Procedure: Pest Management

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# Purpose

The purpose of this procedure is to effectively exclude the presence and potential contamination from all forms of pests (insects, rodents and birds in particular) in the development, manufacture and storage of products using safe practices in compliance with the principles of current Good Manufacturing Practice (GMP) and other regulatory requirements.

# Scope

The scope of this procedure includes GMP TGA PIC/S Guide for Good Manufacturing Practice for Medicinal Products, PE009-13 2017 as of Jan 2018.

<https://www.tga.gov.au/publication/manufacturing-principles-medicinal-products>

manufacturing and storage areas of [Company] located at:

Address 1

Address 2

Insert address(es) as required.

The scope also applies to adjacent surrounding areas in which good house-keeping practices reduce the risk of infestation of pests in the GMP areas.

# Responsibilities

Amend this section to reflect your company’s organisational structure.

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| --- | --- |
| Role | Responsibility |
| Production Manager | Implement and train staff in this procedure.  Anyone designated and trained by the Production Manager may administer pest controls and remove pests. |
| All staff | Inform the Production Manager of the presence of any pests.  Follow standing instructions designed to exclude pests from the facility. |

# Occupational health, safety and environmental assessment

Only suitably trained staff are to handle and manage chemical pest controls. Personal protective equipment (PPE) is to be used as recommended by the vendors of chemical pest controls.

# Procedure

## General

All areas used for the manufacture and storage of raw materials, finished product, primary and secondary packaging are to be kept clear of pests and their waste at all times.

All pest activity and pest control activity (both preventative measures and pest removal) are recorded on Form FP603-1: Pest Treatment and Activity Log.

All pest control records are controlled according to Procedure QP403: Control of Records.

At the discretion of the Production Manager, relevant pest control information is included in batch manufacturing records.

The company may choose to engage a reputable pest control service provider. There must be a written contract which references or summarises a pest management plan.

## Design and practice

The design of the facility and operator practice must effectively exclude pests; particularly flying and crawling insects, rodents and birds.

Whenever possible, specialist pest control advice should be sought from a suitably trained and experienced person or company who is licensed by the Department of Health (in Victoria, Australia).

## Good maintenance and housekeeping

Timely maintenance of the facility is critical in preventing access to pests. The following maintenance tasks must be included in the maintenance program, where applicable:

* Door and window seal integrity
* Window screens and plant air intake screens must be kept in good repair
* Drain covers must be in good repair and have a good fit
* Cracks or holes which may have developed in walls and roofs must be repaired

Proper housekeeping is critical by removing food sources and areas of shelter. The following areas must be considered for addition in the cleaners’ duties, where applicable:

* Drains must be regularly cleared of built up debris
* Pooling of water must be avoided
* Rubbish or unwanted materials must not be left to accumulate, especially near GMP areas
* Waste bins and dumpsters must be frequently emptied
* Incoming goods deliveries must be inspected for signs of inhabitation
* Cartons and boxes must be removed from the areas as soon as possible after unpacking contents
* Trees and shrubs are not permitted near GMP area walls.

## Bait stations

Bait stations are to be located to a written plan and the stations loaded, maintained and inspected to a written schedule which takes into account the manufacturer’s instructions and OHS&E requirements.

Bait stations shall be of a design suitable for the facility and pests commonly found in the area.

## Flying and crawling pest control

Effective measures are to be in place to prevent the ingress of birds and flying and crawling insects. Wherever possible these are to be physical barriers, such as suitably fitted doors, windows and vent covers.

Measures such as appropriate signage are to be in place to ensure that physical measures are effective.

Care must be taken to ensure insecticide sprays do not come into contact with raw materials, finished product, primary or secondary packaging.

Insecticide spraying must be carried out to a written plan and in accordance with the manufacturer’s instructions and OHS&E requirements.

Records of spraying are to be made on Form FP603-1: Pest Treatment and Activity Log.

## Reporting of pest activity

All staff are encouraged to be alert for evidence of pest activity and report this immediately to the Production Manager.

Where possible and safe to do so, staff may remove the pests from the facility and perform appropriate clean up of the area affected.

## Monitoring and acting on pest activity trends

In order to ensure pest control is effective, the pest control log is to be reviewed at least annually to:

* develop and record trends of pest activities to determine that preventative actions are effective
* determine the need for further actions to prevent incursions within the facility
* notify the Quality Manager of the adequacy of the program.

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
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Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
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Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP403 | Control of Records |
| FP603- | Pest Treatment and Activity Log |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
|  |  |

List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

DOCUMENT END