

GLP REPORT

TEST FACILITY:

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SPONSOR:

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CONFIDENTIAL

STUDY TITLE:

ISO Intracutaneous Study - Extract

TEST ARTICLE:

TheraGauze™ Wound Dressing

IDENTIFICATION NO.:

Lot: 336

NAMSA

Summary

The test article, TheraGauze™ Wound Dressing, Lot: 336, was extracted in 0.9% sodium chloride USP solution. This extract was evaluated for intracutaneous reactivity based on the requirements of the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-Type Hypersensitivity.

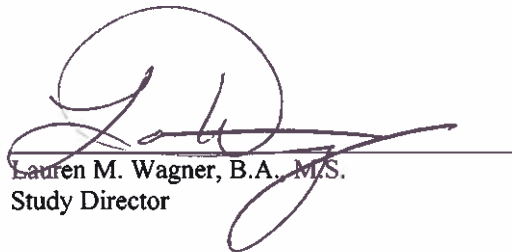
A 0.2 ml dose of the appropriate test article extract was injected by the intracutaneous route into five separate sites on the right side of the back of each rabbit. Similarly, the corresponding control was injected on the left side of the back of each rabbit. The injection sites were observed immediately after injection. Observations for erythema and edema were conducted at 24, 48, and 72 hours after injection.

Under the conditions of this study, there was no erythema and no edema from the extract injected intracutaneously into rabbits. The test article extract met the requirements of the test since the difference between the test extract and corresponding control mean score was less than 1.0.

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2-8-07
Date Completed

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