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TEST RESULT CERTIFICATE

Sponsor	Permabond LLC	**Technical Initiation**	10/6/2006
Address	20 C World's Fair Drive Somerset, New Jersey 08873	**Technical Completion**	10/9/2006
Contact	Manny Dias	**Report Date**	10/16/2006
P.O. Number	06-910000222	**Project Number**	06-4814-N2

Test Article	Loxeal UV30-27	**Ratio**	0.2 g/1.0 mL
Lot/Batch #	616827	**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, 2002, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed–Type Hypersensitivity, as amended 2006. ISO 10993–12, 2002, 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. Two 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, 48, and 72 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, 48, and 72 hours were totaled separately and divided by 12 (2 animals × 3 scoring periods × 2 scoring categories) 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: Both 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 article and control article 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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TEST RESULT CERTIFICATE

Sponsor	Permabond LLC	**Technical Initiation**	9/1/2006
Address	20 C World's Fair Drive Somerset, New Jersey 08873	**Technical Completion**	9/1/2006
Contact	Manny Dias	**Report Date**	9/22/2006
P.O. Number	06-910000222	**Project Number**	06-4367-N1

Test Article	Loxeal UV30-27
Lot/Batch #	616827
Study	Hemolysis – Rabbit Blood – ISO
Comments	None

REFERENCES: The study was conducted based upon the following references: ISO 10993–4, 2002, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, as amended 2006. Hemolysis – Rabbit Blood, Evaluation of Hemodialyzers and Dialysis Membranes, DHEW Publication # (NIH) 77–1294, pg. 213, 1977. Autian Method, ATTP–I, Material Sciences Toxicology Laboratories, University of Tennessee Center for the Health Sciences, Memphis, TN, April 18, 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 10993–12, 2002, 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, 4.6 g, was added to a test vial containing 9.2 mL NaCl. The test article, the positive control (10 mL USP Sterile Water for Injection) and negative control (10 mL NaCl) were prepared in triplicate. All tubes were incubated in a 37 ± 2 °C waterbath for 30 minutes. The rabbit blood was collected in tubes containing an anticoagulant (EDTA) and diluted in NaCl. After the incubation period, 0.18 and 0.2 mL of fresh diluted rabbit blood was added to the test article and control vials respectively. 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 determined spectrophotometrically at 545 nm. The percent hemolysis of the test article was determined.

RESULTS: A test article with a 5% hemolysis or less is considered non–hemolytic. The test article induced 2.6% hemolysis.

CONCLUSION: The test article is considered non–hemolytic under the experimental conditions employed.

AUTHORIZED PERSONNEL:

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TEST RESULT CERTIFICATE

Sponsor	Permabond LLC	**Technical Initiation**	10/9/2006
Address	20 C World's Fair Drive Somerset, New Jersey 08873	**Technical Completion**	10/12/2006
Contact	Manny Dias	**Report Date**	10/18/2006
P.O. Number	06-910000222	**Project Number**	06-4814-N1

Test Article	Loxeal UV30-27	**Ratio**	0.2 g/1.0 mL
Lot/Batch #	616827	**Vehicle**	USP 0.9% Sodium Chloride for Injection (NaCl) and Cottonseed Oil (CSO)
Study	Systemic 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 10993–11, 2006, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity. ISO 10993–12, 2002, 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 Systemic Injection Study is designed to screen solutions and test article extracts for potential toxic effects as a result of a single–dose systemic injection in mice. The extraction conditions were performed as stated above. The test article extracts were injected intravenously (NaCl) and intraperitoneally (CSO) at 50 mL per kg, in groups of five mice. Similarly, groups of five mice were injected with the control articles (vehicles). The animals were observed for signs of biological reactivity for 72 hours post inoculation.

RESULTS: None of the animals injected with the test article extracts or the control articles (vehicles) exhibited any signs of toxicity through the observation period.

CONCLUSION: The animals treated with the test article extracts did not exhibit biological reactions greater than the controls. Therefore, the test article meets the requirements of the ISO 10993–11 guidelines for the Systemic Injection Test.

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TEST RESULT CERTIFICATE

Sponsor	Permabond LLC	**Technical Initiation**	8/4/2006
Address	20 C World's Fair Drive Somerset, New Jersey 08873	**Technical Completion**	8/6/2006
Contact	Manny Dias	**Report Date**	8/11/2006
P.O. Number	Not Supplied by Sponsor	**Project Number**	06-3763-N1

Test Article	Loxeal UV30-27	**Ratio**	0.2 g/1.0 mL
Lot/Batch #	616827	**Vehicle**	Serum–Supplemented (Complete) Minimum Essential Medium (MEM)
Study	L929 MEM Elution Test – ISO	**Extraction Conditions**	37 ± 1 °C for 24 ± 2 hours
Comments	None		

REFERENCES: The study was conducted based upon the following references: ISO 10993–5, 1999, Biological Evaluation of Medical Devices – Part 5: Tests for *In Vitro* Cytotoxicity. ISO 10993–12, 2002, 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 biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test article extract was determined. Test article extract was prepared as stated above. Positive control (Natural Rubber) and negative control (Negative Control Plastic) articles were prepared to verify the proper functioning of the test system. The test article or control article extracts were used to replace the maintenance medium of the cell culture. All cultures were incubated in triplicate for 48 hours, at 37 ± 1 °C, in a humidified atmosphere containing 5 ± 1% carbon dioxide. Biological reactivity (cellular degeneration and malformation) was rated on a scale from Grade 0 (No Reactivity) to Grade 4 (Severe Reactivity). The test article met the requirements of the test if none of the cultures exposed to the test article showed greater than a Mild Reactivity (Grade 2).

