TOXIKON FINAL REPORT: 04-0876-G1

USP CLASS VI TEST

Author
Laurence Lister, B.S., LAT

Final Report Date
March 30, 2004

MANAGEMENT OF THE STUDY

Performing Laboratory
Toxikon Corporation
15 Wiggins Avenue
Bedford, MA 01730

Sponsor
Yokogawa Corporation of America
2 Dart Rd.
Newnan, GA 30265
TABLE OF CONTENTS

Title Page
Table of Contents
Study Summary
Quality Assurance Statement
Study Director Signature and Verification Dates

1.0 Purpose
2.0 References
3.0 Compliance
4.0 Identification of Test and Control Articles
5.0 Identification of Test System
6.0 Justification of Test System and Route of Administration
7.0 Experimental Design
8.0 Dosage
9.0 Evaluation Criteria
10.0 Results
11.0 Conclusion
12.0 Records
13.0 Confidentiality Agreement
14.0 Policy on Pain and Suffering in Animals
15.0 Animal Usage

Table I: Systemic Injection Test: Animal Weights and Clinical Observations
Table II: Intracutaneous and Implant Tests: Animal Weights and Clinical Observations
Table III: Intracutaneous Test: Draize Scale Skin Reactions
Table IV: Implantation Test: Macroscopic Observations

Appendix I: Draize Scale for Scoring Skin Reactions
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.

<table>
<thead>
<tr>
<th>INSPECTIONS</th>
<th>DATE OF INSPECTION</th>
<th>DATE REPORTED STUDY DIRECTOR</th>
<th>DATE REPORTED MANAGEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOSE ADMINISTRATION</td>
<td>02/27/04</td>
<td>02/27/04</td>
<td>02/27/04</td>
</tr>
<tr>
<td>RAW DATA</td>
<td>03/30/04</td>
<td>03/30/04</td>
<td>03/30/04</td>
</tr>
<tr>
<td>FINAL REPORT</td>
<td>03/30/04</td>
<td>03/30/04</td>
<td>03/30/04</td>
</tr>
</tbody>
</table>

Felice Randi LaMadeleine, B.S.  
Quality Assurance  

Date  
03/30/04
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: [Signature]
Date: 03/04/04
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