POLICY ON STABILITY STUDY

INTRODUCTION:

This document provides the policy for execution of stability studies for the intermediates, drug substance and drug products manufactured to assign, evaluate and establish the retest/ shelf life.

SCOPE:

Applicable to all the products monitored on stability at all ……...

POLICY DETAILS:

- ✧ Stability study shall be performed at the appropriate storage conditions and for predefined time intervals.

  Written procedure shall be in place to execute the stability studies.

- ✧ Stability study shall be performed to ensure that the drug product, drug substance, intermediates manufactured are stable throughout its retest/ shelf life assigned.

- ✧ A stability study shall be executed as per approved protocol.

- ✧ Stability study shall be performed for the predefined numbers of intervals and different storage conditions (temperature and humidity) as below, selected based on the climatic zone in which the drug product / substance will be marketed.

  - Real time storage condition,
  - Accelerated storage conditions.
  - Intermediate storage conditions.

- ✧ Whenever real time stability study is performed at higher temperature and humidity like 30ºC/ 75% RH then study at lower temperature and humidity shall be justified e.g. 25ºC/60% RH or 30ºC/ 65% RH.

- ✧ There shall be predefined detail criteria's for batch selection, number of batches to be kept and tests to be performed for stability.

- ✧ Stability study at intermediate condition shall be initiated whenever study at accelerated condition result shows any failure or as required.

- ✧ Stability specification shall include testing of those attributes that are susceptible to change during storage and are likely to influence quality, safety and / or efficacy of the product.

- ✧ The stability indicative test parameters shall be checked at predefined time points throughout the stability study.

- ✧ Sufficient sample quantity shall be incubated to perform the individual interval analysis as well as the investigations. Sample kept for stability study shall simulate the marketed pack of the respective product.

- ✧ There shall be defined time window for pull out of the stability samples and its analysis. Walk in chamber/ Incubators used for stability study shall be adequately qualified.

- ✧ Justification of temperature excursions shall be based on impact on mean kinetic temperature (Mean kinetic temperature shall be calculated considering 30 days prior to excursion).

- ✧ Wherever the product is packed in the semi permeable containers, the water loss test shall be performed as part of stability study.

- ✧ Microbial testing shall be performed at reduced interval i.e. initial, last interval of accelerated storage condition and at expiry interval of real time storage condition.

- ✧ Preservative Efficacy Test shall be performed on one batch at initial, last interval of accelerated storage condition and at expiry interval of real time storage condition.

- ✧ Each intervals results shall be compared against the previous interval and initial results. Review of ongoing stability programme shall be done at least annually.

- ✧ Monitoring of the critical parameters shall be performed through trending. Bracketing and matrixing approach shall be applied wherever applicable.

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- ✧ Stability study performed at any …….. shall be valid at other units. All such units shall perform a verification stability study.
- ✧ Any significant change or failure to the acceptance criteria shall be investigated as per defined procedure. Failure of routine stability batch shall be reviewed by Stability Review Board.

AMENDMENT AND WAIVER :

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

DEFINITION:

Not applicable.

ABBREVIATIONS:

ICH	:	International Conference on Harmonization
RH	:	Relative Humidity
USP	:	United States Pharmacopoeia
ºC	:	Degree Celsius
%	:	Percentage

REFERENCES :

ICH,Q1A,(R2)	:	Stability testing of new drug substances and products
ICH Q1C	:	Stability testing of new dosage form
USP General Chapter <1150>	:	Pharmaceutical stability