

GLP REPORT AMENDMENT

TEST FACILITY

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CONFIDENTIAL

STUDY TITLE

Two Week Systemic Toxicity Study in Rats Following
Parenteral Administration of Two Extracts

TEST ARTICLE NAME

pCAS Pump-Oxygenator

TEST ARTICLE IDENTIFICATION

10055


NAMSA

The final report for this study is being amended to correct the conclusion statement in the summary. Originally the conclusion in the summary of the report indicated that the test article did produce systemic toxicity in rats, however, this statement is not supported by the data and is inconsistent with the conclusion section of the report. The conclusion statement was corrected to the following:

Summary

Clinical observations, body weights, hematology and clinical chemistry values, necropsy results, organ weights, organ/brain weight ratios and organ/body weight ratios were similar between test and control groups. There were no microscopic changes considered to be related to treatment with the test article extract. Parenteral administration of the test article extract did not produce systemic toxicity in rats.

Reviewed by:



Lisa M. Byrd, RQAP-GLP, CQA, ALAT
Quality Assurance

8-23-12
Date Completed

Approved by:



Rachel K. Valis, B.S.
Study Director

8-23-12
Date Completed