

SUMMARY CERTIFICATE

This document is the basis for a comprehensive materials qualification-testing program (non-GLP) for GE Plastics. These test procedures were part of a Standard Operating Procedure, specific to Armoloy of CT. Samples were tested and the reports were as specified in the SOP. This enables Armoloy of CT to provide comprehensive testing data/reports in compliance with both USP and ISO requirements.

JUSTIFICATION:

This testing strategy fulfils or exceeds both USP and ISO guideline requirements for Biocompatibility Testing of materials for Armoloy of CT, and resulted in test reports that fulfill or exceed both USP and ISO requirements.

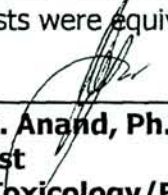
SUMMARY:

The Test Article, Armoloy of CT/Lot#: Not Supplied, was tested comprehensively for biological compatibility in the tests specified by ISO 10993 and USP 24, 2000 (see list below), and was found to be biocompatible in all aspects of the testing procedures, under the experimental conditions utilized.

TEST	PROCEDURE	COMPLIANCE	REPORT REFERENCE
(1) Cytotoxicity	MEM Extract USP/ISO	USP/ISO	USP/ISO*
(2) Systemic Toxicity	4 Extracts USP/ISO	USP/ISO	USP/ISO*/@
(3) Intracutaneous Irritation	4 Extracts USP/ISO	USP/ISO	USP/ISO*/@
(4) Implantation 2 Weeks in Rabbits with Histopathology	USP/ISO	USP/ISO	USP/ISO*/@
(5) Sensitization	2 Extracts ISO	ISO	ISO*
(6) Hemolysis Human Blood-Direct Contact	ISO	ISO	ISO*
(7) Material-mediated Pyrogenicity	ISO	ISO	ISO*

*These tests either met or exceeded the requirements of USP/ISO guidelines.

@ These tests were equivalent to or exceeded Class VI requirements.



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Date