

Confidential
TCLAS_VI5

Mike Bohrer
Chromis Fiberoptics
6 Powder Horn Drive
Warren, NJ 07059

Lab No. 07T_48922_10
P.O. No. MB070905
Test Facility: NAMSA
6750 Wales Road
Northwood, OH 43619

CERTIFICATE OF COMPLIANCE
USP BIOLOGICAL REACTIVITY TESTS, *IN VIVO*

USP PLASTIC CLASS VI

Test Article: Giga POF-200SR
ID No. Code: 070505-02


USP Systemic Toxicity Study in the Mouse: The test article was prepared as indicated below and injected into mice. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater systemic reaction than the blank extractants.

USP Intracutaneous Toxicity Study in the Rabbit: The test article was prepared as indicated below and injected intracutaneously into rabbits. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater tissue reaction than the blank extractants.

USP Muscle Implantation Study in the Rabbit: The macroscopic reaction of the test article, implanted in rabbit muscle for 5 days, was not significant when compared to the USP negative control plastic.

The test article was prepared at a ratio of 120 cm²:20 ml and extracted at 131°C for 1 hour. The test article extracts met the requirements of a USP Plastic Class VI.

clo Date Completed 10-2-07

Approved By 
Christina L. Ovall, B.A.
Technical Writer