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Biological Test on SPT's injected ZrO_2 bars (SPT material denomination Z)

Due to SPT's internal requirement and marketing activities, SPT decided to start biological evaluation on moulded ZrO_2. Tests were made on Ceramic bars item # 440-00159-DW with lot # Z309673P. Following tests were made:

Project #	Study	Conclusion
04-4382-N1	MEM ELUTIONS CYTOTOXICITY - ISO	The test article is considered non-cytotoxic and meets the requirements of the Elution Test, ISO 10993-5
04-4382-N2	KLIGMAN MAXIMIZATION TEST - ISO	The skin treated with the test article extracts 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 extracts (as prepared) are classified as having weak allergenic potential. A Grade I sensitization rate is not considered significant.
04-4382-N3	HEMOLYSIS - RABBIT BLOOD - ISO	The test article is considered non-hemolytic based on the methods employed
04-4382-N4	INTRACUTANEOUS INJECTION TEST - ISO	The test article meets the requirements of ISO 10993-10, 2002 for the Intracutaneous Test using extracts prepared with 0,9% USP Sodium Chloride for Injection (NaCl) and Cottonseed Oil (CSO)
04-4382-N5	SYSTEMIC INJECTION TEST - ISO	The animals treated with the test article extracts did not exhibit biological reactions greater than the controls. Therefore, the test article meets he requirements of ISO 10993-11 for the Systemic Injection Test.
04-4382-N6	SHORT TERM INTRAMUSCULAR IMPLANTATION TEST - ISO	The test article was implanted in the paravertebral muscle of albino rabbits for a period of 1 week. The results indicated that the test article was non-toxic when implanted for 1 week (Toxicity Rating of -0.04) when compared to the control article implant sites.
04-4382-N7	RABBIT PYROGEN TEST (MATERIAL MEDIATED) - ISO	The test article meets the requirements of ISO 10993-11, 1993 for the absence of pyrogens as specified for Pyrogen Test.

This is an extract of the "Test Result Certificate" sub-contracted by Small Precision Tools (Report Date 6th October 2004).