TOXIKON

ADVANCING YOUR INNOVATION

TEST RESULT CERTIFICATE

Sponsor	KRAIBURG TPE GmbH & Company KG	**Technical Initiation**	11/21/2014
Address	Friedrich-Schmidt-Str. 2 Waldkraiburg 84478 Germany	**Technical Completion**	11/25/2014
Contact	Oliver Lippert	**Report Date**	12/8/2014
P.O. Number	Not Supplied by Sponsor	**Final Non-GLP Report**	14-04155-N2

Test Article	THERMOLAST ® M TM9MED	**Ratio**	3 cm^2/mL
Lot/Batch #	Not Supplied by Sponsor	**Vehicle**	USP 0.9% Sodium Chloride for Injection (NaCl)
Physical State	Solid		
Color	translucent		
Density	0.89		
Study	Hemolysis – Human Blood – ISO Indirect Contact	**Extraction Conditions**	70 ± 2 °C for 24 ± 2 hours
Comments	None		

REFERENCES: The study was conducted based upon the following references: Autian Method, ATTP–I, Material Sciences Toxicology Laboratories, University of Tennessee Center for the Health Sciences, Memphis, TN, April 18, 1977. Hemolysis – Rabbit Blood, Evaluation of Hemodialyzers and Dialysis Membranes, DHEW Publication # (NIH) 77–1294, pg. 213, 1977. Feldman, Bernard F., Joseph G. Zinkl, and Nemi C. Jain, eds. Schalm's Veterinary Hematology. 5th edition. Baltimore: Lippincott Williams & Wilkins, 2000. 858–859. ISO 10993–4, 2002, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, as amended 2006. ISO 10993–12, 2012, 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 test article was added to a test vial containing USP 0.9% Sodium Chloride for Injection (NaCl) and extracted as specified above. The test article extract (10 mL each) was transferred to three test vials. The positive control (10 mL USP Sterile Water for Injection (SWFI)) and negative control (10 mL negative control plastic extract, extracted at 3 cm^2 per 1 mL in NaCl) and untreated control (10 mL NaCl) were prepared in triplicate. All tubes were incubated in a 37 ± 2 °C waterbath for 30 ± 2 minutes. Human blood was collected in tubes containing an anticoagulant (EDTA) and diluted in NaCl. After the incubation period, 0.2 mL of fresh diluted human blood was added to all vials. All vials were incubated in a 37 ± 2 °C waterbath for an additional 60 ± 4 minutes. After incubation, the vials were centrifuged. The absorbance of each supernatant was determined spectrophotometrically at 545 nm. The percent hemolysis of the test article was determined. A test article with a 5% hemolysis or less is considered non–hemolytic.

RESULTS: The test article extract induced 0.05% hemolysis.

CONCLUSION: The test article is considered non–hemolytic based on the methods employed.

AUTHORIZED PERSONNEL:

Brittany Dufault, B.S.
Quality Assurance

Franck Grall, Pharm.D., Ph.D.
Study Director