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TEST RESULT REPORT N°:11-B0963-N1

Project Number:	**TE 11344**	**Study Number:**	**11-B0963-N1**
Sponsor:	**Kraiburg TPE GmbH & Co.KG**	**Report Date:**	**22/04/2011**
Contact:	*Mr. Oliver Lippert*		
Address:	Friedrich-Schmidt-Strasse 2		
	84478 Waldkraiburg	Date Sample Arrival:	13/03/2011
	Germany	Technical Initiation:	21/04/2011
P.O.Number:	N/S	Technical Completion:	22/04/2011

Study	**Indirect Hemolysis**	Temp/Time	70°C/24 hours
Test item	TM9HET	Extraction Ratio	60cm² /20mL
Lot	N/S	Vehicle	0.9% NaCl

REFERENCE: ISO 10993-4: Biological Evaluation of Medical Devices Part 4: Selection of Tests for Interactions with Blood, 2002; Autian Method - ATTP-I, Material Sciences Toxicology Laboratories, University of Tennessee Center for the Health Sciences, Memphis, TN April 18, 1977; Schalm, O.W., Veterinary Hematology, pp. 51-53, Lea & Febiger, Philadelphia, 1965; Evaluation of hemodialyzers and Dialysis Membranes DHEW publication # (NIH) 77-1294, pg.213, 1977; Extraction procedures were based on the standards set by ISO 10993-12.
Procedure Ref.: Toxikon SOP 3.1.2.2 rev. 01

PROCEDURE: The test item was extracted with 0.9% USP Sodium Chloride for Injection (NaCl) in a 70±2°C waterbath for 24 hours. The test item extract (10 ml each) was transferred to three test vials. The positive control (10 mL USP Sterile Water for Injection) and negative control (10 mL NaCl) were prepared in triplicate. The Human blood was collected in tubes containing an anticoagulant (EDTA) and diluted in NaCl. 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 minutes. After incubation, the vials were centrifuged. The absorbance of each supernatant was measured at 545 nm. The percent hemolysis of the test item was determined.
A test item with a percent hemolysis of 5% or less is considered non-hemolytic.

RESULTS: The percent hemolysis of the test item extract was 0.1 %.

OPINION AND INTERPRETATION : The test item is considered non-hemolytic.

RECORD STORAGE: All raw data generated in this study will be archived at Toxikon Europe, according to SOP 4.2.8.

AUTHORIZED PERSONNEL

Ir. Peter Cornelis
Study Director

Gaby Boonen
Quality Assurance