RESULTS: No signs of reactivity (Grade 0) were exhibited by the cell cultures exposed to the test article extract or the negative control article extract at the 48 hour observations. Severe signs of reactivity (Grade 4) were observed for the positive control article extract at the 48 hour observation.

CONCLUSION: The test article is considered non–cytotoxic and meets the requirements of the Elution Test, ISO 10993–5 guidelines.

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TEST RESULT CERTIFICATE

Sponsor	Permabond LLC	**Technical Initiation**	1/23/2007
Address	20 C World's Fair Drive Somerset, New Jersey 08873	**Technical Completion**	2/19/2007
Contact	Manny Dias	**Report Date**	2/27/2007
P.O. Number	Not Supplied by Sponsor	**Project Number**	07-0044-N1

Test Article	Loxeal UV30-27	**Ratio**	0.2 g/1.0 mL
Lot/Batch #	616827	**Vehicle**	USP 0.9% Sodium Chloride for Injection (NaCl)
Study	Kligman Maximization 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, 2002, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed–Type Hypersensitivity, as amended 2006. ISO 10993–12, 2002, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials. Zhai, H. and H.I. Maibach, eds. Dermatotoxicology. 6th edition. Boca Raton: CRC Press, 2004. 729–732. Magnusson, B. and A.M. Kligman. "The Identification of Contact Allergens by Animal Assay. The Guinea Pig Maximization Test." J. Invest. Dermatol. 52 (1969): 268–276. Magnusson, B. and A.M. Kligman, Allergic Contact Dermatitis in the Guinea Pig. Identification of Contact Allergens. Springfield, IL.: Thomas, 1970.

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

GENERAL PROCEDURE: The purpose of the study was to detect the allergenic potential of a test article. Hartley guinea pigs, 10 experimental, 5 negative control, and 5 positive control, were used for this study. The test article was extracted at the conditions specified above. The Induction Phase (Day 0) was conducted by intradermally injecting the test article extract or control. The Topical Application Phase (Day 7) was conducted by applying the test article extract or control article for 48 hours, at the site of the intradermal injections. The 24 hour Challenge Phase was performed on Day 23. Test and control animals were scored for erythema and edema according to the Classification System for Scoring Skin Reactions at 24, 48, and 72 hours post Challenge Phase. The study and its design employed methodology to minimize uncertainty of measurement and control or bias for data collection and analysis.

RESULTS: The skin sites that were exposed to the test article extract and negative control showed no signs of erythema or edema. The skin sites exposed to the positive control showed the expected signs of erythema and edema.

CONCLUSION: The skin treated with the test article extract exhibited no reaction to the challenge (0% sensitization). Therefore, as defined by the scoring system of Kligman, this is a Grade I reaction and the test article extract (as prepared) is classified as having weak allergenic potential. A Grade I sensitization rate is not considered significant.

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Sponsor	Permabond LLC	**Technical Initiation**	8/4/2006
Address	20 C World's Fair Drive Somerset, New Jersey 08873	**Technical Completion**	8/6/2006
Contact	Manny Dias	**Report Date**	8/11/2006
P.O. Number	Not Supplied by Sponsor	**Project Number**	06-3763-N1

Test Article	Loxeal UV30-27	**Ratio**	0.2 g/1.0 mL
Lot/Batch #	616827	**Vehicle**	Serum–Supplemented (Complete) Minimum Essential Medium (MEM)
Study	L929 MEM Elution Test – ISO	**Extraction Conditions**	37 ± 1 °C for 24 ± 2 hours
Comments	None		

REFERENCES: The study was conducted based upon the following references: ISO 10993–5, 1999, Biological Evaluation of Medical Devices – Part 5: Tests for *In Vitro* Cytotoxicity. ISO 10993–12, 2002, 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 biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test article extract was determined. Test article extract was prepared as stated above. Positive control (Natural Rubber) and negative control (Negative Control Plastic) articles were prepared to verify the proper functioning of the test system. The test article or control article extracts were used to replace the maintenance medium of the cell culture. All cultures were incubated in triplicate for 48 hours, at 37 ± 1 °C, in a humidified atmosphere containing 5 ± 1% carbon dioxide. Biological reactivity (cellular degeneration and malformation) was rated on a scale from Grade 0 (No Reactivity) to Grade 4 (Severe Reactivity). The test article met the requirements of the test if none of the cultures exposed to the test article showed greater than a Mild Reactivity (Grade 2).

RESULTS: No signs of reactivity (Grade 0) were exhibited by the cell cultures exposed to the test article extract or the negative control article extract at the 48 hour observations. Severe signs of reactivity (Grade 4) were observed for the positive control article extract at the 48 hour observation.

CONCLUSION: The test article is considered non–cytotoxic and meets the requirements of the Elution Test, ISO 10993–5 guidelines.

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