

PEOPLE > SCIENCE > SOLUTIONS

Test Facility  
6750 Wales Road  
Northwood, OH 43619  
419.666.9455

**TEST ARTICLE NAME**

PAPC II

**TEST ARTICLE IDENTIFICATION**

II OVA

**TEST ARTICLE PHYSICAL DESCRIPTION**

Polyamide, Polyolefin and Cellulose plaques

**TEST ARTICLE RECEIVED**

March 28, 2018

**SPONSOR**

Robert Joyce  
FibreTuff Medical Biopolymers  
PO Box 353211  
Toledo, OH 43635-3211

**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**

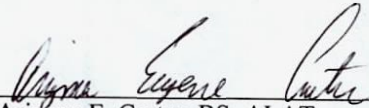
The macroscopic reaction of the test article, implanted in rabbit muscle for 1 week, was not significant when compared to the USP negative control plastic.

The test article was prepared at a ratio of 25cm<sup>2</sup>:20mL and extracted at 50°C for 72 hours. The test article extracts met the requirements of a USP Plastic Class VI.

**Microscopic Examination of Implant Sites**

The microscopic reaction of the test article was minimal as compared to the USP negative control plastic.

APPROVAL

  
Arizona E. Carter, BS, ALAT  
Technical Reviewer

05-01-18  
Date