TOXIKON
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Sponsor:
Epoxy Technology
14 Fortune Drive
Billerica, Massachusetts 01821

Date of Test Completion: March 3, 2011
Project Numbers: 10–5998
Page: 1 of 2

ATTN: Robin Dickie

Certificate of Compliance
ISO 10993 Biological Tests

Test Article Name: EPO-TEK 353ND
CAS/Code #: Not Supplied by Sponsor (N/S)
Lot/Batch #: AA91405100/PB061381

L929 MEM ELUTION CYTOTOXICITY (ISO) –
Toxikon Project 10–5998–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.

KLIGMAN MAXIMIZATION TEST (ISO) –
Toxikon Project 10–5998–G2: 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 saline and cottonseed oil are evaluated for allergenic potential or sensitizing capacity. Based on the scoring and other evaluation standards set by the study protocol, the saline and cottonseed oil 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 Delayed–Type Hypersensitivity, ISO 10993–10, 2002, as amended 2006.

INTRACUTANEOUS INJECTION (ISO) –
Toxikon Project 10–5998–G3: The purpose of this test is to evaluate the irritation potential of the test article extracts in rabbits after intracutaneous injection. Test article extract in saline and cottonseed oil, did not produce a significantly greater biological reaction than blank extract when injected intracutaneously into rabbits. Based on the criteria of the protocol, the test article meets the requirements of the ISO 10993-10.
Reference: Biological Evaluation of Medical Devices – Part 10: Test for Irritation and Skin Sensitization, ISO 10993–10, 2010.

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ACUTE SYSTEMIC INJECTION (ISO) –
Toxikon Project 10–5998–G4: 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 saline and cottonseed oil, 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.

HEMOLYSIS (ASTM) –
Toxikon Project 10–5998–G5: The purpose of this study was to assess the hemolytic activity of a test article in direct and indirect contact with rabbit blood. The hemolytic activity of the test article was considered non-hemolytic (0-2%) under the experimental conditions employed.
References: Standard Practice for Assessment of Hemolytic Properties of Materials, ASTM F756-08, 2008
Standard Practice for Extraction of Medical Practices, ASTM F619-03, 2008.

MUSCLE IMPLANTATION TEST (ISO) –
Toxikon Project 10–5998–G6: 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.

These studies are in conformance to all applicable laws and regulations. Specific regulatory requirements include the current Good Laboratory Practice for Nonclinical Studies (GLP), FDA, 21 CFR, Part 58.

Director of Biocompatibility

Quality Assurance

Date of Certificate: April 4, 2011