Fanslly-800 Disinfectant Powder (Non Sterile)

<Lot No.: 1090225>

White Rabbit Skin Irritation Test

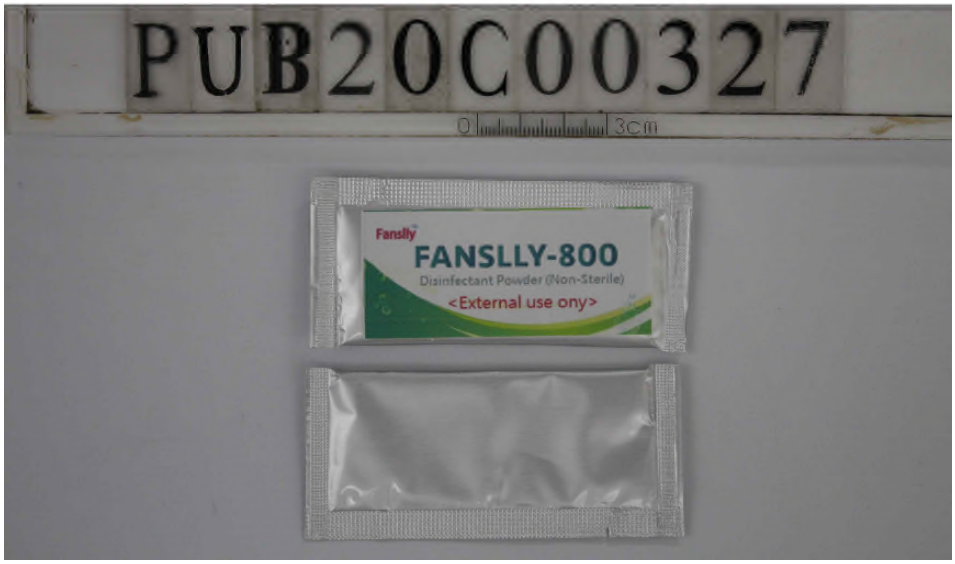
Client: **Fanslly Biotechnology Co., Ltd.**
Institution: **SGS Taiwan Ltd.**
Ultra Trace &Industrial Safety Hygiene
Test Article No.: **PUB20C00327**

Note:

1. The analytical report is the test result issued by the testing institutions as requested by the consignor. Regarding to the legitimacy of the product, it shall be determined by the authorities according to the law.
2. Any unauthorized alteration, forgery or falsification of the content or appearance of this report is unlawful and offenders may be prosecuted to the fullest extent of the law.
3. The results shown in this test report refer only to the test article(s) tested.
4. The content of this report is invalid if it is not presented as the entire report.
5. Please refer to the photos for test article shown at the next page
6. All items in this testing report is based on the request from sponsor and we are responsible for that.
7. The test was performed by qualified outsourcing lab which recognized by SGS.
8. This testing was performed by Biocompatibility Lab. of LEON Biotech. Co., Ltd. (Report No. R-SR-KL20210106)

TEST ARTICLE PHOTO

PUB20C00327



Fanslly-800 Disinfectant Powder (Non Sterile)
(PUB20C00327)

White Rabbit Skin Irritation Test

Final Report

Client	**Fanslly Biotechnology CO., Ltd.**
Testing Institution	**Biocompatibility Lab. of LEON Biotech. Co., Ltd.**
Report No.	**R-SR-KL20210106**

Note:
1. The content of this Final Report is invalid if it is not presented as the entire Final Report.
2. Any unauthorized alteration, forgery or falsification of the content or appearance of this Final Report is unlawful, and offenders may be prosecuted to the fullest extent of the law.
3. The results shown in this Final Report refer to the test article(s) tested only.

Contents

Schedule

Study	White rabbit skin irritation test
Test article	Fanslly-800 Disinfectant Powder (Non Sterile)
Service No.	KL20210106
Study initiation date	2021.03.03
Experimental starting date	2021.03.09
Experimental completion date	2021.03.12
Study completion date	See Study Director's signature date in the report

Study Director

Name	Ho-Ching Chiu
Address	4F.-2, No.288-8, Xinya Rd., Qianzhen Dist., Kaohsiung City 80673, Taiwan.

