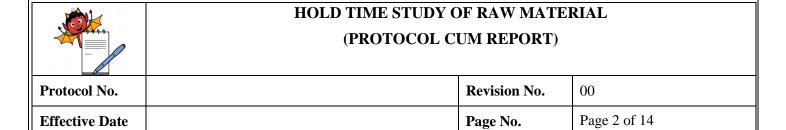
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HOLD TIME STUDY OF RAW MATERIAL



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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							
	F	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 at

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.
- Analysing 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 poly bag at a temperature NMT 25°C and Relative humidity NMT 60%.
- 9.2 Store the sample of dispensed raw material (moisture sensitive) in fresh poly bag at a temperature NMT 25°C and Relative humidity NMT 40%.
- 9.2 Store the light sensitive materials in black poly bag.

10.0 HOLD TIME STUDY PROCEDURE:

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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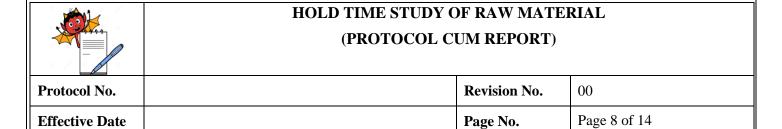
10.2 SAMPLING SIZE, PLAN AND FREQUENCY:

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

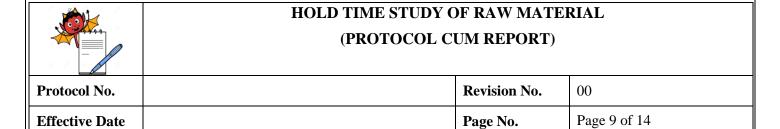
Sampling Plan for Dispensed Raw Material Hold Time Study					
S.No.	Storage Time	Test Parameters	Quantity of Sample	Acceptance Criteria	
1.	Initial (0)	a) Appearanceb) Microbial test	20 gm for every storage time	QC Test	
2.	5 th Day	a) Appearanceb) Microbial test	Total quantity: 60 gm		
3.	10 th Day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

11.0 Result/Observation:

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



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



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

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	Test Paran	neters of Raw N	A aterial						
	Raw Material Details				Time		Appeara	nce	Microbial Test
	Name	Item Code	A.R. No.	Vendor Name	(Day Inter				Test
					Initia	al (0)			

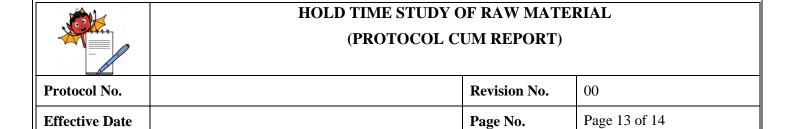
	Raw Material Details			Time	Appearance	Microbial
Name	Item Code	A.R. No.	Vendor Name	(Day) Interval		Test
				Initial (0)		
				5 th Day		
				10 th Day		
				10 th Day		
				Initial (0)		
				5 th Day		
				10 th Day		
Limit =	⇒			As per QC	Specification No.:	

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:
•	

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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

S.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								