

GLP REPORT AMENDMENT

TEST FACILITY

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SPONSOR

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CONFIDENTIAL

STUDY TITLE

ISO Intracutaneous Study in Rabbits

TEST ARTICLE NAME

pCAS Pump-Oxygenator

TEST ARTICLE IDENTIFICATION

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:

 4-9-12

Lauren M. Michaels, B.S.P.S.
Quality Assurance

Date Completed

Approved by:

 4-17-12

Rachel K. Valis, B.S.
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Date Completed