Study Personnel

Participants	H. C. Chiu, Y. T. Feng

Test Institution

Name	Biocompatibility Lab. of LEON Biotech. Co., Ltd.
Address	4F.-2, No.288-8, Xinya Rd., Qianzhen Dist., Kaohsiung City 80673, Taiwan.
Contact	Ming-Yang Tsao (07) 841-9003 service@leon-bio.com.tw

Client

Name	Fanslly Biotechnology CO., Ltd.
Address	9F-1, No. 100, Zhongxiao E. Rd. Sec. 2, Zhongzheng Dist., Taipei, Taiwan

Test Article Information

Name	Fanslly-800 Disinfectant Powder (Non Sterile)
Supplier/Manufacturer	Fanslly Biotechnology Co., Ltd.
Model Number (REF)	N/A
Lot No.	1090225
Manufacture Date	2020/03/04
Expiry Date	2022/03/03
Storage Condition	Room temperature
Sterilization Condition	Non
Package	Aluminum bag
Main Ingredient	Hypochlorous Acid
Purity	100% Hypochlorous Acid
Concentration	200ppm and above
Stability	N/A
Homogeneity	Homogeneity
Appearance Description	Powder; White color
Category	Medical device
Pre-treatment	Mix the Powder with 5 Liters of water only when need to use. Store in a opaque container and avoid direct sunlight. Store the sample in a cool place.
✦ **Sponsor, who provided test facility with the test article information, will take full responsibility for all the facts of it.**	
Received Date	**2021.01.27**
Test Article No.	**KL20210106-a**

Report No. R-SR-KL20210106

Statement of GLP Compliance

Study activities performed by Biocompatibility Lab. of LEON Biotech. Co., Ltd. are carried out in compliance with current OECD Principles of Good Laboratory Practice (Organization for Economic Cooperation and Development, Paris, ENV/MC/CHEM (98) 17) and U.S. Food and Drug Administration Good Laboratory Practice Regulations, 21 CFR Part 58. The study was conducted in accordance with the test plan and standard operating procedures and monitored in conformity with the test plan. All laboratory data are accurately recorded and verified. Biocompatibility Lab. of LEON Biotech. Co., Ltd. makes no GLP compliance claim for characterization and verification of the test article identity and properties (6.2.2, 6.2.3, 6.2.4 and 6.2.5 in OECD principle on Good Laboratory Practice), which are the responsibility of the sponsor.

Study Director	Ho Ching Chiu	2021. 03. 18
	Ho-Ching Chiu / LEON Biotech. Co., Ltd.	**Date Completed**
Facility Manager	M. M. T	2021. 03. 18
	Ming-Yang Tsao / LEON Biotech. Co., Ltd.	**Date Completed**

Quality Assurance Statement

Fanslly-800 Disinfectant Powder (Non Sterile)

White Rabbit Skin Irritation Test

This study was inspected by Quality Assurance Unit of LEON Biotech. Co., Ltd. Inspection activities included reviewing the draft test plan, auditing test procedure as below, and reviewing the raw data and the draft final Report.

Study-base audit

Study Phase	Inspection Date	Date Reported to	
		Study Director	Facility Manager
Test plan draft [KL20210106-SR]	2021/02/09	2021/02/09	2021/02/09
Pre-treatment of test article and administration of test article and control solutions	2021/03/09	2021/03/09	2021/03/09
Review raw data	2021/03/18	2021/03/18	2021/03/18
Final Report draft [R-SR-KL20210106] [R-SR-KL20210106TC]	2021/03/18	2021/03/18	2021/03/18

The final report has been found to reflect the raw data obtained.

Quality Assurance Auditor

Yu-Ting Su

2021.03.18

Yu-Ting Su / LEON Biotech. Co., Ltd. **Date Completed**

Archiving

All the study-related records, test plan, raw data and the final report will be kept in the GLP cabinet of archives room and the remainder test articles or control articles if any will be kept in the GLP cabinet of sample room in LEON Biotech. for 6 years. All the records and test articles will be handled according to GLP guideline.

