

TEST RESULT CERTIFICATE

Sponsor	Coates Screen Inks GmbH	Technical Initiation	8/9/2007
Address	Wiederholdplatz 1 90451 Nürnberg Germany	Technical Completion	8/16/2007
Contact	Tilman Goertler	Report Date	8/23/2007
P.O. Number	Not Supplied by Sponsor	Project Number	07-3084-N1

Test Article	Pad Printing Ink TP 313 w/hardener TP 219 10:1 ratio Mixture of black and white 1:1	Ratio	120 cm ² /20 mL
Lot/Batch #	Not Supplied by Sponsor	Vehicles	USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG)
Study	Class VI Test – USP	Extraction Conditions	70 ± 2 °C for 24 ± 2 hours
Comments	None		

REFERENCES: The study was conducted based upon the following references: USP 30, NF 25, 2007.
<88> Biological Reactivity Tests, *In Vivo*.


ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

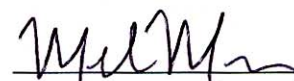
GENERAL PROCEDURE: The extraction conditions were performed as stated above. The test article extracts and corresponding blanks were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP, including the further dilution 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 macroscopically for signs of hemorrhage, 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, necrosis, discoloration, encapsulation, or infection compared with the control sites.

CONCLUSION: The test article meets the requirements of the guidelines for the Biological Test for Plastics, Class VI – 70 °C.

AUTHORIZED PERSONNEL:


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