POLICY ON INHOUSE ISOLATES

INTRODUCTION:

This document provides the policy for Identification and maintenance of In-house isolates.

SCOPE:

This policy applicable to Isolates obtained from Water for Pharmaceutical Use, Environment, Drug Products, Drug Substances, Excipients, Packaging Material, Inprocess Bioburden, Inhouse / Readymade Microbiological media and Utilities such as, Steam, Compressed air and Nitrogen.

POLICY DETAILS:

- ✧ Procedure shall be in place for Selection, Identification, Maintenance and Storage of In-house Isolates. Any growth observed from Samples of Critical areas should be identified.
- ✧ Representative colonies from Non-critical areas and Water shall be identified to determine normal flora of Environment and Water.
- ✧ All cultures isolated from contaminated Sterility tests and from Media fill failures shall be preserved. Each Isolate shall be allocated with unique Identity number.
- ✧ Qualified identification systems shall be used to carry out identification of isolates.
- ✧ Database of in-house isolates shall be maintained and evaluated to establish the Predominant flora.
- ✧ Data shall be summarised to explain existing flora, change in flora, impact of new flora and action to be taken. In house isolates used in tests shall not exceed 5 passages.
- ✧ Representative isolates shall be used for Media release and Tests wherever applicable. All relevant records shall be maintained.
- ✧ 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:

In-house isolate:

Microbial flora from Water for Pharmaceutical Use, Environment, Drug Products, Drug Substances Excipients, Packaging Material, Inprocess Bioburden, Inhouse / Readymade Microbiological media and Utilities such as, Steam, Compressed air and Nitrogen.

In-house isolates Database:

A list of all in-house cultures identified which is used to determine “typical”

flora and for periodic review of possible changes in the types of microorganisms being recovered.

Drug Product:

A finished dosage form, such as tablet, capsule or solution that contains a drug substance generally associated with one or more other ingredients.

Drug Substance:

Active pharmaceutical ingredients in a product formulation that are responsible for that Product's therapeutic activity.

Excipients:

Inactive pharmaceutical ingredients in a Product formulation that are responsible for the Manufacturability and physicochemical attributes.

ABBREVIATIONS: Not Applicable

REFERENCES:

Bergey's Manual of Systematic Bacteriology Prokaryotes

Exclusion of Objectionable Microorganisms from Nonsterile Pharmaceuticals, Medical Devices and Cosmetics Technical Report No. 67, 2014 Parenteral Drug Association.