



PEOPLE > SCIENCE > SOLUTIONS

Test Facility
6750 Wales Road
Northwood, OH 43619
419.666.9455

TEST ARTICLE NAME
PF 6000

TEST ARTICLE IDENTIFICATION
LBI 70215-25709

TEST ARTICLE PHYSICAL DESCRIPTION
Off white slab

TEST ARTICLE RECEIVED
February 20, 2017

SPONSOR
Jason Page
OTECH Corporation
4744 E Oaknoll Road
Rolling Prairie, IN 46371

USP Biological Reactivity Tests, *In Vivo*
USP Plastic Class VI

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 1 week, 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.

APPROVAL 
Arizona E. Carter, BS, ALAT
Technical Reviewer


Date