
Guidance for Industry: Microbiology Laboratories

Version 1.0

Drug Office
Department of Health

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1. Introduction

This guideline is intended to provide general guidance on the interpretation of the *PIC/S Guide to Good Manufacturing Practice for Medicinal Products* (PIC/S Guide to GMP) with respect to requirements for microbiology laboratories engaged in microbiological testing associated with the manufacture of non-sterile pharmaceutical products.

More detailed information may be obtained by referring to the *WHO Technical Report Series No.961 Annex 2: WHO good practices for pharmaceutical microbiology laboratories*.

It should be noted that the requirements of the *Chinese Pharmacopoeia* with respect to premises of microbiology laboratories are mandatory and must be taken into account.

There may be other acceptable approaches that provide an equivalent level of quality assurance. This guideline is not intended to create additional requirements and is not intended to form the basis for GMP inspections.

2. Purpose of this document

To provide guidance to industry on microbiology laboratories performing tests on non-sterile pharmaceutical products.

3. Scope

This guidance document relates to microbiology laboratories involved in any microbiological testing activities associated with the manufacture of non-sterile pharmaceutical products.

4. Personnel

The number of employees should be sufficient for the activities performed. Job descriptions should be available for all staff, clearly defining responsibilities and the reporting structure.

Testing should be performed and supervised by experienced and appropriately trained personnel. Management/supervisory staff of microbiology laboratories should have appropriate education, training and practical experience in microbiology.

There should be a training programme relevant to all personnel and include any personnel who may enter the laboratory or perform any function in the laboratory.

5. Environment

5.1 Premises

Microbiology laboratories should be separated from production areas and have an air handling system separated from the production areas.

Microbiology laboratories should be designed and have sufficient space to suit the operations carried out in them and to avoid mix ups, contamination and cross contamination. If necessary, this could include separate cleanrooms with access via airlocks, and appropriate entry and exit procedures including gowning.

Microbiology laboratories must have appropriate classified areas according to the requirements of the *Chinese Pharmacopoeia*.

5.2 Environmental monitoring

An environmental monitoring programme should be established which covers, for example, viable and non-viable particles, pressure differentials, temperature.

Alert and action limits should be defined. Environmental monitoring results should be trended.

5.3 Cleaning, disinfection and hygiene

There should be a documented cleaning and disinfection programme that also deals with spillages.

Appropriate hand washing and disinfection facilities should be available.

6. Equipment

Microbiology laboratories should be appropriately equipped to perform all of the activities undertaken.

There should be a documented programme for the qualification, calibration, performance verification, maintenance, and a system for monitoring the use of its equipment.

6.1 Maintenance of equipment

Equipment should be maintained and calibrated (as applicable) at specified intervals according to documented procedures.

6.2 Qualification and performance verification

Equipment should be appropriately qualified prior to use and, as applicable, the performance verified at appropriate intervals according to a documented plan.

7. Reagents and culture media

There should be a procedure that describes the receipt, assessment, acceptance and identification of reagents and culture media. Shelf-life should be appropriately assigned and monitored.

Reagents, media, diluents, etc. should be adequately labelled.

7.1 Reagents

The suitability of each batch of critical reagents should be verified initially and during its shelf-life.

7.2 Media

Media may be prepared in-house or purchased from approved vendors, either partially or fully prepared. Growth promotion and, if appropriate, other suitable performance tests, should be done on all media (every batch and every shipment).

Media should be prepared in accordance with the media manufacturer's instructions. A batch record or processing sheet should be available to record the materials, equipment and testing performed, including the identification of the person(s) responsible, for each batch of media prepared.

8. Reference materials and cultures

Whenever possible, international standards and/or pharmacopoeial reference substances, or reference materials traceable to these standards, should be utilised.

Reference strains used in the laboratory should be acquired from a recognized national or international collection (e.g. ATCC). Subculturing from the original reference culture should be limited to five generations (or passages). Commercial derivatives may be used as working cultures provided that they have been shown to be equivalent to that from a recognized national or international collection.

9. Sampling and sample handling

Sampling should be performed aseptically using sterile equipment, and by trained personnel following documented procedures. Any disinfection processes used in obtaining the sample (e.g. disinfection of sample points) should not compromise the microbial level within the sample. The sampling location, number of units or quantity of material should be pre-defined and documented.

Transport and storage of samples should be under conditions that maintain the integrity of the sample. Testing should be performed as soon as possible after sampling.

A procedure for the delivery and receipt of samples, and sample identification, should be available. Relevant records should be maintained.

10. Disposal of contaminated waste

Procedures for the disposal of contaminated materials should be documented and designed to minimize the possibility of contaminating the test environment or materials.

11. Internal quality assurance or quality control

There should be internal quality assurance or quality control systems (e.g. handling deviations, use of spiked samples, replicate testing and participation in proficiency testing, where appropriate) to ensure the consistency of results and their conformity with defined criteria.

12. Testing procedures

12.1 Validation of test methods

Pharmacopoeial test methods are considered validated. However, the specific test method to be used by a specific laboratory for testing a specific product should be shown to be suitable for use in recovering bacteria, yeast and mould in the presence of the specific product or sample, before use.

Non-pharmacopoeial methods should be validated prior to use.

12.2 Testing procedures

Testing should normally be performed according to procedures described in the national, regional or international pharmacopoeias.

Alternative testing procedures may be used if they are appropriately validated and equivalence to official methods has been demonstrated.

13. Test reports

Results of microbiological testing should be properly reported so as to accurately represent the result in a defined quantity or volume of sample.

Document Information

Version	Date	Description of Change
1.0	27 Dec 2013	First version

References

Document Title
PIC/S Guide to Good Manufacturing Practices for Medicinal Products PE 009-10: Part I and Annexes
WHO Technical Report Series No.957 Annex 1: WHO good practices for pharmaceutical quality control laboratories
WHO Technical Report Series No.961 Annex 2: WHO good practices for microbiological laboratories
Chinese Pharmacopoeia 2010: Pharmacopoeia of the People's Republic of China, 2010 Edition

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