



Leaders in Life Science and Technology

## TEST RESULT CERTIFICATE

<b>Sponsor</b>	Master Bond, Inc.	<b>Technical Initiation</b>	12/10/99
<b>Address</b>	154 Hobart Street	<b>Technical Completion</b>	12/17/99
	Hackensack, NJ 07601	<b>Report Date</b>	12/22/99
<b>Contact</b>	Dr. Walter Brenner	<b>Amended Report Date</b>	9/3/08
		<b>Second Amended</b>	9/5/08
<b>P.O. Number</b>	Not Supplied	<b>Project Number</b>	99-3525-N1

<b>Test Article</b>	UV10MED	<b>Ratio</b>	60 cm <sup>2</sup> per 20 mL
<b>Lot #/ Part #</b>	EXP 11-29-99A/ UV10MED	<b>Vehicles</b>	0.9% USP Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1:20 Alcohol in NaCl (EtOH) and Polyethylene Glycol 400 (PEG)
<b>Study</b>	Biological Test for Plastics Class VI (4 Extracts)	<b>Temp/Time</b>	70°C for 24 hours


**REFERENCE:** USP 23, NF18, 1995, pp. 1699-1702, 1995.

**GENERAL PROCEDURE:** The test article extracts and corresponding blanks (control extracts) were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP 23, 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 7 days and observed for signs of hemorrhage, inflammation, necrosis, discoloration, and encapsulation.

**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, inflammation, necrosis, discoloration, or encapsulation compared with those of control sites.

**CONCLUSION:** The test article meets the requirements of USP 23, NF18, 1995, for the Biological Test for Plastics, Class VI-70°C.

**AUTHORIZED PERSONNEL:**

  
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