep the supporting test data and information of this test report for a period of six years. The data and information will be disposed of after the aforementioned retention period has elapsed. Under no circumstances shall we provide any data and information which has been disposed of after the retention period. Under no circumstances shall we be liable for damages of any kind, including (but not limited to) compensatory damages, lost profits, lost data, or any form of special, incidental, indirect, consequential or punitive damages of any kind, whether based on breach of contract of warranty, tort (including negligence), product liability or otherwise, even if we are informed in advance of the possibility of such damages.

12. Issuance records of the Report are available on the internet at www.gdstc.group. Further enquiry of validity or verification of the Reports should be addressed to the Company.

TEST REPORT

Date: 2024.02.06
No.: DY24010291E

TEST FACILITY

STC(Guangdong) Company Limited.
No.68, Fumin South Road, Dalang, Dongguan, Guangdong, China. Zip Code: 523770

SPONSOR

Ningbo BODI Seals Co., Ltd
1128 Building A, JiuWu Busi, No.598, JiangNan Road, High-Tech, Ningbo, China

CONFIDENTIAL

STUDY TITLE

Muscle Implantation Test in Rabbits Following USP-NF 2022, General Chapter <88>, Biological Reactivity Tests, In Vivo for local effects after implantation, 1 week.

TEST SAMPLE NAME

FFKM White USP Class VI

TEST SAMPLE IDENTIFICATION

CP-MD-8709
CSD NO.: CL20240105830

TEST REPORT

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Summary

The test sample, FFKM White USP Class VI, was implanted in muscle tissue of the rabbit to evaluate the local tissue response in accordance with the USP-NF 2022, General Chapter <88>, Biological Reactivity Tests, In Vivo. Implant test samples and negative control samples were sterilized by Steam. The test sample and negative control were intramuscularly implanted and animals were euthanized 7 days later. Muscle tissues were excised and the implant sites examined macroscopically.

The macroscopic reaction was not significant as compare to the negative control sample. The implanted test sample met the USP requirements.

Authorized Signatory Approval: Emilly

Emilly Chen

1. Introduction

1.1 Purpose

The purpose of this study is to evaluate for local effects after sample implanted into the muscles tissue of Rabbits.

1.2 Testing Guidelines

This study was based on the requirements of the USP-NF 2022, General Chapter <88>, Biological Reactivity Tests, In Vivo.

1.3 Dates

Test Sample Received: 2024.01.16
Treatment Started: 2024.01.21
Observations Concluded: 2024.02.02

2. Identification of Test and Control Samples

The test sample provided by the sponsor was identified and handled as described below:

Table 1 - Test Sample

Name	FFKM White USP Class VI
Size	20*2
Thickness	N/A
CAS	N/A
Model	I
Lot	N/A
Initial State	N/A
Strength, Purity and Composition	FFKM White
Color	N/A
Physical Description of the Test Sample	Solid
Manufacture Date	N/A

Expiration Date	N/A
Intended Clinical Use of Test Sample	N/A

Table 2 - Negative Control Sample

Name	High Density Polyethylene (HDPE)
CAS	25213-02-9
Lot	C-221
Source Component	Hatano Research Institute, Food and Drug Safety Center High Density Polyethylene

3. Test System

3.1 Test System

Species:	Rabbit (Oryctolagus cuniculus)
Breed:	New Zealand White
Source:	Guangzhou Baiyun District Suibei Experimental Animal Farm
Sex:	Female (Females were nulliparous and nonpregnant)
Age:	Young adult
Acclimation Period:	Minimum 5 days
Number of Animals:	2
Identification Method:	Name card

3.2 Justification of Test System

The rabbit (animal) is the animal model identified for USP implant testing. The muscle tissue is evaluated because the response to an implanted test sample is easily graded and compared to a known negative control sample. As defined in USP-88-Biological Reactivity Tests, In Vivo, a minimum of 8 test and 4 control sites for each sample are needed for a valid evaluation of tissue reaction. Use at least two animals for each material and sufficient sites to yield a total of 8 tests and 4 control samples for each material and implantation period. Implant site sections shall be 2.5–5 cm from the midline and parallel to the spinal column, and about 2.5 cm apart from each other.

4. Animal Management

4.1 Husbandry, Housing and Environment

Conditions conformed to STC Standard Operating Procedures. Animals were housed in groups in stainless steel identified by a card indicating the animal numbers, test code, sex, animal code and date dosed.

