

# GLP REPORT

**TEST FACILITY:**

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**STUDY TITLE:**

USP and ISO Systemic Toxicity Study - Extract

**TEST ARTICLE:**

TheraGauze™ Wound Dressing

**IDENTIFICATION NO.:**

Lot: 336

**NAMSA**

## Summary

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The test article, TheraGauze™ Wound Dressing, Lot: 336, was extracted in 0.9% sodium chloride USP solution. This extract was evaluated for systemic toxicity in accordance with the guidelines of the current United States Pharmacopeia (USP) and the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity (ISO).

A single dose of the test article extract was injected into each of five mice by the intravenous route. Similarly, five mice were dosed with the blank vehicle. The animals were observed immediately and at 4, 24, 48, and 72 hours after systemic injection.

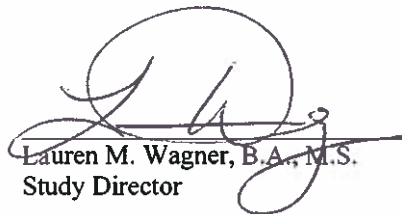
Under the conditions of this study, there was no mortality or evidence of systemic toxicity from the extract injected systemically into mice. The test article extract met the test requirements.

### Study and Supervisory

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2-8-07  
Date Completed

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