

## TEST RESULT CERTIFICATE

<b>Sponsor</b>	KRAIBURG TPE GmbH & Co. KG	<b>Technical Initiation</b>	11/20/2014
<b>Address</b>	Friedrich-Schmidt-Str.2 84478 Waldkraiburg Germany	<b>Technical Completion</b>	12/12/2014
<b>Contact</b>	Oliver Lippert	<b>Report Date</b>	12/23/2014
<b>P.O. Number</b>	Not Supplied by Sponsor (N/S)	<b>Final Non-GLP Report</b>	14-04155-N1

<b>Test Article</b>	THERMOLAST ® M TM9MED	<b>Ratio</b>	60 cm <sup>2</sup> /20 mL
<b>Lot/Batch #</b>	Not Supplied by Sponsor (N/S)	<b>Vehicles</b>	USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG)
<b>Study</b>	Class VI Test – USP	<b>Extraction Conditions</b>	70 ± 2 °C for 24 ± 2 hours
<b>Comments</b>	Storage Condition: Room Temperature Physical State: Solid Color: translucent Density: 0.89		

**REFERENCES:** The study was conducted based upon the following references: United States Pharmacopeia 37, National Formulary 32, 2014. <88> Biological Reactivity Tests, *In Vivo*.

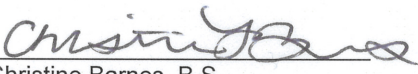
ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.


**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 6 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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