The animal housing room is conventional system lab. Guangdong Science and Technology Department, certificate No.: SYXK (Guangdong province) 2023-0159. The animal housing room temperature and relative humidity were monitored daily. The temperature for the room was set to 18-26°C and the relative humidity was set to 40-70%. There were no significant temperature or relative humidity excursions that adversely affected the health of the animals.

The light cycle was controlled (12 hours light, 12 hours dark).

4.2 Food, Water and Contaminants

Food: Laboratory animal formula feed (Rabbit), Shenyang Maohua Biotechnology Co., Ltd, was provided daily.

Water: The water quality met the "Sanitary standard for drinking water" (GB5749-2022)

Food and water meet animal welfare requirements and were sterile. No contaminants present in the feed and water impacted the results of this study.

4.3 Personnel

Associates involved in this study were appropriately qualified and trained.

4.4 Sedation, Analgesia or Anesthesia

It had been determined that the used of sedation, analgesia or anesthesia was necessary during the routine course of this procedure.

4.5 Veterinary Care

All anesthetics, analgesics, and other medications may be given or altered at the discretion of the attending veterinarian in accordance with standard veterinary practice and the study objectives. This applies to specific medication, dose, and dosing intervals. In the unlikely event that an animal should become injured, ill, or moribund, care was conducted in accordance with current veterinary medical

practice. If warranted for humane reasons, euthanasia was conducted in accordance with the current report of the American Veterinary Medical Association's Guidelines on Euthanasia. The objective of the study is given due consideration in any decision and the study sponsor was advised.

4.6 IACUC

This procedure has been approved by the STC Institutional Animal Care and Use Committee (IACUC) and is reviewed at least annually by the same committee.

4.7 Selection

Select healthy, adult rabbits weighing not less than 2.5 kg. If female, then nulliparous and nonpregnant.

5. Method

5.1 Test and Control Sample Preparation

8 strips of the test sample and 4 strips of negative control were prepared for the implantation. Each strip was measured not less than 10 × 1 mm. The edges of the strips should be as smooth as possible to avoid additional mechanical trauma upon implantation. Sterilize test sample and negative control substance with high-pressure steam sterilization (121°C).

5.2 Test Procedure

The animals were weighed within a day of surgery. For general anesthesia, each animal was injected intramuscularly with anesthetic. A veterinary ophthalmic ointment was applied to both eyes of each animal to protect the corneas from excessive drying. After the anesthetic has taken effect, animals were clipped free of fur over the paravertebral muscles. The surgical sites were scrubbed with iodine and wiped with 75% alcohol. The animals were maintained on a supplemental heating source.

On the day of the test, the fur of the animals was clipped on both sides of the spinal column. Four strips of the Sample were implanted into the paravertebral muscle on one side of the spine of each of two rabbits, 2.5 to 5 cm from the midline and

parallel to the spinal column, and about 2.5 cm apart from each other. In a similar fashion two strips of negative control were implanted in the opposite muscle of each animal. The skin was closed with appropriate suture.

5.3 Laboratory Observations

1. Animals will be observed daily for general health.
2. Body weights was recorded prior to implantation and at termination.

5.4 Terminal Procedures

At 7 days, the animals were weighed and then euthanized. The paravertebral muscles were dissected free and methodically cut to locate four test sample sites and two negative control sites in each animal. Capsule formation or other evidence of irritation was scored using low magnification and the scores were recorded as follows:

Table 3 - 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

All times and temperatures reported herein are approximate and are within ranges established by the external standards described in the References section of this report and/or STC standard operating procedures.

6. Evaluation

The average macroscopic score for test sample sites is compared with the average score for control sample sites. Calculations are rounded to the nearest 0.1. The requirements of the test are met if the difference does not exceed 1.0, or if the difference between the Sample and Control mean scores for more than one of the four implant sites does not exceed 1 for any implanted animal.

7. Results

7.1 Clinical observation

All animals appeared normal throughout the study. See appendix 2 for details.

7.2 Body weight

Body weight dada for individual animals were considered acceptable. Body weight data for individual animals are presented in appendix 2.

7.3 Macroscopic observations

The macroscopic observation evaluation of implantation site encapsulation is show in appendix 1. The necropsy observations of each animal are shown in appendix 3.

8. Conclusion

The implanted test sample met the USP requirements.

Results and conclusions apply only to the test sample tested. Any extrapolation of these data to other samples is the sponsor's responsibility.

9. Records

All raw data pertaining to this study and a copy of the final report are retained in designated STC archive files in accordance with STC SOPs. All of the files were storage in DGSTC MD Archiving room.

10. ISO Compliance

All procedures were compliance to ISO 17025.

