HOLD TIME STUDY PROTOCOL

CUM REPORT

FOR

OINTMENTS

PROTOCOL NO.	
SUPERCEDES	Nil
PROTOCOL EFFECTIVE DATE	
REPORT EFFECTIVE DATE	

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1.0 PROTOCOL PREAPPROVAL

PROTOCOL PREPARED BY:

DEPARTMENT	NAME	DESIGNATION	SIGNATURE	DATE
QUALITY ASSURANCE				

PROTOCOL REVIEWED BY:

DEPARTMENT	NAME	DESIGNATION	SIGNATURE	DATE
PRODUCTION				
QUALITY CONTROL				

PROTOCOL APPROVED BY:

DEPARTMENT	NAME	DESIGNATION	SIGNATURE	DATE
QUALITY ASSURANCE				

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1.0 Objective:

The objective of this protocol is to study the effect of "Hold Time" on the bulk of …….. to verify that during the hold period, the Product shall meet predetermined quality specifications. The protocol also details the responsibilities and activities associated with this Hold Time Study.

2.0 Introduction:

The Samples of …… subjected to Hold Time Study shall be stored under simulated conditions and shall be analyzed as per the established specifications at different time points of study as specified.

Analytical methods for testing of bulk of ……. have been satisfactorily adopted into the QC laboratory.

On completion of the study, a report shall be prepared and final conclusion shall be drawn in the same. It shall be implemented in routine manufacturing. This document shall form the basis of the production scale batches. Any variation to the established Hold Time shall be explained and justified, in accordance with the change control procedure.

3.0 RESPONSIBILITIES:

S.No	Department	Responsibilities
01	Production	Review of Hold time study protocol and Report
02	Quality Control	Review of Hold time study protocol & report Analysis of samples and reporting the results
03	Quality Assurance	Preparation, Review & Approval of Hold time study protocol & report, Sampling and compilation of results

4.0 PROCEDURE:

4.1 Bulk hold time study:

Test the sample from the bulk from the three batches at Zero (0) time point. Store sample from three batches for a period of specific time period given different process stage under simulated conditions at Temp. NMT 27°C and Relative humidity NMT 50 %.

S.No	Name of stage	Sample Qty. Required for hold time study
01	Ointment Bulk	0.200 kg

Section 5.0 (Matrix for Hold Time Study).

Acceptance criteria:

Bulk sampled at different time points shall meet the acceptance criteria as mentioned in Table No. 1.

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5.0 Matrix for hold time study

5.1.1 Matrix for hold time study of Bulk stage

Storage Time	Sample Quantity for testing	Tests to be performed
Type of Sample: Binder Solution		
Initial	20 gm +10 gm (Chemical + microbiological sample)	Description , pH Value ,Wt.Per ml ,Assay & Microbiological testing
12 Hours	20 gm +10 gm (Chemical + microbiological sample)	Description , pH Value ,Wt.Per ml ,Assay & Microbiological testing
24 Hours	20 gm +10 gm (Chemical + microbiological sample)	Description , pH Value ,Wt.Per ml ,Assay & Microbiological testing
36 Hours	20 gm +10 gm (Chemical + microbiological sample)	Description , pH Value ,Wt.Per ml ,Assay & Microbiological testing
48 Hours	20 gm +10 gm (Chemical + microbiological sample)	Description , pH Value ,Wt.Per ml ,Assay & Microbiological testing
72 Hours	20 gm +10 gm (Chemical + microbiological sample)	Description , pH Value ,Wt.Per ml ,Assay & Microbiological testing

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5.1.2: specifications for Bulk stage

S.No.	Tests	Limits
01	Description	
02	pH Value	
03	Wt. per ml	
04	Assay	
Additional Test		
05	Microbial limit test	
	A. Total viable aerobic count	
	Aerobic bacteria	NMT 10^2 cfu/gm
	Fungi	NMT 10^1 cfu/gm
	B. Pathogens	
	1. *E. coli*	Absent

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6.0 Deviation and Change Control:

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7.0 Summary and Conclusion:

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8.0 Reference :.

ICH,FDA,EMEA and Annexure IV WHO TRS 992

9.0 Abbreviation:.

S.No	Abbreviation	Extended Form
01	SOP	Standard Operating Procedure
02	HTSP	HOLD Time Study Protocol
03	LOD	Loss on Drying

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10.0 REPORT POSTAPPROVAL

COMPILED BY:

DEPARTMENT	NAME	DESIGNATION	SIGNATURE	DATE
QUALITY ASSURANCE				

REVIEWED BY:

DEPARTMENT	NAME	DESIGNATION	SIGNATURE	DATE
PRODUCTION				
QUALITY CONTROL				

APPROVED BY:

DEPARTMENT	NAME	DESIGNATION	SIGNATURE	DATE
QUALITY ASSURANCE				

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ANNEXURE I

RESULTS OF BULK STAGE

BATCH NO.		**MFG. DATE**	
BATCH SIZE		**EXP. DATE**	

S.No.	Tests	Limits	0 hours (Initial)	12 Hours	24 Hours	36 Hours	48 Hours	72 Hours
01	Description							
02	pH Value							
03	Wt. per ml							
04	Assay							
Additional Test								
05	Microbial limit test							
	A. Total viable aerobic count							
	Aerobic bacteria	NMT 10^2 cfu/g						
	Fungi	NMT 10^1 cfu/g						
	B. Pathogens							
	1. E. coli	Absent						

Compiled By_____ **Reviewed By**_____