

TEST FACILITY:

NAMSA
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Northwood, OH 43619

SPONSOR:

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STUDY TITLE:

Cytotoxicity Study Using the ISO Elution Method

TEST ARTICLE:

TheraGauze™

IDENTIFICATION NO.:

Lot: 01031607

NAMSA

Summary

An *in vitro* biocompatibility study, based on the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity: *in vitro* Methods guidelines, was conducted on the test article, TheraGauze™, Lot: 01031607, to determine the potential for cytotoxicity. A single extract of the test article was prepared using single strength Minimum Essential Medium supplemented with 5% serum and 2% antibiotics (1X MEM). This test extract was placed onto three separate monolayers of L-929 mouse fibroblast cells propagated in 5% CO₂. Three separate monolayers were prepared for the reagent control, negative control and for the positive control. All monolayers were incubated at 37°C in the presence of 5% CO₂ for 48 hours. The monolayer in the test, reagent control, negative control and positive control wells was examined microscopically at 48 hours to determine any change in cell morphology.

Under the conditions of this study, the 1X MEM test extract showed no evidence of causing cell lysis or toxicity. The 1X MEM test extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity). The reagent control, negative control and the positive control performed as anticipated.

Study and Supervisory Personnel:

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Date Completed

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