Archiving List	
Records	Application form (SOP-Q07-F01) Test article information (SOP-Q10-F01, SOP-Q10-F03) Test article control form (SOP-Q10-F02) and other supplementary records
Test Plan	Test plan Test plan amendment (if necessary)
Raw Data	Test article extraction record (SOP-T01-F01) White rabbit skin irritation test data sheet (SOP-T04-F01)
Final Report	Final Report Final Report amendment (if necessary)
Test Article and Control Article	Test articles (if any) Control articles (if any)

Objective

When direct contact with human tissues is anticipated, medical device should be carefully tested for biocompatibility according to the nature and duration of the contact to avoid potential physiological damage caused by hypersensitive substances produced or contaminated during manufacture. The study was performed in accordance with ISO 10993-10 and internal document of standard operating procedure SOP-T04, to investigate the response of skin irritation of "Fanslly-800 Disinfectant Powder (Non Sterile)" solution on New Zealand White Rabbits.

Test System

Species / Strain	New Zealand White Rabbit (NZW)
Resource	Taiwan Livestock Research Institute (TLRI) (Animal purchasing procedure was based on SOP-Q02)
Reason	According to ISO10993-10
Body weight / Age	>2 kg
Sex	Female The female rabbits were nulliparous and non-pregnant.
Numbers	3
Quarantine / Acclimation	Once animals are introduced in-house, they are subjected to quarantine and acclimatize before treatment. Animals are selected based on health status by qualified staff. (according to SOP-A02)
Animal restraint	The restraint of animals was according to internal document of standard operating procedure SOP-T00.
Identification	
Individual identification	Animals are identified by ear-marking.
Cage identification	Cages are properly labeled for identification including species/strain, sex, in-housing date, IACUC number, animal I.D. number.
Housing condition (according to SOP-A01)	
Environment temperature	23±3℃
Humidity	30~70%
Cage and animal number	1 animal/cage
Fodder / Supply	Lab Diet #5326, *ad libitum*
Drinking water / Supply	Tap water from Taiwan water corporation purified by water purifier; *ad libitum*

Materials and Methods

Reagent

1. 0.9% normal saline (Tai Yu Pharmaceutical Co., Ltd. Lot No. VD2404)
2. Distilled water (Tai Yu Pharmaceutical Co., Ltd. Lot No. VL1301, UH0102)

Preparation

According to ISO 10993-12 guidelines, internal document of standard operating procedure SOP-T01 and the client's request, mix a package of test article and 5 liters of distilled water (Lot No. VL1301) before test. The test article solution was tested directly. The pH value of polar extract was 7 which measured by the pH test strip (ADVANTEC, Lot No. 71222012) before administration. Both White Rabbit Skin Irritation Test and Ocular Irritation Test were performed using the same test article solution.

Grouping

Test group	Control group
3 animals	
Test article solution	0.9% normal saline

Note: The control article and the test article were applied to different regions of the same rabbit.

Test Method

1. Preparation

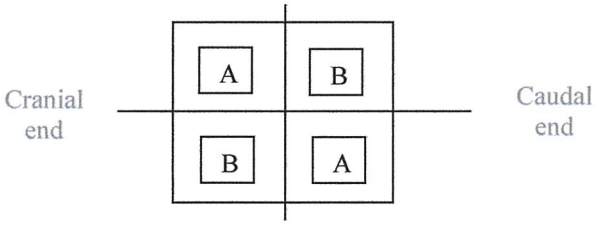
1.1. Within a 4 h to 24 h period before testing, furs of NZW rabbit backside from scapula to middle back were clipped before test. Clipped zone was about 10 cm × 15 cm to exposure skin surface.

1.2. The animals were weighed before the test commences.

1.3. A marker pen was used to divide clipped zone into four regions (see figure below). Animals with scratches or skin diseases in the clipped zone were rejected from study.

2. Administration of test article and control article

2.1. Sterile gauze (2.5 cm x 2.5 cm) saturated with 0.5 mL test article solution and applied on both B sites (see figure below). In addition, A sites was applied with sterile gauze (2.5 cm×2.5 cm) saturated with 0.9% saline for control. The application sites were wrapped with elastic and porous bandages.



2.2. After 4 hours, the elastic and porous bandages and gauzes were all removed, and then the test article solution and control article were washed off with distilled water (Lot No. UH0102).

