# 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)

# 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)<br>(Animal purchasing procedure was based on SOP-Q02) |
| Reason | ISO 10993-10 |
| Body weight | 2~3 kg |
| Sex | Female<br>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" Clinical observation time (h) | | | | Ctrl group (Right eye) "0.9% normal saline" 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

# 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.