

Confidential
TU006-600

Lab No. 97T 12031 00
P.O. No. 20644

DTM
1611 HEADWAY CIRCLE BLDG 2
AUSTIN, TX 78754-5138
ATTN: MARGO MYERS

ID NO. NOT SUPPLIED

CERTIFICATE OF COMPLIANCE
USP BIOLOGICAL REACTIVITY TESTS, IN VIVO

CLASSIFICATION VI

Test Article: DURAFORM

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 cottonseed 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 cottonseed 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 60 cm²:20 ml and extracted at 70°C for 24 hours. The test article extracts met the requirements of a USP Plastic Class VI.

lms
baj

Date Completed

Oct 15, 1997

Approved By

Kerri A. Herkowskie

Kerri A. Herkowskie, BS

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