Fanslly-800 Disinfectant Powder (Non Sterile)

<Lot No.: 1090225>

White Rabbit Ocular Irritation Test

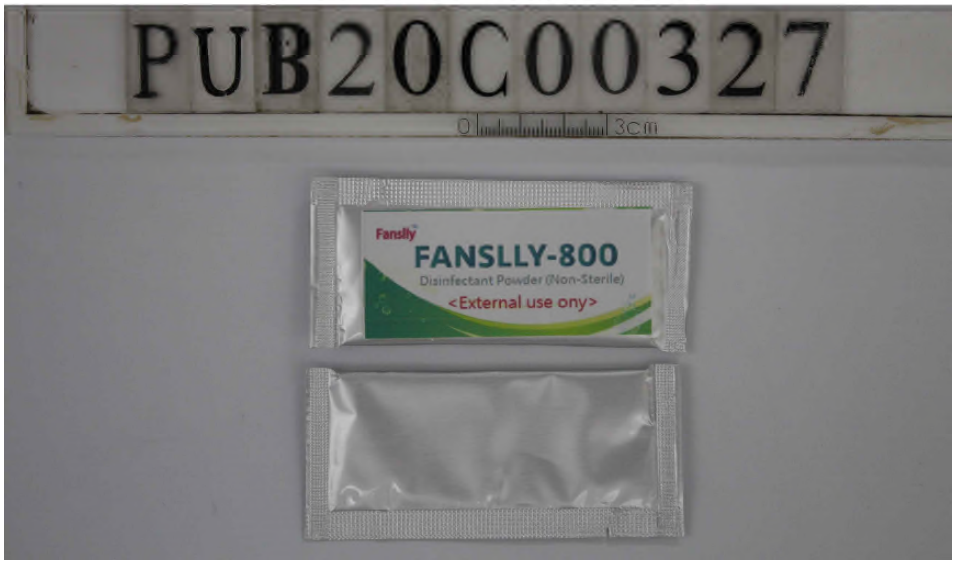
Client: **Fanslly Biotechnology Co., Ltd.**
Institution: **SGS Taiwan Ltd.**
Ultra Trace &Industrial Safety Hygiene
Test Article No.: **PUB20C00327**

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-OcI-KL20210106)

TEST ARTICLE PHOTO

PUB20C00327



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

White Rabbit Ocular Irritation Test

Final report

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

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 — 2021.03.17

Ho-Ching Chiu / LEON Biotech. Co., Ltd. — **Date Completed**

Facility Manager

M. Y. T — 2021.03.17

Ming-Yang Tsao / LEON Biotech. Co., Ltd. — **Date Completed**

Quality Assurance Statement

Fanslly-800 Disinfectant Powder (Non Sterile)

White Rabbit Ocular 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-OcI]	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	2021/03/17	2021/03/17	2021/03/17
Final report draft [R-OcI-KL20210106] [R-OcI-KL20210106TC]	2021/03/17	2021/03/17	2021/03/17

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

Quality Assurance Auditor

Yu-Ting Su

Yu-Ting Su / LEON Biotech. Co., Ltd.

2021.03.17

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 are 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 records (SOP-T01-F01) White rabbit ocular irritation test data sheet (SOP-T06-F01)
Final Report	Final report Final report amendment (if necessary)
Test Article and Control Article	Test articles (if any) Control articles (if any)

Objective

The constituent materials of medical devices are considered potentially produce irritation. 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 irritative substances produced or contaminated during manufacture. The experiment was performed by following ISO 10993-10 and internal document of standard operating procedure SOP-T06 to investigate the possibility of local irritant reaction after a single instillation of test article solution on the ocular of 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	ISO 10993-10
Body weight	2~3 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 and 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)

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 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: Test group and control group were executed on the different side of each rabbit.

Test Method

1. Administration of test article and control solution

1.1. Eyes of rabbit were checked normality before test, animals with eye diseases were rejected from the study.

1.2. 0.1 mL test article solution was dropped into left eye of rabbit and 0.1 mL control solution into the right eye of same rabbit. The following instillation was holding the eyelids together for approximately 1 second. The procedure was repeated on three rabbits.

