



瑞德生物科技有限公司
MASTER LABORATORY CO.,LTD.

Acute Oral Toxicity Study

Master Laboratory Co., Ltd. Animal laboratory

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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

Jhen Ru Shih

10.07.2020

Date

Facility Management

Alan Hsieh

Alan Hsieh

10.07.2020

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



FINAL REPORT

Report No.: MSA-202009-333-T07

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).....	10.07.2020

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.