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Acute Oral Toxicity/ Pathogenicity

About the author

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Mr Rahul Badgha is experienced in the Industrial Microbiology. He is actively involved in microbial method validation and Acute Pathogenicity studies. He is instrumental in maintaining the GLP and AAALAC approved Animal Breeding Facility for different species of laboratory animals for toxicology studies. He is also involved in the health monitoring of laboratory animals. Apart from this he is study director for various acute pathogenicity studies.

Acute oral toxicity or pathogenicity is defined as the adverse effects caused by the single oral exposure of a Microbial Pesticide Control Agent (MPCA). The guideline for acute oral toxicity/pathogenicity is obtained from the test guideline developed by the Office of Prevention, Pesticides and Toxic Substances (OPPTS 885 3050), United States Environmental Protection Agency (USEPA). The purpose of this guideline is to evaluate the toxic or pathogenic characteristics of an MPCA after the acute high dose oral exposure.

Principle of the test

The test substance or MPCA is administered in the experimental animals at a single high dose level by oral gavage. The animals are observed for any mortality or adverse effect. The necropsy of the animals died during the experimental period as well as at the end of the study is performed to check any gross abnormality of vital organs. The infectivity and the rate of clearance of the MPCA are evaluated.

01 Acute oral toxicity / pathogenicity

02 Test procedure

- Single oral dose of MPCA in rodents
- Observation of 21 days

03 Observation parameters

- Morbidity
- Mortality
- Clinical signs
- Gross pathology
- Rate of clearance of MPCA

Study outline

Dose Quantification:

Before starting any Study of MPCA, we perform Microbiological Method validation for better clarity of the behaviour of the active ingredient. Method validation part contains,

1. Purity of Test Item (MPCA)
2. Limit of Detection (LOD).
3. Limit of Quantification (LOQ)

Healthy young adult rodent species preferably mice and rats of at least 6 numbers of either sex (n = 3 per sex) are used in the study. The experimental animals are randomized into untreated control and test groups. The control animals are treated with inactivated MPCA. Whereas, one dose level of at least 10^8 units of MPCA per test animal is used in test group. The animals are fasted overnight and administered with the single dose by oral gavage. The animals are observed for a period of at least 21 days after dosing. They are observed for skin and fur, eyes and mucus membrane, respiratory system, circulatory system, autonomic and central nervous system, somatomotor activity, behavior pattern, tremor, convulsion, diarrhea, lethargy, sleep, coma, salivation etc. Gross pathology of the animals is recoded after necropsy. The fecal samples of the test animals are subjected to the examination for the presence of MPCA.

Test	Necropsy & Interim Sacrifice / Terminal Sacrifice	Biometrics collection for MPCA clearance & enumeration
Acute Oral Toxicity / Pathogenicity (OCSPP 885.3050)	On Day 3,7,14 & 21	Microbiological enumeration of MPCA done from major biological matrices like Blood, Lung, brain, liver, kidney, heart, stomach, whole intestine, caecum, mesenteric lymph node, and spleen was also examined.

Outcomes

This assay helps to identify the toxic components present in the dosing material or MPCA and performs the risk assessment for human and environmental health.

Jai Research Foundation (JRF) located at Vapi in the southern region of Gujarat has a well-equipped animal house facility and trained staff to perform toxicity studies as per regulatory guidelines and provides the service to the customers throughout the year.

References:

1. Farag, A. A. G., & Ali, S. S. (2022). Acute Oral Toxicity of two Products from a Microbial Pest Control Agent (Beauveria bassiana) on Physiological Status Aspects of Male Albino Rats. The Egyptian Journal of Hospital Medicine, 86(1), 943-951.
2. Microbial Pesticide Test Guidelines, OPPTS 885.3050 : Acute Oral Toxicity/Pathogenicity (1996), EPA712–C–96–315.

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