

POLICY ON DATE LOGGER

INTRODUCTION:

This document provides policy for use of data logger for monitoring of temperature during storage and transportation of products.

SCOPE:

This policy is applicable to all products of and its Associated units which need temperature monitoring.

POLICY DETAILS:

- ✧ Written procedure shall be in place for Management of Data Loggers.
- ✧ Data logger shall be placed with the product/consignment which needs temperature monitoring.
- ✧ Data loggers shall be placed based on the requirement in Technical Agreement, Customer, Regulatory, Product requirement or laid down procedure.
- ✧ Data loggers shall be calibrated.
- ✧ Temperature Excursion observed during transit or storage shall be investigated for its impact on product quality and the suitability of product for use.
- ✧ Data from data loggers shall be downloaded as per the laid down procedure.
- ✧ Temperature spikes shall be evaluated on the basis of acceptance criteria provided in the laid down procedures. Data logger and its documentation shall be handled by qualified and trained personnel.

AMENDMENT AND WAIVER:

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

DEFINITION: Not Applicable

ABBREVIATIONS:

USP: United States Pharmacopoeia

REFERENCES:

USP 1079 – Good Storage and Shipping Practices.