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TEST RESULT CERTIFICATE

Sponsor	KRAIBURG TPE GmbH & Co. KG	**Technical Initiation**	4/26/2011
Address	Friedrich-Schmidt-Strasse 2 84478 Waldkraiburg, Germany	**Technical Completion**	5/6/2011
Contact	Oliver Lippert	**Report Date**	5/13/2011
P.O. Number	N/S	**Project Number**	11-1658-N1

Test Article	TM9HET	**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	None		

REFERENCES: The study was conducted based upon the following references: United States Pharmacopeia 33, National Formulary 28, 2010. <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.

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