3. Irritant reaction evaluation

3.1. The dermal reactions at the treated areas were observed and recorded at 1±0.1h, 24±2h, 48±2h and 72±2h after the removal of the gauzes of test and control group. The observation items included erythema, oedema, and other toxicity reactions (Table 1).

4. Determination of dermal reaction

4.1. After a single dose treatment, the skin responses at 24±2h, 48±2h and 72±2h after the gauze removed were checked and evaluated, according to "Score System of Skin Reaction" described in Table 1.

4.2. Primary Irritation Index (PII) was calculated based on the erythema and oedema scores for evaluating dermal response (Table 2).

Results

1. Grades in clinical observation of individual rabbit were as below.

Animal ID / Body Weight (kg)	Sex	Items for Grading	Test (Site B) Clinical Observation Time Point (h)				Control (Site A) Clinical Observation Time Point (h)			
			1±0.1	24±2	48±2	72±2	1±0.1	24±2	48±2	72±2
RB-200730-02	F	Erythema and eschar formation	0	0	0	0	0	0	0	0
3.6626		Edema formation	0	0	0	0	0	0	0	0
RB-200730-04	F	Erythema and eschar formation	0	0	0	0	0	0	0	0
3.8376		Edema formation	0	0	0	0	0	0	0	0
RB-210114-06	F	Erythema and eschar formation	0	0	0	0	0	0	0	0
3.2980		Edema formation	0	0	0	0	0	0	0	0
Abbreviations; F: Female										

Primary irritation index (PII) of polar group was calculated as shown below.

$PIS_1 = \frac{0-0}{6} = 0$	$PIS_2 = \frac{0-0}{6} = 0$	$PIS_3 = \frac{0-0}{6} = 0$
Primary irritation index (PII) $= \frac{0+0+0}{3} = 0$		

◆ PIS: primary irritation score for individual animals

The results showed that there was no obvious erythema and edema finding in either the test or control group. There was no mortality in this study. Furthermore, the primary irritation index (PII) value was 0, which indicated the negative results.

Conclusion

The results showed that there was no obvious erythema and edema finding in either the test or control group. There was no mortality in this study. Furthermore, the primary irritation index (PII) value was 0, which indicated the negative results. It represented that the test article solution was non-irritant under this test condition. Therefore, a single topical application of "Fanslly-800 Disinfectant Powder (Non Sterile)" solution did not cause skin irritation.

Tables

1. Score System of Skin Reaction

Reaction	Primary Irritation Score
Erythema and eschar formation	
· No erythema	0
· Very slight erythema (barely perceptible)	1
· Well-defined erythema	2
· Moderate erythema	3
· Severe erythema (beet redness) to eschar formation preventing grading of erythema	4
Oedema formation	
· No oedema	0
· Very slight oedema (barely perceptible)	1
· Well-defined oedema (edges of area well-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

2. Evaluation Table of Single Dermal Irritation

Primary Irritation Index（PII）	Irritation Interpretation
0 ～ 0.4	Non-irritant
0.5 ～ 1.9	Slightly irritant
2.0 ～ 4.9	Moderately irritant
5.0 ～ 8.0	Severely irritant

PIS = $S_T - S_C / 6$ (Two test sites, three observation time points)

PIS = Primary Irritation Scores of each animal

S_T = Total scores of two test sites in three observation time points

S_C = Total scores of two control sites in three observation time points

PII = (Total PIS of 3 animals)/3

References

1. Good Laboratory Practice for Nonclinical Laboratory Studies. Title 21 of the U.S. Code of Federal Regulations, Part 58. United States Food and Drug Administration.
2. Current OECD Principles of Good Laboratory Practice (Organization for Economic Cooperation and Development, Paris, ENV/MC/CHEM (98) 17).
3. Biological evaluation of medical device- Part 10 (2010): Tests for irritation and skin sensitization. ISO 10993-10:2010
4. Biological evaluation of medical devices- Part 12: Sample preparation and reference materials. ISO 10993-12:2021.
5. Biological evaluation of medical devices- Part 2: Animal welfare requirements. ISO 10993-2:2006.