Title: Hold Time Study			
SOP No.:		**Revision No.:**	00
Effective Date:		**Supersedes No.**	Nil
Review Date:		**Page No.**	1 of 3

1.0 PREPARATION, REVIEW &APPROVAL:

Following personnel are involved in various activities like preparation, review & approval of this SOP.

Name	Department	Function	Designation	Specimen Signature
		SOP Preparation		
		SOP Review		
		SOP Review		
		SOP Approval		

2.0 PURPOSE:

2.1 The purpose of this SOP is to define the documented procedure for hold time study and to define the stability of the product in bulk container before packing.

3.0 SCOPE

3.1 This SOP is applicable for to establish time limit for completion of each phase of the product.

4.0 RESPONSIBILITY:

4.1 **Head Quality Control shall be responsible for:**

4.1.1 To make entry of the sample as per defined procedure.

4.1.2 To analyze the sample as per defined procedure

4.1.3 To send duly filled test requisition cum report to QA department.

4.2 **Head Quality Assurance shall be responsible for :**

4.2.1 To collect the hold time in process samples as per Sampling Protocol.

4.2.2 To send duly filled test requisition cum report to QC department.

4.2.3 To maintain documentation.

4.2.4 To prepare hold time study protocol.

5.0 DISTRIBUTION

5.1 Quality Assurance

5.2 Quality Control

5.3 Production

6.0 DEFINITION & ABBREVIATION(S)

6.1 **Definitions**

6.2 **Hold Time Study**: The time during which the product is stored in the bulk container, prior to packing into the final immediate container, constitutes part of the approved shelf life, i.e., the date of expiry remains a function of the date of manufacture, not the date of packing. Bulk products, which are stored for a period of time prior to packing into the final containers for **25%** or more of the approved shelf life, should be tested, with stability indicating methods, prior to packaging.

6.3 **Abbreviations**

6.3.1 QA : Quality Assurance

6.3.2 QC : Quality Control

6.3.3 SOP : Standard Operating Procedure

6.3.4 BPR : Batch Packing Record

6.3.5 Mfg./Exp. : Manufacturing/ Expiry

6.3.6 WHO : World Health Organization

6.3.7 TRS : Technical Report Series

7.0 PROCEDURE

7.1 QA shall be prepared Hold time study Protocol & Report for each new product launched, as per required and control the Protocol & Report as per the **SOP.**

7.2 Three initial batches are to be considered for hold time study and as per required.

7.3 In this Protocol& Report consider all the intermediate stages as per product considered as per format (for tablet and Capsules), format (for Injection) and format (for Dry powder Injection) for stages to be considered.

7.4 QA shall be responsible for assign the Hold Time Study No. as follows:

HTS/ XXXXX/YY/ZZ

Where:

HTS : Hold Time Study

/ : For Separation

XXXXX : Product Code

YYY : Serial no. for HTS (start from 01 to 99 for every year)

ZZ : represents the revision no.

7.5 Special precautions to be incorporated for each stage of Protocol.

7.6 Store them in process samples in simulated containers as used for routine production under similar conditions as that of manufacturing area.

7.7 All the hold time study samples shall be transfer to QC with Intimation sheet as per format for Testing as per approved specification**.**

7.8 Specification to be followed as per respective test procedure.

7.9 Stage to be considered as per respective batch manufacturing procedure.

7.10 In case of dry powder having two ingredient hold time after blend has to be done as per Hold Time Study Protocol.

7.11 Hold Time Study is also required any change in Storage condition and Process change of the product.

7.12 During routine production if any of the products exceed a holding time, then deviation shall be raised as per **SOP** and the product shall be tested again before final processing.

7.13 The completed hold time study Protocol & report will be archived in Quality assurance department.

8.0 REFERENCE(S) & FORMAT(S):

8.1 **References**

8.1.1 WHO TRS No. 992 : Annexure 4 (General guidelines for Hold Time Study)

8.2 **Formats**

8.2.1 Format- I : Hold time Study Protocol & Report (Tablets & Capsules)

Format- II: Hold time Study Protocol & Report (Liquid Injection)

Format- III: Hold time Study Protocol & Report (Dry Syrup & Dry Powder Injection)

8.2.2 Format IV: Intimation For Analysis of Hold Time Study Samples

9.0 REVISION HISTORY

9.1 Refer SOP for SOP Format-X (Format for Document History Sheet) as attached.