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TEST RESULT CERTIFICATE

Sponsor	Trans Tech	Technical Initiation	2/23/2010
Address	475 North Gary Avenue Carol Stream, Illinois 60188	Technical Completion	3/4/2010
Contact	Dan Novak	Report Date	3/15/2010
P.O. Number	269115	Project Number	10-0635-N1

Test Article	Ink UV 2002 Black	Ratio	60 cm ² per 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 32, NF 27, 2009.
<88> Biological Reactivity Tests, *In Vivo*.

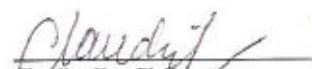
ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

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:


Claudine Kos, Ph.D.
Study Director


Jamie Lynne Metzinger, B.A., B.S.
Quality Assurance

Trans Tech 475 North Gary Avenue, Carol Stream, IL 60188, USA
United Silicone 4471 Walden Avenue, Lancaster, NY 14086, USA
Morlock Lise-Meitner-Straße 9, 72280 Dornstetten, Germany
CER 85 rue Castellion, 01117 Oyonnax Cedex, France

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Trans Tech 475 North Gary Avenue, Carol Stream, IL 60188

Tel +1 (630) 752 4000 Fax +1 (630) 752 4467

Email sales@itwtranstech.com

www.itwtranstech.com www.itwids.com

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