TOXIKON

ADVANCING YOUR INNOVATION

Sponsor:

Epoxy Technology
14 Fortune Drive
Billerica, Massachusetts 01821

Date of Test Completion: October 3, 2013
Project Numbers: 13 – 00600
13 – 02376
13 – 03058
Page: 1 of 2

ATTN: Robin Dickie

Certificate of Compliance
ISO 10993 Biological Tests

Name	EPO-TEK OG116-31 Cured by UV and Heat (80°C for 2 Hours)
CAS/Code Number	Not Supplied by Sponsor
Lot/Batch Number	Not Supplied by Sponsor

L929 MEM ELUTION CYTOTOXICITY (ISO) –
Toxikon Project 13-00600-G1: The purpose of the MEM Elution is to determine biological reactivity of the mammalian cell culture (L929) in response to the test article extract via microscopic observation. The test article is considered non–cytotoxic and meets the requirements of the MEM Elution Test, ISO 10993–5.*Reference: Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity, ISO 10993–5:2009.*

Name	EPO-TEK OG116-31 Cured with UV + 80°C/2 hours
CAS/Code Number	Not Supplied by Sponsor
Lot/Batch Number	Not Supplied by Sponsor

HEMOLYSIS (ASTM) –
Toxikon Project 13-02376-G1: The purpose of this assay is to evaluate the hemolytic potential of the test article. Hemolytic activity of the test article with rabbit blood indicated that the test article was non–hemolytic. (< 5%).
Reference: ASTM F 756–08, Standard Practice for Assessment of Hemolytic Properties of Materials, 2008

KLIGMAN MAXIMIZATION TEST (ISO) –
Toxikon Project 13-03058-G1: The test is used as a procedure for screening of contact allergens in guinea pigs and extrapolating the results to humans. The test article extracts in the USP 0.9% Sodium Chloride for Injection (NaCl) and Cottonseed Oil (CSO) are evaluated for allergenic potential or sensitizing capacity. Based on the scoring and other evaluation standards set by the study protocol, the (NaCl) and (CSO) extracts did not elicit any significant reaction during challenge exposure following an induction phase. The test article is not considered a sensitizer and passes the criteria set in the study protocol.
Reference: Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization, ISO 10993–10, 2010.

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INTRACUTANEOUS INJECTION (ISO) –
Toxikon Project 13-03058-G2: The purpose of this test is to evaluate the irritation potential of the test article extracts in rabbits after intracutaneous injection. USP 0.9% Sodium Chloride for Injection (NaCl), cottonseed Oil (CSO), did not produce a significantly greater biological reaction than blank extract when injected intracutaneously into rabbits. The test article is not considered an irritant and passes the criteria set forth by the protocol,
Reference: Biological Evaluation of Medical Devices – Part 10: Test for Irritation and Skin Sensitization, ISO 10993–10, 2010

ACUTE SYSTEMIC INJECTION (ISO) –
Toxikon Project 13-03058-G3: The purpose of this assay is to evaluate the test article extracts for potential toxic effects as a result of single dose systemic injection in mice. Test article extracted in USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO) did not produce a significantly greater biological reaction than blank extract when injected into mice. The test article did not show greater biological reactivity compared to the control material.
Reference: Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity, ISO 10993–11:2006

MUSCLE IMPLANTATION TEST (ISO) –
Toxikon Project 13-03058-G4: The purpose of the implant test is to evaluate local toxicity from direct exposure to the test article. The test article is implanted in the paravertebral muscle tissue of New Zealand White rabbits for a period of two weeks. The results indicate that the test article does not demonstrate any remarkable difference as compared to the control implant sites in local tissue responses and the potential to induce local toxic effects.
Reference: Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects After Implantation, ISO 10993–6: 2007.

Director of Biocompatibility

Quality Assurance

Date of Certificate: October 11, 2013