(주)더마글루 DERMA GLUE

Derma Glue®

ISO 10993 Biological Safety Test Results Summary

Summary based on the Certificate of Compliance

1. Test Article and Basic Information

Test Article	Derma Glue®
Bulk Number	Bulk KDG-100
Lot Number	L24DG1222
FDA Registration No.	3031700076
CE EMDN Code	M9002
KFDA License No.	24-880

2. Test Results

1) Intracutaneous Injection

This test was performed to evaluate the irritation potential of extracts of the test article following intracutaneous injection in rabbits. Extracts prepared using saline, cottonseed oil, polyethylene glycol 400 (PEG 400), and alcohol in saline did not produce a significantly greater tissue reaction than the blank extract. Based on the criteria set forth in the protocol, the test article was considered a negligible or slight irritant and was determined to conform.

Reference: ISO 10993-10:2002, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed Type Hypersensitivity, as amended in 2006.

2) Acute Systemic Injection

This test was performed to evaluate potential toxic effects resulting from a single-dose systemic injection of test article extracts in mice. Extracts prepared using saline, cottonseed oil, polyethylene glycol 400, and alcohol in saline did not produce a significantly greater systemic reaction than the blank extract. The test article did not show greater biological reactivity compared with the control material and was determined to conform.

Reference: ISO 10993-11:2006, Biological Evaluation of Medical Devices – Part 11: Biological Tests.

3) Cytotoxicity

The MEM Elution test was performed using L929 monolayer cell cultures to determine the biological reactivity of the test article. The test article was considered non-cytotoxic at dilutions of 1:2, 1:4, and 1:8 and met the requirements of the MEM Elution Test.

Reference: ISO 10993-5:1999, Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity.

4) Hemolysis

This assay was performed to evaluate the hemolytic potential of extracts of the test article. Testing with rabbit blood indicated that the test article was non-hemolytic, with hemolytic activity of less than 5% (<5%).

Reference: ISO 10993-4:2002, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, as amended in 2006.

5) In Vitro Hemocompatibility Assay

This assay was performed to determine whether the test material extract adversely affected cellular components of blood and selected hematological parameters. The parameters evaluated included complete blood count, platelets, hematocrit, and erythrocyte indices. The test article met the requirements of the test.

Reference: ISO 10993-4:2002, Part 4: Selection of Tests for Interactions with Blood, as amended in 2006.

6) Physicochemical Test

The physical and chemical properties of extracts of the test material were evaluated. The test article passed the USP Physicochemical Tests for Plastics.

Reference: United States Pharmacopeia 29, National Formulary 24, 2006; <661> Containers, Physicochemical Tests – Plastics.

7) Implantation Test

The macroscopic and histological reactions to the test article implanted in rabbit muscle for two weeks were not significant when compared with negative control sites. The test article was determined to conform.

Reference: ISO 10993-6:1994, Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects After Implantation.

3. Summary of Results

Test Item	Key Result	Conclusion
Intracutaneous Injection	No significantly greater tissue reaction; negligible or slight irritant	Conforms
Acute Systemic Injection	No significantly greater systemic reaction	Conforms
Cytotoxicity	Non-cytotoxic at 1:2, 1:4, and 1:8 dilutions	Requirements met
Hemolysis	Hemolytic activity <5%	Non-hemolytic
In Vitro Hemocompatibility	Requirements for evaluated hematological parameters met	Conforms
Physicochemical Test	Passed USP Physicochemical Tests for Plastics	Passed
Implantation Test	No significant macroscopic or histological reaction after 2 weeks	Conforms

4. Regulatory and Study Compliance

The Certificate of Compliance states that these studies were conducted in conformance with all applicable laws and regulations.

The document also identifies applicable regulatory requirements including current Good Laboratory Practice (GLP) for non-clinical studies, FDA, CE EMDN, and KFDA 24-880.

5. Overall Summary

Based on the results stated in the Certificate of Compliance, Derma Glue® demonstrated conforming or acceptable results, within the scope of the tests performed, for irritation, acute systemic response, cytotoxicity, hemolysis, hemocompatibility, physicochemical properties, and local response following implantation.

Note: This document is an English summary prepared from the original Certificate of Compliance for ease of review. It does not replace the original test report.