2. Observation and evaluation

2.1. Rabbit eyes were observed and evaluated in the test and the control group at 1±0.1h, 24±2h, 48±2h, and 72±2h after administration of test article solution and control solution. The use of an ophthalmoscope is recommended. Extended observation may be necessary if there are persistent lesions, in order to determine the progress of the lesions or their reversal; this need not exceed 21 days. Score of observation was based on "System for grading ocular lesions" (Table 1).

Results

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

No	Animal ID	Sex	Items for Grading	Test group (Left eye) "Test article solution"				Ctrl group (Right eye) "0.9% normal saline"			
				Clinical observation time (h)				Clinical observation time (h)			
	Body weight (kg)			1±0.1	24±2	48±2	72±2	1±0.1	24±2	48±2	72±2
1	RB-210114-05	F	Cornea								
			Degree of opacity	0	0	0	0	0	0	0	0
			Area of cornea involved	0	0	0	0	0	0	0	0
			Iris	0	0	0	0	0	0	0	0
			Conjunctivae								
			Redness	0	0	0	0	0	0	0	0
			Chemosis	0	0	0	0	0	0	0	0
	2.8090		Discharge	0	0	0	0	0	0	0	0
2	RB-210114-09	F	Cornea								
			Degree of opacity	0	0	0	0	0	0	0	0
			Area of cornea involved	0	0	0	0	0	0	0	0
			Iris	0	0	0	0	0	0	0	0
			Conjunctivae								
			Redness	0	0	0	0	0	0	0	0
			Chemosis	0	0	0	0	0	0	0	0
	2.9460		Discharge	0	0	0	0	0	0	0	0
3	RB-200917-02	F	Cornea								
			Degree of opacity	0	0	0	0	0	0	0	0
			Area of cornea involved	0	0	0	0	0	0	0	0
			Iris	0	0	0	0	0	0	0	0
			Conjunctivae								
			Redness	0	0	0	0	0	0	0	0
			Chemosis	0	0	0	0	0	0	0	0
	2.7470		Discharge	0	0	0	0	0	0	0	0

F : Female

The results showed that there were no significant clinical signs and gross findings in either the control or the test group, and there were no mortalities.

Conclusion

The study results showed that a single dose application of "Fanslly-800 Disinfectant Powder (Non Sterile)" solution induced neither significant clinical signs nor ocular gross changes on New Zealand White Rabbits at each observation time point. Therefore, ocular application with 0.1 mL of "Fanslly-800 Disinfectant Powder (Non Sterile)" solution did not cause ocular irritation on New Zealand White Rabbits.

Table

1 System for grading ocular lesions (ISO 10993-10)

Reaction	Grade
Cornea	
Degree of opacity (most dense area)	
No opacity	0
Scattered of diffuse areas, details of iris clearly visible	1*
Easily discemible translucent areas, details of iris slightly obscured	2*
Opalescent areas, no details of iris visible, size of pupil barely discemible	3*
Opaque, iris visible	4*
Area of cornea involved	
One-quarter(or less), not zero	0
Greater than one-quarter, but less than half	1
Greater than half, but less than three-quarters	2
Greater than three-quarters, up to whole area	3
Iris	
Normal	0
Folds above normal, congestion swelling, circumcorneal injection(any or all or combination of the these), iris still reacting to light(sluggish reaction is positive)	1*
No reaction to light, haemorrhage, gross destruction(any or all of these)	2*

Continued to next page

Conjunctivae	
Redness (refers to palpebral and bulbar conjunctiva excluding cornea and iris)	
Vessels normal	0
Vessels definitely injected above normal	1
More diffuse, deeper crimson red, individual vessels not easily discemible	2*
Diffuse beefy red	3*
Chemosis	
No swelling	0
Any swelling above normal (include nictitating membrane)	1
Obvious swelling with partial cversion of lids	2*
Swelling with lids about half-closed	3*
Swelling with lids about half-closed to completely closed	4*
Discharge	
No discharge	0
Any amount different from normal (does not include small amounts observed in inner canthus of normal animals)	1
Discharge with moistening of the lids and hairs just adjacent to lids	2
Discharge with moistening of lids and hairs, and considerable area around the ocular	3

*Positive results

References

1. Good Laboratory Practice for Nonclinical Laboratory Studies. Title 21 of the U.S. Code of Federal Regulations, Part 58. The 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 devices-Part 10: 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.