Standard Operating Procedure

Title: Choice of Effective Sanitizing Agents for Microbiology Laboratory

Department	Micro Laboratory		Document no	MICLAB 145	
Title	Choice of Effective Sanitizing Agents for Microbiology Laboratory				
Prepared by:		Date:		Supersedes:	
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Approved by:		Date:		Review Date:	

1.0 DOCUMENT OWNER

Laboratory/Quality Manager

2.0 PURPOSE

The choice of sanitising agents and their dilutions are critical for the microbiological cleanliness of equipment and the manufacturing plant.

3.0 SCOPE

This Standard Operating Procedure outlines the criteria and rationale of selection of sanitising agents, their quality control and documentation required. Cleaning validation of the sanitizers with direct contact with equipment will be covered in the cleaning validation policy.

4.0 RESPONSIBILITY \ BUSINESS RULES

The Microbiologist is responsible for accepting or rejecting any proposed new disinfectant and/or sanitising agents,

- conducting validation studies
- approving instruction for preparation and use.

5.0 PROCEDURE

5.1 Change control and validation protocol should be prepared whenever a new disinfectant is proposed.

5.2 Disinfectant validation protocol should include the following:

5.2.1 Obtain and review manufacturer's technical data sheet.

5.2.2 Obtain and review material safety data sheet.

5.2.3 Obtain and review copies of certificate of analysis supporting biocidal properties of disinfectant.

5.2.4 Confirm biocidal properties of in use concentration.

5.2.5 Determine minimum contact time.

5.2.6 Determine compatibility of disinfectants with surface finishes in manufacturing areas, e.g. stainless steel, glass, plastic, vinyl.

5.2.7 Determine in use concentration.

5.2.8 Determine expiry date on diluted disinfectants (if appropriate).

5.3 An operator instruction should be prepared by the area supervisor outlining the preparation and use of each new approved disinfectant/sanitiser.

The instruction should state;

- concentration
- method of preparation
- expiry date
- labeling requirements
- safety precautions
- storage instruction (including storage container which must not be similar to any product container).

5.4 The instruction must be available to the operators at their workplace. Operators must be trained in the use of the instruction.

5.5 A validation protocol should be prepared by the Microbiologist in order to test the effectiveness and appropriateness of the disinfectant/sanitiser under in-house conditions.

Such a protocol should incorporate worst case criteria such as challenging the disinfectant/sanitiser with the dirtiest in-house condition.

Continued effectiveness of disinfectants should be evaluated at regular intervals to ensure that initial criteria are consistently met.

5.6 All approved sanitising agents will be listed in – Starting Material Register (Chemical)

6.0 DEFINITIONS / ACRONYMS

Disinfectant/Sanitiser - an agent capable of reducing the number of viable micro-organisms. Note: Viable micro-organism is a living micro-organism.

7.0 RELATED DOCUMENTS

As appropriate

8.0 SUMMARY OF CHANGES

Version #	Revision History
MicLab-145	New

