

**TOXIKON FINAL REPORT: 04-0876-G1**

USP CLASS VI TEST

Author

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Final Report Date

March 30, 2004

MANAGEMENT OF THE STUDY

Performing Laboratory

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## **STUDY SUMMARY**

The 0.9% USP Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 dilution of Ethanol in NaCl (EtOH) and Polyethylene Glycol 400 (PEG) extracts of the test article, and the test article, ISC40 Inductive Conductivity, Sensor Glass Loaded Peek, did not produce a biological response following intramuscular implantation in rabbits, intracutaneous injection in rabbits, or systemic injection in mice. Therefore, the test article meets the requirements of USP 27, NF 22, 2004, for Class VI Plastics-70 °C.

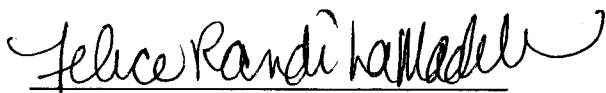
**QUALITY ASSURANCE STATEMENT**

This study was conducted in compliance with U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of Toxikon Corporation, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Parts 58.105 and 58.113.

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to Toxikon's Management.

INSPECTIONS	DATE OF INSPECTION	DATE REPORTED STUDY DIRECTOR	DATE REPORTED MANAGEMENT
DOSE ADMINISTRATION	02/27/04	02/27/04	02/27/04
RAW DATA	03/30/04	03/30/04	03/30/04
FINAL REPORT	03/30/04	03/30/04	03/30/04



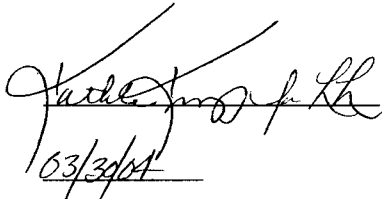
Felice Randi LaMadeleine, B.S.  
Quality Assurance



Date

**STUDY DIRECTOR SIGNATURE AND VERIFICATION DATES**

This study meets the technical requirements of the protocol. The study also meets with the requirements of the Good Laboratory Practice Regulations, 21 CFR, Part 58, with the exemptions as stated in the Quality Assurance Statement.

Protocol Number: YCA/VIVO/001-04/000  
Study Director: Laurence Lister, B.S., LAT  
Company: Toxikon Corporation  
Signature:   
Date: 03/31/04  
Study Supervisor: William Entwistle, A.S., LATG

VERIFICATION DATES:

The Toxikon Protocol Effective Date is the GLP Study Initiation Date. The study dates were as follows:

Protocol Effective Date: 02/18/04  
Test Article Receipt: 02/20/04  
Project Log Date: 02/23/04  
Extraction Dates: 02/26/04 – 02/27/04  
Technical Initiation: 02/27/04  
Technical Completion: 03/05/04