

TEST RESULT CERTIFICATE

Test Article	Tampapur (TPU)	Ratio	120 cm ² per 20 mL
Lot # / Part #	980 Black	Vehicles	0.9% USP Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1:20 Alcohol in NaCl (EtOH), Polyethylene Glycol 400 (PEG)
Study	Biological Test for Plastics Class VI (4 Extracts)	Temp/Time	70±2° C for 24 hours

REFERENCE: USP 24, NF19, 2000, pp. 1832-1835.

GENERAL PROCEDURE: The test article extracts and corresponding blanks were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP 24; including the further dilution of the extracts prepared with PEG. The animals were observed for signs of toxicity and skin reactivity for up to 72 hours post treatment. In addition, the test article was implanted into the paravertebral muscles of rabbits for 7 days and observed for signs of hemorrhage, inflammation, necrosis, discoloration, encapsulation, and infection.

RESULTS: None of the mice injected with the test article extracts exhibited any signs of toxicity in the Systemic Injection Test. In addition, none of the rabbits injected intracutaneously with the test article extracts exhibited any signs of erythema, edema or clinical toxicity. In both the Systemic and Intracutaneous Tests the controls were normal through 72 hours. Also, the implant sites exhibited no significant signs of hemorrhage, inflammation, necrosis, discoloration, encapsulation, or infection compared with the control sites.

CONCLUSION: The test article meets the requirements of USP 24, NF19, 2000, for the Biological Test for Plastics, Class VI-70 C.

AUTHORIZED PERSONNEL:


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