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TEST RESULT CERTIFICATE

Sponsor	Pröll KG	**Technical Initiation**	5/29/2015
Address	Treuchtlinger Straße 29, D-91781 Weißenburg i. Bay. Germany	**Technical Completion**	6/21/2015
		Report Date	7/16/2015
Contact	S. Wernet	**Amended Report Date**	7/23/2015
P.O. Number	16042015	**Final GLP Report**	15-01422-G1

Test Article	NoriPUR® 948 (article no. 1067S948XXX), batch no. 155211 and NoriPUR® 945 (article no 1067S945XXX), batch no. 147585 (printed with 10% Hardener PUR®-ZK No.2 (article no. 6004M000002)	**Ratio**	120 cm^2 /20 mL
Lot/Batch #	155211 / 147585	**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	Sponsor Note: 2 Screen and pad printing inks are printed on inert carrier made of polycarbonate foil (Makrofol DE 1-1, 250 ym). The test article was autoclaved prior to testing at 121 ± 2°C for 30 minutes (Toxikon project #15-01422-N2).		

REFERENCES: The study was conducted based upon the following references: United States Pharmacopeia 38, National Formulary 33, 2015. <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:

Christine Barnes, B.S.
Quality Assurance

Christopher Parker, M.S., M.B.A.
Study Director