POLICY ON STATUS LABELING

INTRODUCTION:

This document provides the policy for labelling of area, material/products, equipment, containers used in manufacturing and storage for identification and to prevent mix up and cross contamination.

SCOPE:

POLICY DETAILS:

- ♦ There shall be procedure in place for status labelling.
- ♦ Each material/product containers, equipment and area shall be labelled to identify the status.
- ♦ The contents defined in the scope of label shall be written with the required information to demonstrate their current status.
- ♦ Each status label entries shall be legible, initialled and dated by the authorized staff.
- Different colour coded labels shall be used to indicate the status of the material/product. (For example: under test, approved etc.)
- Every equipment and analytical instrument shall have calibration status displayed on it.
- Any equipment or instrument undergoing maintenance shall have label that shall be signed and dated. Any area, material/products, equipment, containers without label shall be investigated.
- ♦ Whenever labels are printed through software, reconciliation of labels shall be done. Change in content of label shall undergo change management procedure.
- ♦ Self inspection shall cover the check points on status labelling.

AMENDMENT AND WAIVER:

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

DEFINITION: Not Applicable

ABBREVIATIONS: Not Applicable

REFERENCES:

Schedule M Eudralex Volume 4