

# GLP REPORT AMENDMENT

**TEST FACILITY**

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CONFIDENTIAL

**STUDY TITLE**

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ISO Systemic Toxicity Study in Mice - Extract

**TEST ARTICLE NAME**

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pCAS Pump-Oxygenator

**TEST ARTICLE IDENTIFICATION**

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10055

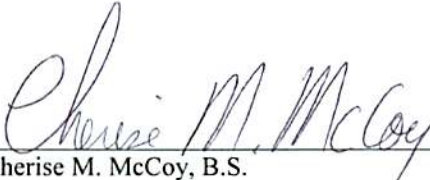
**NAMSA**

The final report for this study is being amended to include a deviation discussion for the 50°C incubator that was out of specification during the extraction procedure. The following was added to the report:

**Deviation**

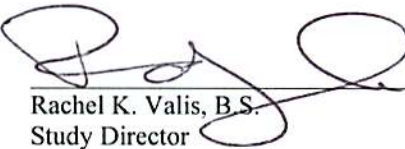
The test article and vehicle control were to be extracted at 50°C ± 2°C for 72 ± 2 hours. During the 0.9% sodium chloride USP solution (SC) and sesame oil (SO) extractions, the incubator temperature went down to 47°C and was out of specification for 64 minutes. The extracts still met the extraction time and temperature requirements of the test at 71 hours and 28 minutes. Although there was a 1°C decrease from specification, this does not represent a significant excursion to the incubation conditions. Therefore, this deviation had no impact upon the results or conclusions of the study.

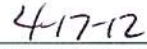
Reviewed by:

  
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