

POLICY ON CULTURE MAINTENANCE & IDENTIFICATION

INTRODUCTION:

This document provides the policy for standard microbial cultures.

SCOPE:

This policy applicable to culture procurement, identification, maintenance and storage.

POLICY DETAILS:

- ✧ Procedures for procurement, maintenance, identification and storage for cultures shall be in place.
- ✧ Cultures for use in compendial tests shall be acquired from a national culture collection or a qualified secondary supplier.
- ✧ Cultures can be acquired frozen, freeze-dried, on slants, or in ready-to-use forms.
- ✧ Confirmation of the purity and the identity of the culture shall be performed before its use in quality control testing. Identity up to genus and species level shall be confirmed.
- ✧ Handling and storage of cultures by the user laboratory shall be done in a way that it will minimize the opportunity for contamination or alteration of growth characteristics.
- ✧ The number of transfers of working control cultures shall be tracked and the culture solutions used for testing shall not exceed five passages.
- ✧ The use before date shall be defined for each culture prepared.
- ✧ Used cultures should be disposed after decontamination as per validated loading pattern and record shall be maintained.

AMENDMENT AND WAIVER:

The company reserves the right to amend, alter and/or terminate this policy at any time.

DEFINITION: Not Applicable.

ABBREVIATIONS:

NF : National Formulary
USP : United States Pharmacopoeia

REFERENCES:

USP 43 – NF 38 Chapter <1117> Microbiology Best Laboratory Practices.