11. References

International Organization for Standardization (ISO) 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (2018).

International Organization for Standardization (ISO) 10993-2, Biological evaluation of medical devices - Part 2: Animal welfare requirements (2022).

International Organization for Standardization (ISO) 10993-6, Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (2016).

International Organization for Standardization (ISO) 17025, General requirements for the competence of testing and calibration laboratories (2017).

USP-NF 2022, General Chapter <88>, Biological Reactivity Tests, In Vivo

Appendix 1 – Individual Implant Site Evaluation of Encapsulation

Scores	Implantation site					
Animal number	**Control Sites-1**	**Control Sites-2**	**Test Sites-1**	**Test Sites-2**	**Test Sites-3**	**Test Sites-4**
2023122823	0	0	0	0	0	0
2023122824	0	0	0	0	0	0
Mean Scores	0		0			
Difference	0					

Appendix 2 – Body Weight and Detailed Examination for Individual Animals

Sex	Animal	Body Weight(kg)		Clinical Observations
		Day 1	Day 7	
Female	2023122823	3.25	3.37	No obvious adverse effect observed
Female	2023122824	3.20	3.34	No obvious adverse effect observed

Appendix 3 – Necropsy Observations for Individual Animals

Animal	Necropsy Observations
2023122823	Macroscopically normal.
2023122824	Macroscopically normal.

Appendix 4 – Photograph(s) of Test Samples

******* END OF TEST REPORT *******

Conditions of Issuance of Test Reports

1. All samples and goods are accepted by The STC (Guangdong) Company Limited (the "Company") solely for testing and reporting in accordance with the following terms and conditions. The Company provides its services on the basis that such terms and conditions constitute express agreement between the Company and any person, firm or company requesting its services (the "Clients").

2. Any report issued by the Company as a result of this application for testing service (the "Report") shall be issued in confidence to the Clients and the Report will be strictly treated as such by the Company. It may not be reproduced either in its entirety or in part and it may not be used for advertising or other unauthorized purposes without the written consent of the Company. The Clients to whom the Report is issued may, however, show or send it, or a certified copy thereof prepared by the Company to his customer, supplier or other persons directly concerned. Subject to clause 3, the Company will not, without the consent of the Clients, enter into any discussion or correspondence with any third party concerning the contents of the Report, unless required by the relevant governmental authorities, laws or court orders.

3. The Company shall be at liberty to disclose the testing-related documents and/or files anytime to any third-party accreditation and/or recognition bodies for audit or other related purposes. No liabilities whatsoever shall attach to the Company's act of disclosure.

4. The Company shall not be called or be liable to be called to give evidence or testimony on the Report in a court of law without its prior written consent, unless required by the relevant governmental authorities, laws or court orders.

5. The results in the Report apply only to the sample as received and do not apply to the bulk, unless the sampling has been carried out by the Company and is stated as such in the Report. The Clients provide the sample's relevant information, and the Company will not be liable for or accept responsibility for the truth of the sample information.

6. When a statement of conformity to a specification or standard is provided, the ILAC-G8 Guidance document (and/or IEC Guide 115 in the electrotechnical sector) with 95% coverage probability will be adopted as a decision rule for the determination of conformity unless it is inherent in the requested specification or standard, or otherwise specified in the Report.

7. In the event of the improper use the report as determined by the Company, the Company reserves the right to withdraw it, and to adopt any other additional remedies which may be appropriate.

8. Sample submitted for testing are accepted on the understanding that the Report issued cannot form the basis of, or be the instrument for, any legal action against the Company.

9. The Company will not be liable for or accept responsibility for any loss or damage howsoever arising from the use of information contained in any of its Reports or in any communication whatsoever about its said tests or investigations.

10. Clients wishing to use the Report in court proceedings or arbitration shall inform the Company to that effect prior to submitting the sample for testing.

11. Subject to the variable length of retention time for test data and report stored hereinto as to otherwise specifically required by individual accreditation authorities, the Company will only keep the supporting test data and information of this test report for a period of six years. The data and information will be disposed of after the aforementioned retention period has elapsed. Under no circumstances shall we provide any data and information which has been disposed of after the retention period. Under no circumstances shall we be liable for damages of any kind, including (but not limited to) compensatory damages, lost profits, lost data, or any form of special, incidental, indirect, consequential or punitive damages of any kind, whether based on breach of contract of warranty, tort (including negligence), product liability or otherwise, even if we are informed in advance of the possibility of such damages.

12. Issuance records of the Report are available on the internet at www.gdstc.group. Further enquiry of validity or verification of the Reports should be addressed to the Company.