TOXIKON

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TEST RESULT CERTIFICATE

Sponsor	Permabond LLC	**Technical Initiation**	8/4/2006
Address	20 C World's Fair Drive Somerset, New Jersey 08873	**Technical Completion**	8/6/2006
Contact	Manny Dias	**Report Date**	8/11/2006
P.O. Number	Not Supplied by Sponsor	**Project Number**	06-3764-N1

Test Article	Loxeal UV30-11	**Ratio**	0.2 g/1.0 mL
Lot/Batch #	613211	**Vehicle**	Serum–Supplemented (Complete) Minimum Essential Medium (MEM)
Study	L929 MEM Elution Test – ISO	**Extraction Conditions**	37 ± 1 °C for 24 ± 2 hours
Comments	None		

REFERENCES: The study was conducted based upon the following references ISO 10993–5, 1999, Biological Evaluation of Medical Devices – Part 5: Tests for *In Vitro* Cytotoxicity. ISO 10993–12, 2002, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test article extract was determined. Test article extract was prepared as stated above. Positive control (Natural Rubber) and negative control (Negative Control Plastic) articles were prepared to verify the proper functioning of the test system. The test article or control article extracts were used to replace the maintenance medium of the cell culture. All cultures were incubated in triplicate for 48 hours, at 37 ± 1 °C, in a humidified atmosphere containing 5 ± 1% carbon dioxide. Biological reactivity (cellular degeneration and malformation) was rated on a scale from Grade 0 (No Reactivity) to Grade 4 (Severe Reactivity). The test article met the requirements of the test if none of the cultures exposed to the test article showed greater than a Mild Reactivity (Grade 2).

RESULTS: Mild signs of reactivity (Grade 2) were exhibited by the cell cultures exposed to the test article extract at the 48 hour observation. Grade 2 reactivity is not considered significant per ISO 10993–5 guidelines. No signs of reactivity (Grade 0) were exhibited by the cell cultures exposed to the negative control article extract at the 48 hour observation. Severe signs of reactivity (Grade 4) were observed for the positive control article extract at the 48 hour observation.

CONCLUSION: The test article is considered non–cytotoxic and meets the requirements of the Elution Test, ISO 10993–5 guidelines.

AUTHORIZED PERSONNEL:

Patricia S. Grutkoski, Ph.D.
Study Director

Allison Lyons-Hook, B.A.
Quality Assurance