TITLE: HOLDING TIME STUDIES

1.0 PURPOSE:

To lay down the procedure for conducting holding time study of Intermediates.

2.0 SCOPE:

This procedure is applicable for holding time study of Intermediates manufactured at Discovery.

3.0 RESPONSIBILITY:

3.1 Analyst-QC is responsible to follow this SOP.

3.2 Head-QC/Designee is responsible for ensuring implementation of this SOP.

3.3 Head-QA/Designee is responsible for monitoring overall compliance of this SOP.

4.0 DEFINITIONS:

NIL

5.0 PROCEDURE :

5.1 **Basis for holding time study:**

5.1.1 The studies shall be performed to:

- New product
- Significant changes in existing process
- As per Head-QA recommendation

5.1.2 Holding time studies shall be carried based on approved protocol.

5.2 **Holding time study protocol:**

5.2.1 Holding time study shall be conducted for intermediates as per protocol of intermediates a holding time study protocol shall be prepared as per current version of format No QC025-FM091.

5.2.2 Intermediates stored beyond the specific period shall be used only after retesting, performance test and re-approval by Head-QA.

5.2.3 Holding time study protocol shall be prepared by QC personnel, checked by Head-QC/Designee and approved by Head-QA/Designee.

5.2.4 Based on the holding time study protocol QC personnel shall prepare the schedule as per format No. QC025-FM062.

5.3 **Numbering system of the Holding time study protocol as follows:**

HT-AAA-Z-YYNNN

Where,

HT : Holding time study protocol.

AAA : Product Code.

Z : Product Stage.

YY : Last two digits of Calendar Year.

NNN : Serial number.

e.g.: HT-DAH-I-16001

5.4 **Selection of batches:**

Process validation batches and any other batches recommended by QA after consultation with QC and Production shall be selected for holding time study.

5.5 **Sampling and Packing:**

5.5.1 Minimum one batch shall be kept for holding time study.

5.5.2 Twice the quantity of the sample required for single analysis shall be kept to carrying out holding time study.

5.5.3 Quality control personnel shall collect sufficient quantity of sample from approved batch.

5.5.4 Based on the study performed the sample shall be packed in pre labeled, as per prescribed packing condition.

5.5.5 The sample pack shall have label as per format No. QC025-FM064.

5.6 **Monitoring of storage condition:**

Continuous monitoring and recording of temperature and humidity shall be done where applicable.

5.7 **Storage and holding time study samples:**

Holding time study sample shall be stored at prescribed storage conditions.

5.8 **Specification and test procedure:**

The holding time study samples shall be analyzed as per test parameters mentioned in protocol against current specification and test procedure.

5.9 **Analysis of samples:**

5.9.1 QC shall withdraw the sample on due date of analysis.

5.9.2 Holding time study samples shall be analyzed at specific intervals. Any deviation from due date may be allowed +7 days.

5.9.3 Holding time study shall be carried out 12 months or as per recommendation of Head-QA.

5.9.4 Holding time study analysis shall be carried out at intervals 3months, 6months, 9months and 12 months or recommendation of Head-QA.

5.9.5 During holding time study if any adverse changes are observed in physical, chemical parameters of the sample and then the same shall be bring to the attention of Head-QC/ Designee.

5.10 **Evaluation of report:**

5.10.1 Holding time study data shall be reported in the holding time study report as per current version of format no. QC025-FM090.

5.10.2 Holding time study report shall be prepared by QC and shall be approved by Head–QA / Designee at the end of each station.

5.10.3 Evaluation data shall be done at each station.

5.10.4Based on the holding time studies establish the retest period.

6.0 FORMATS / ANNEXURE(S):

6.1 Holding time study inward register : QC025-FM061

6.2 Holding time study schedule : QC025-FM062

6.3 Holding study sample Label : QC025-FM064

6.4 Holding time study Report : QC025-FM090

6.5 Holding time study protocol : QC025-FM091

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	01.10.2010	New SOP is introduced	---
01	13.07.2011	Stability term was replaced	---
02	07.11.2012	1. Incorporate wet material & intermediates Holding time studies procedure. 2. Format change with clear and clarity	---
03	01.01.2014	1. Formats are the part of SOP. So prepared separately. 2. SOP title changed form hold time study to holding studies.	---
04	01.01.2017	1. SOP format changed make to in line with SOP-QA-001-04 2. Holding study inward register and label contents were modified. 3. Holding study report included. 4. Holding study schedule contents were modified. 5. Altogether procedure has been rephrased for better clarity.	QC-CRF-025/16