



PEOPLE > SCIENCE > SOLUTIONS

Test Facility  
6750 Wales Road  
Northwood, OH 43619  
419.666.9455

**TEST ARTICLE NAME**

Dursan® coated samples

**TEST ARTICLE IDENTIFICATION**

COUPONS

**TEST ARTICLE PHYSICAL DESCRIPTION**

32.66 CM<sup>2</sup> and 1mm x 10mm

**TEST ARTICLE RECEIVED**

June 16, 2020

**SPONSOR**

Rick Edmiston  
SilcoTek Corporation  
225 PennTech Drive  
Bellefonte, Pennsylvania 16823

**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 6 cm<sup>2</sup>:1 mL and extracted at 121°C for 1 hour. The test article extracts met the requirements of a USP Plastic Class VI.

APPROVAL Sharayah M. Bonner  
Sharayah M. Bonner, MS  
Senior Technical Reviewer

20 Jun 2020  
Date