



Ensuring Medical Device
Safety and Compliance™

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TCLAS-VI7

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FORMOSA CHEMICAL AND FIBRE CORPORATION
201 TUNG HWA NORTH ROAD
PLASTICS DIVISION, 9F, BACK BUILDING
TAIPEI, 105 TAIWAN, REPUBLIC OF CHINA

Lab No. 02C 17337 00
P.O. No. PREPAID
Y2988-1P
ID No. Not Supplied

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

USP PLASTIC CLASS VI

Test Article: TAIRIPRO PP K4515

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.

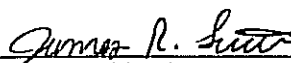
USP Muscle Implantation Study in the Rabbit: The macroscopic reaction of the test article, implanted in rabbit muscle for one week, was not significant when compared to the USP negative control plastic.

The test article was prepared at a ratio of 4 g:20 ml and extracted at 70°C for 24 hours. The test article extracts met the requirements of a USP Plastic Class VI.

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Date Completed 12-10-02

Approved By


James R. Smith, Ph.D.