



瑞德生物科技有限公司
MASTER LABORATORY CO.,LTD.

Repeated Dose Inhalation Toxicity Study in Rats

Master Laboratory Co., Ltd. Animal laboratory

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BioBumper-19
Repeated Dose Inhalation Toxicity Study
in Rats
STUDY REPORT

Sponsor: AMET BioCore Corp.

Testing Institution: Master Laboratory Co., Ltd.

October 2020



SIGNATURE OF STUDY PERSONNEL

Experiment executor: Shi Wei Xu and Xin Han Huang

Study Director

Jhen Ru Shih
Jhen Ru Shih

10.21, 2020
Date

Facility Management

Alan Hsieh
Alan Hsieh

10.21, 2020
Date



GLP COMPLIANCE STATEMENT

The study met with the technical requirements of the protocol, and all applicable guidance and regulations, which included the Good Laboratory Practice for Non-clinical Laboratory Studies (FDA, 21 CFR, Part 58, 2019) and Good Laboratory Practice for Non-clinical Laboratory Studies (Food and Drug Administration, R.O.C., 2019). There were no deviations from the approved study plan and no adverse problem that would affect the integrity of this study or the interpretation of the study result. Because the test article is a proprietary product of the sponsor, all the contents related with test article in 21 CFR Part 58 (US FDA) are not applicable to this study (21 CFR §58.105, §58.113, FDA).

Study Director**Jhen Ru Shih****Date**



QUALITY ASSURANCE STATEMENT

To comply with the “Good Laboratory Practice for Nonclinical Laboratory Study”, Quality Assurance Department has audited the facility, equipment, personnel, test methods, raw data, and records regularly.

The study report has been reviewed and approved. The experiments were conducted according to the protocol. All original records, raw data, and documents are truthfully transferred and addressed in the results of this report.

Inspection record:

Inspection Contents	Date of inspection
Before the test (test execution protocol, requisitions, contracts).....	09.17.2020
Test (test substance data sheet, animal quarantine, standard operating procedures).....	09.21.2020
After the test (complete the original data, report reviews).....	10.20.2020

Quality Assurance unit in charge

Ying Chun Chen
Ying Chun Chen

10-21-2020
Date



SUMMARY

The present study was performed in compliance with ISO 10993-11:2017 guidance to evaluate the potential inhalation toxicity in Sprague-Dawley rats of test article “BioBumper-19” by atomizing machine 2 hours daily for 14 days repeated dose administration. Total 10 male and 10 female rats were equally divided into control group (Water for injection) and treatment group (BioBumper-19) respectively. After 14 days repeated dose administration, all animals were sacrificed and observed. The results showed that there were no significant clinical signs and gross findings in either the control or treatment groups after 14 days. Therefore, the “BioBumper-19” did not cause acute inhalation toxicity reactions or death in Sprague-Dawley rats after 14 days repeated dose administration. According to the histopathology examination, there was no statistical difference noted in severity of all lesions between test and control groups. Based on these study results, there was no observable toxic evidence of the test article under this toxicity study. All data generated from the study would provide safety criteria information for human exposure.