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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**	5/7/2011
Contact	Oliver Lippert	**Report Date**	5/9/2011
P.O. Number	N/S	**Project Number**	11-1658-N2

Test Article	TM9HET	**Ratio**	3 cm^2/1 mL
Lot/Batch #	N/S	**Vehicles**	USP 0.9% Sodium Chloride for Injection (NaCl) and Cottonseed Oil (CSO)
Study	Intracutaneous Injection Test – ISO	**Extraction Conditions**	70 ± 2 °C for 24 ± 2 hours
Comments	None		

REFERENCES: The study was conducted based upon the following references: ISO 10993–10, 2010, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization. ISO 10993–12, 2007, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials.

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

GENERAL PROCEDURE: The Intracutaneous Test is designed to evaluate local responses to the extracts of test articles, following intracutaneous injection into rabbits. The extraction conditions were performed as stated above. Control extracts were prepared in a similar manner with each extracting medium. Three rabbits were injected intracutaneously, using one side of the animal for one test article extract and the other side for the other extract, at 0.2 mL per site. The injected sites were examined immediately after injection and at 24 ± 2 hours, 48 ± 2 hours, and 72 ± 2 hours post inoculation for gross evidence of tissue reaction such as erythema, edema, and necrosis. Observations were scored according to the Classification System for Scoring Skin Reactions and included all clinical signs. All average erythema and edema scores for the test and control sites at 24 ± 2 hours, 48 ± 2 hours, and 72 ± 2 hours were totaled separately and divided by 15 (3 scoring time points × 5 test or vehicle control injection sites) to determine the overall mean score for the test article versus the corresponding control article. The requirements of the test are met if the difference of the mean reaction score (erythema/edema) for the test article and the control article is 1.0 or less.

RESULTS: All of the test animals increased in weight. None of the animals exhibited overt signs of toxicity at any of the observation points. The requirements of the test were met because the difference of the mean reaction score for the test and control articles was 0.0.

CONCLUSION: The test article meets the requirements of the Intracutaneous Test, ISO 10993–10 guidelines using extracts prepared with NaCl and CSO.

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