Bio-Pesticides: New Era for Global Agro World

1. Introduction

Bio-fertilisers and bio-pesticides, in contrast with the past, is continuously replacing chemical fertilisers and pesticides, as they are easy to apply, eco-friendly in nature, cost-effective, and non-toxic.

Bacillus thuringiensis (Bt) is highly toxic to a wide variety of healthy agricultural insect/ pests, as well as other invertebrates.

The bio-pesticide market is classified into bio-herbicides, bio-insecticides, and bio-fungicides based on the product type. With respect to ingredients, it is again subdivided into:

- **Microbial pesticides (MCP)**
  Bacteria, fungi, viruses, protozoans, or algae
- **Biochemical pesticides (BCP)**
  Plant extracts or sex pheromones
- **Plant-Incorporated-Protectants (PIPs)**
  Insecticidal transgenic crops

2. Why use Bio-pesticide?

In the field of agronomy, there are numerous complications of pests like insects, fungi, and weeds from the ancient period resulting in a decrease in yield as well as the efficiency of crops.

- Bio-pesticides are mainly designed to affect target species only and nontoxic to beneficial insects.
- Bio-pesticides are eco-friendly biodegradable, decomposing rapidly without any negative impact on the water resources – either underground or on the surface.
- Bio-pesticides, in miniature, has the potential to effectively eliminate various pollutions environmentally.
- Bio-pesticides ends in low-residue, high in performance, with less toxic side effects.
- Insects find difficulty to develop resistance against bio-pesticides.
- Bio-pesticides are comparatively less toxic to chemical pesticides.

3. Data Requirements for Registration

For registration of Bio-pesticides, each dominion has requirements for the data package submitted.

3.1 Data requirements for the formulated product

- Identity and composition of the formulation
- Physical and chemical properties
- Application, labelling, and packaging
- Further information
- Analytical methods
- Efficacy data
- Toxicology and exposure
- Residues
- Fate and behaviour in the environment
- Effects on non-target organisms
- Summary

4. Regulatory Testing for MPCA as per OCSPP guidelines series 885

4.1 Test System

Rat (Wistar) or Mice (Cd1)

4.2 Method Validation

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,

LOD → LOQ

After Method validation, the Main study is to be initiated.

Test	Necropsy & Interim Sacrifice / Final Sacrifice	Biometrics collection for MPCA Clearance & Enumeration
Acute Oral Toxicity / Pathogenicity (AOP)	On Day 3, 7, 14 & 21	Microbiological enumeration of MPCA done from major tissue like Faeces (AOP), Blood (APP), Lung (AIP) & other matrices like brain, liver, kidney, stomach, whole intestine, caecum, mesenteric lymph node, and spleen was also examined.
Acute Pulmonary Toxicity / Pathogenicity (APP)	On Day 0, 3, 7, 14 & 21	
Acute Injection Toxicity/ Pathogenicity (AIP)	On Day 3, 7, 14 & 21	

4.3 Tier Progression

If MPCA noticed as Pathogenic/ Toxic than higher tier testing may be performed.

5. JRF Aspects

JRF has vast experience in MPCA regulatory studies with GLP compliances for different microbial strains

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 breeding and health monitoring of laboratory animals.

Founded in 1977, JRF Global is one of the oldest (41+) and most respected non-clinical Contract Research Organization in Asia. JRF's capabilities spanning from Discovery to Development phase provides integrated services to both innovator and generic pharma companies.

Salient Features:

- GLP and AAALAC accredited
- 300+ Employees, 700+ Clients across 60+ Countries
- Spread across 6 locations worldwide (USA, Canada, Spain, UK, India, Japan)
- 33500+ GLP Studies across all industries and have been well received by US FDA, EMA, MHRA and other regulatory agencies.
- State-of-the-art animal house facility which is among the best in Asia

Experienced in handling small molecules, biologics / biosimilars, vaccines & herbal products JRF's fully integrated chemistry and toxicology services offers an attractive value proposition in terms of efficiency, deliverables and cost.

Services at a Glance:

- P-C Chemistry, Analytical/Bioanalytical Chemistry
- Med-Chem & Custom Synthesis
- ***In vitro*** DMPK
- ***In vivo*** Pharmacokinetics
- Efficacy models
- Safety Pharmacology
- Genotoxicity
- DART - Segment I, II, III