Procedure: Environmental Monitoring

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The standard for the environment depends on the product to be manufactured, particularly the microbiological quality. Qualities are to be taken from PE 009-13 (Annexes) for pharmaceutical products and Part II of the PIC/S GMP Guide (see PE 009‑13 (Part II) for active pharmaceutical ingredients and intermediates.

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>

# Purpose

The purpose of this procedure is to ensure that [Company] controls and maintains the manufacturing environment and that this environment complies with the principles of Good Manufacturing Practice (GMP) and other regulatory requirements

# Scope

It may be useful to describe the exact areas that are described by this procedure.

The scope of this procedure includes all areas that are used in the manufacture of pharmaceutical product; including preparation, cleaning, dispensing of raw materials, preparation of bulk batch, mixing, filling, labelling and storage of raw materials, labels and finished product.

# Responsibilities

Amend responsibilities to reflect the organisational structure of your company.

|  |  |
| --- | --- |
| Role | Responsibility |
| Quality Manager | * Develop and implement this procedure. * Perform routine audits of this procedure. |
| Production Manager | * Develop and implement this procedure. * Train staff in this procedure. |
| Production Personnel | Maintain the environment in a satisfactory condition. |

# Procedure

## General

It is a requirement upon the company to control the environment in which they produce pharmaceutical products. The environment refers to:

* the air quality within the facility
* the microbiological levels within the potable water used in manufacturing products.

The Company controls the background levels within the facility by effective cleaning and sanitising of:

* equipment, internally and externally
* rooms
* staff (through personnel hygiene training and qualification)

The following sections detail how the various environmental areas are controlled and monitored.

## Air quality - microbiological

Air quality is monitored within the manufacturing areas to demonstrate compliance to Class D unclassified (Class 7000). This involves testing the air quality at the locations detailed in Table 1. Air quality is determined by a combination of particle counts per litre and microbiological load.

## Air quality – particle counts

Air quality is monitored within the manufacturing areas to demonstrate compliance to Class D unclassified (Class 7000). This involves testing the air quality at the locations detailed in Table 2. Particulate air quality is determined by particle counts per litre. The particle count limits for the Product facility are indicator limits only; there is no requirement to meet these standards. These limits will be assessed after one year of operation.

## Surface quality - microbiological

Surface swabs and touch-plate testing is carried out within the manufacturing areas to demonstrate compliance to Class D unclassified (Class 7000) (refer to Table 1).

## Water quality microbiological counts

Water quality is monitored within the manufacturing areas to demonstrate compliance to the World Health Organisation (WHO) potable water standard. This involves testing the water at the locations detailed in Table 3. Water quality is determined by the microbiological load per 100 mL.

## Operator qualification

Operator qualification is only required at the discretion of the Quality Manager. Operators will typically wear gloves that are to be changed regularly, thereby keeping the microbiological load to a low level. Testing will be to the limits specified in the attached Tables.

Table : Environmental monitoring - Microbiological air / surface counts

|  |  |  |  |
| --- | --- | --- | --- |
| Location | Environmental Standard required | Settle plate limits | Frequency of test |
| Room 1.05  (Production Room 1) |  |  |  |
| Location 1 |  | Action >100 cfu/m3  Satisfactory <100 cfu/m3 | Determine frequency |
| Location 2 |  |
| Location 3 |  |
| Room 1.06  (Production Room 2) |  |  |  |
| Location 1 |  | Action >100 cfu/m3  Satisfactory <100 cfu/m3 | Baseline only |
| Location 2 |  |
| Location 3 |  |
| Room 1.15  (Dispensary) |  |  |  |
| Location 1 |  | Action >100 cfu/m3  Satisfactory <100cfu/m3 | Baseline only |
| Location 2 |  |

Complete the tables as required for your company’s specific requirements.

\* Limits are nominal, these will be confirmed after one year of operation.

\*\* Other locations will be included as required and as requested by the Quality Manager.

Table 2: Airborne particle counts

|  |  |  |  |
| --- | --- | --- | --- |
| Location | Environmental Standard required | Particulate limits | Frequency of test |
| Room 1.05  (Production Room 1) |  |  |  |
| Location 1 |  | Action >7000 particles/L  Satisfactory <7000 particles/L | 3 Monthly |
| Location 2 |  |
| Location 3 |  |
| Room 1.06  (Production Room 2) |  |  |  |
| Location 1 |  | Action >7000 particles/L  Satisfactory <7000 particles/L | 3 Monthly |
| Location 2 |  |
| Location 3 |  |
| Room 1.15  (Dispensary) |  |  |  |
| Location 1 |  | Action >7000 particles/L  Satisfactory <7000 particles/L | 3 Monthly |
| Location 2 |  |

\* Limits are guideline values only and will be confirmed after one year of operation.

\*\* Other locations will be included as required and as requested by the Quality Manager.

Table 3: Microbiological water counts

|  |  |  |  |
| --- | --- | --- | --- |
| Location | Environmental Standard required | Limit \* | Frequency |
| Room 1.15 (Dispensary) |  |  |  |
| Fume Cabinet |  | TAMC <100 cfu/mL  E. coli absent in 100 mL  Total Coliforms absent in 100 mL | 3 Monthly |

\* Limits are nominal, these will be confirmed after 1 year of operation.

\*\* Other locations will be included as required and as requested by the Quality Manager.

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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| Associated forms and procedures | |
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| Doc. No. | Document Title |
| PE 009-11 | PIC/S Guide to Good Manufacturing Practice for Medicinal Products |

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

| Associated records | |
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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.

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