瑞德生物科技有限公司
MASTER LABORATORY CO.,LTD.

Acute Oral Toxicity Study

Master Laboratory Co., Ltd. Animal laboratory

Address: 3F, No.221, Sec. 1, Zhongxing Rd., Zhudong Township,

Hsinchu County 31053, Taiwan (R.O.C.) TEL：(886-2)25176117

瑞德生物科技有限公司
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Repeated Dose Inhalation Toxicity Study in Rats

Master Laboratory Co., Ltd. Animal laboratory

Address: 3F, No. 221, Sec. 1, Zhongxing Rd., Zhudong Township,

Hsinchu County 31053, Taiwan (R.O.C.) TEL：(886-2)25176117

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

Jhen Ru Shih

10.21.2020

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.

BioBumper-19
Acute Oral Toxicity Study in Rats
STUDY REPORT

Sponsor: AMET BioCore Corp.

Testing Institution: Master Laboratory Co., Ltd.

October 2020

SIGNATURE OF STUDY PERSONNEL

Experiment executor: Kuo Shu Huang and Bo Han Huang

Study Director

Jhen Ru Shih 10. 07. 2020

Jhen Ru Shih **Date**

Facility Management

Alan Hsieh 10.07.2020

Alan Hsieh **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

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10.07.2020

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Quality Assurance unit in charge

Ying Chun Chen
Ying Chun Chen

10. 07. 2020
Date

SUMMARY

The present study was to investigate the oral toxicity responding to the test article "BioBumper-19" by a single dose of oral administration in SD rats. The testing was performed in compliance with OECD 420. All of test and control animals were in overall good health over the course of the study and none of the animals treated with the test article extract showed significantly greater reaction than the control animals. All animals survived to their scheduled time point, the final body weights of animals in treatment group were no significant difference compared with the control group. The results showed that there were no significant clinical signs and gross findings in either the control or treatment group after 14 days administration. Therefore, the test article "BioBumper-19" did not cause toxicity reaction in SD rats.