HOLD TIME STUDY PROTOCOL CUM REPORT OF RAW MATERIAL

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1.0 Pre-approval Protocol:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution.

Functional area	Name	Designation	Signature	Date
PREPARED BY				
Validation QA				
REVIEWED BY				
Production Head				
Quality Control Head				
Warehouse Head				
Engineering Head				
Quality Assurance				
APPROVED BY				
QA Head				
Plant Head				

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2.0 OBJECTIVE:

Objective of hold time study is to establish the storage time of raw material with documented evidence.

3.0 SCOPE:

This protocol is applicable for hold time study of raw material used in manufacturing activity.

4.0 RESPONSIBILITY:

QUALITY ASSURANCE:

- Preparation, Execution & reviewing the protocol.
- Collection of the samples as specified in protocol.
- Reviewing the QC result and draw conclusion.

QUALITY CONTROL:

- Reviewing of hold time study protocol.
- Analyzing the hold time study samples as per this protocol and reporting the result.

PRODUCTION:

- Reviewing of hold time study protocol.
- To intimate the collection of sample of hold time study after completion of dispensing.

WAREHOUSE:

- Reviewing of hold time study protocol.
- To dispense the raw material required for hold time study.

ENGINEERING:

- Reviewing of hold time study protocol.
- Maintaining the required environmental condition of the storage area.

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5.0 VALIDATION TEAM TRAINING DETAILS:

Availability of training status and training record of all personnel involved in the validation / assessment exercise should be recorded.

DEPARTMENT	NAME	TRAINING STATUS	SIGNATURE
Quality Assurance			
Quality Control			
Production			
Warehouse			
Engineering			

6.0 VERIFICATION OF INSTRUMENTS FOR CALIBRATION:

S.No.	Instrument Name	Instrument Code	Calibration done on	Calibration due on	Checked by Sign/Date
1	Weighing Balance				

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7.0 REFERENCE OF STANDARD OPERATING PROCEDURE/ DOCUMENTS:

S.No.	SOP/ Document Name	SOP/ Doc. No.
1	SOP for Hold time study of products at different stages	
2	SOP for Microbiological analysis of raw material, finish product and Stability samples	
3	SOP for Incident Reporting and Investigation	
4	SOP for Deviation	
5	SOP for Quality Risk Management	
6	SOP for Handling of out of specification (OOS) results	

8.0 Reference Analytical Method Validation protocol number/ QC Specification no. to be recorded.

Test	Analytical Method Validation Protocol No. / QC specification number	Checked by (Sign/ Date)
Microbiological analysis		

9.0 Raw Material Storage Condition:

9.1 Store the sample dispensed raw material in fresh polybag at a temperature NMT 25^0C and Relative humidity NMT 60%.

9.2 Store the sample of dispensed raw material (moisture sensitive) in fresh polybag at a temperature NMT 25^0C and Relative humidity NMT 40%.

9.2 Store the light sensitive materials in black polybag.

10.0 HOLD TIME STUDY PROCEDURE:

10.1 Selection of Raw material: Raw material shall be selected based on its nature and scientific rationale.

10.2 Dispensed Raw Material Details:

The raw materials used in the manufacturing of the batches selected for Hold Time Study shall be tested, analyzed and approved before use in the production as per their respective approved specifications. Details of the raw material shall be recorded in the report as shown below in the table.

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10.2 SAMPLING SIZE, PLAN AND FREQUENCY:

Hold time study samples of raw materials shall be collected as per below mentioned quantity:

Sampling Plan for Dispensed Raw Material Hold Time Study				
S.No.	**Storage Time**	**Test Parameters**	**Quantity of Sample**	**Acceptance Criteria**
1	Initial (0)	a) Appearance b) Microbial test	20 gm for every storage time Total quantity: 60 gm	QC Test
2	5th Day	a) Appearance b) Microbial test		
3	10th Day	a) Appearance b) Microbial test		

11.0 Result/ Observation:

Test Parameters of Raw Material						
Raw Material Details				**Time (Day) Interval**	**Appearance**	**Microbial Test**
Name	**Item Code**	**A.R. No.**	**Vendor Name**			
				Initial (0)		
				5th Day		
				10th Day		
				Initial (0)		
				5th Day		
				10th Day		
				Initial (0)		
				5th Day		
				10th Day		
				Initial (0)		
				5th Day		
				10th Day		

PHARMADEVILS

QUALITY ASSURANCE DEPARTMENT

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Test Parameters of Raw Material					Appearance	Microbial Test
Raw Material Details				Time (Day) Interval		
Name	Item Code	A.R. No.	Vendor Name			
				Initial (0)		
				5th Day		
				10th Day		
				Initial (0)		
				5th Day		
				10th Day		
				Initial (0)		
				5th Day		
				10th Day		
				Initial (0)		
				5th Day		
				10th Day		
				Initial (0)		
				5th Day		
				10th Day		
				Initial (0)		
				5th Day		
				10th Day		
				Initial (0)		

PHARMADEVILS

QUALITY ASSURANCE DEPARTMENT

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Test Parameters of Raw Material						
Raw Material Details				Time (Day) Interval	Appearance	Microbial Test
Name	Item Code	A.R. No.	Vendor Name			
				Initial (0)		
				5th Day		
				10th Day		
				5th Day		
				10th Day		
				Initial (0)		
				5th Day		
				10th Day		
				Initial (0)		
				5th Day		
				10th Day		
				Initial (0)		
				5th Day		
				10th Day		
				Initial (0)		
				5th Day		
				10th Day		
				Initial (0)		
				5th Day		

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Test Parameters of Raw Material						
Raw Material Details				Time (Day) Interval	Appearance	Microbial Test
Name	Item Code	A.R. No.	Vendor Name			
				Initial (0)		
				5th Day		
				10th Day		
				10th Day		
Limit ⟹				As per QC Specification No.: _____ _____		

12.0 Acceptance criteria:

Acceptance criteria for each raw material shall be as per the respective Quality Control specification for individual raw material.

13.0 Details of Deviation / Non Compliance / OOS:

14.0 Risk management study (if any):

15.0 Summary of the study activity:

16.0 Recommendation:

17.0 Attachments:

Attachment No.	Title of Attachment

18.0 Abbreviations:

SOP: Standard operating procedure

OOS: Out of specification

QC: Quality Control

QA: Quality Assurance

No.: Number

Qty.: Quantity

Sr. No.: Serial number

g: Gram

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19.0 Review and Post approval:

Functional area	Name	Designation	Signature	Date
PERFORMED BY				
Validation QA				
Quality Control				
Production				
Warehouse				
Engineering				
Quality Assurance				
APPROVED BY				
QA Head				
Plant Head				