TRANSTECH

Class VI

Certified Medical Grade

Certificates - Type PG (Black)

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TEST RESULT CERTIFICATE

Sponsor	ITW Trans Tech	**Technical Initiation**	12/21/2006
Address	475 North Gary Avenue Carol Stream, Illinois 60188	**Technical Completion**	12/28/2006
Contact	Chris Schaafsma	**Report Date**	1/2/2007
P.O. Number	604190	**Project Number**	06-5890-N1

Test Article	Pad Printing Ink: PG 1 NT BLACK	**Ratio**	60 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	Per Sponsor, the material being tested is the ink coated onto the negative control strips.		

REFERENCES: The study was conducted based upon the following references: USP 29, NF 24, 2006. <88> Biological Reactivity Tests, *In Vivo*. Draize Scale for Scoring Skin Reactions, Draize, J.H. "Dermal Toxicity", Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics – Dermal Toxicity, pp. 49–52. Association of Food and Drug Officials of the United States, Topeka, Kansas, 1965.

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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Class VI
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Pad Printing Inks

Several of ITW Trans Tech's inks, including ultra violet (UV) cure, have been approved for use in applications that require United States Pharmacopoeia (USP) 30, NF 25, 2007 certification, known as Medical Class VI. This classification is widely used in public quality standards for drugs, medical devices, and dietary supplements to comply with FDA standards for products which may come in physical contact with the human body.

The USP-NF includes a full range of tests, procedures, and industry best practices for all phases of pharmaceutical development and manufacturing. The world-recognized standards are FDA enforceable for pharmaceutical and medical device exports to the United States and used in many other countries.

Commonly used pad printing applications on medical devices include: trocars, catheters, tubing, syringes, surgical instruments, medical fittings, skin staplers, vials, medication dials, dosage dispensers, pill containers, and pipettes.

Compatible substrates suitable for pad printing include: treated and untreated polypropylene, acrylic, polycarbonate, polyester, ABS, polystyrene, vinyl, PVC and other plastics. Printing on polyolefins such as polyethylene and polypropylene is possible but requires surface pretreatment. Sample testing is always recommended.

For information on using medical-grade inks in your specific applications, please contact your Customer Service representative.

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