CHANGE CONTROL FORM

Change Control No.	

Note: Attach additional sheets wherever required

1. Proposal for Change: *(To be filled by Initiator)*

Initiator's Name		Dept.	
Date		Location/site	
Tick ✔ as applicable	☐ Temporary change	☐ Permanent change	
Short description of the change			
Product/ Material and Batch No.			
Scope/ Market		Customer	

Type of Change (Tick ✔ as applicable)	☐ Facility ☐ Document ☐ Material ☐ Formulation ☐ Equipment ☐ other if any_____

Current Status:
Proposed Changes:
Reason/ Justification for Change : (Provide the supporting data)

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2. Assessment of the change*(To be filled by Initiator)*

Sr. No.	Impact of Change On	Yes / No	Document number(If any)	Remark
2.1	**Facility**			
	Modification/renewal			
	Design and Construction			
	Layout , P& ID			
	Qualification			
2.2	**Document** (Note: Supersede documents to be invalidated prior to issuance of the revised document)			
	SOP's			
	Formats			
	Master lists			
	SMF			
	VMP			
	MFR			

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Note: Attach additional sheets wherever required

Sr. No.	Impact of Change On	Yes / No	Document number(If any)	Remark
	BMR			
	MPR			
	BPR			
	Specification/ Test Protocol			
	Training			
	Stability Protocol			
2.3	**Material**			
	New vendor/ additional mfg. site			
	Item Code Generation			
	Artwork			
	Approved Vendor List			
	Specification			
	Method of Analysis			
2.4	**Formulation**			
	Process Validation			
	Cleaning validation			
	Hold time study			
	Stability			
2.5	**Equipment/ Instrument**			
	New/ modification			
	Qualification (IQ, OQ, PQ)			
	Equipment ID			
	Calibration			
	PM schedule			
	Cleaning Validation			
	Assessment for CSV			
2.6	**Other Impact (If any)**			

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Risk Analysis for the change :

Are additional sheets attached? Yes ☐ No ☐. Provide details of no. of pages on last page change control form

Initiators sign		Date	
Concurrence from Department Head			
Dept. Head sign		Date	

CHANGE CONTROL FORM

Change Control No.	

Note: Attach additional sheets wherever required

3. Review by Change Control Coordinator (QA):

Is the data provided adequate for assessment of the change	Yes ☐ No ☐
Is the section 1 and 2 complete and correct	Yes ☐ No ☐
Is effectiveness check required	Yes ☐ No ☐
If no specify reason:	
Category of Change (Tick ✔ as applicable)	☐ **Major** (Definition: Any change in the product, production process, quality controls, equipment, facilities, or responsible personnel that have a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product).
	☐ **Minor** (Definition: Any Changes in the product, production process, quality controls, equipment, facilities, or responsible personnel that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness).

3.1 Impact assessment required from (Tick as per the requirement except initiating dept.)**:**

Quality Control Department	Yes ☐ No ☐	Regulatory Affairs	Yes ☐ No ☐
Manufacturing Department	Yes ☐ No ☐	Formulation Research & Development	Yes ☐ No ☐
Packaging Department	Yes ☐ No ☐	Analytical Research & Development	Yes ☐ No ☐
Warehouse Department	Yes ☐ No ☐	Packaging development	Yes ☐ No ☐
Engineering Department	Yes ☐ No ☐	Information Technology Department	Yes ☐ No ☐
Purchase	Yes ☐ No ☐	Marketing	Yes ☐ No ☐
Artwork	Yes ☐ No ☐	Planning	Yes ☐ No ☐
Human Resource & Admin	Yes ☐ No ☐	Technology transfer	Yes ☐ No ☐
Customer/ QP approval	Yes ☐ No ☐	Quality Assurance	Yes ☐ No ☐
Customer to be informed	Yes ☐ No ☐	Corporate Quality Assurance Department	Yes ☐ No ☐
Other (Please specify)			

Change Control Coordinator	Name		Sign		Date	

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4. Impact assessment/Actions identified(*To be filled By the Dept. HOD/SME identified in above table)*

Reviewer's Name:		**Dept.**	**Quality control**
☐**Acceptable** ☐**Not Acceptable**	**Sign**		**Date**

Reviewer's Name:		**Dept.**	**Manufacturing**
☐**Acceptable** ☐**Not Acceptable**	**Sign**		**Date**

Reviewer's Name:		**Dept.**	**Packaging**
☐**Acceptable** ☐**Not Acceptable**	**Sign**		**Date**

CHANGE CONTROL FORM

Change Control No.	

Note: Attach additional sheets wherever required

Reviewer's Name:			Dept.	Warehouse
☐Acceptable	☐Not Acceptable	Sign		Date

Reviewer's Name:			Dept.	Engineering
☐Acceptable	☐Not Acceptable	Sign		Date

Reviewer's Name:			Dept.	Purchase
☐Acceptable	☐Not Acceptable	Sign		Date

Reviewer's Name:			Dept.	Artwork
☐Acceptable	☐Not Acceptable	Sign		Date

Reviewer's Name:			Dept.	Human Resource & Admin department
☐Acceptable	☐Not Acceptable	Sign		Date

Reviewer's Name:			Dept.	Formulation Research & Development
☐Acceptable	☐Not Acceptable	Sign		Date

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Reviewer's Name:			Dept.	Analytical Research & Development
☐Acceptable	☐Not Acceptable	Sign		Date

Reviewer's Name:			Dept.	Packaging development
☐Acceptable	☐Not Acceptable	Sign		Date

Reviewer's Name:			Dept.	Information Technology department
☐Acceptable	☐Not Acceptable	Sign		Date

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Change Control No.	

Note: Attach additional sheets wherever required

Reviewer's Name:			**Dept.**	**Marketing**	
☐**Acceptable**	☐**Not Acceptable**	**Sign**		**Date**	

Reviewer's Name:			**Dept.**	**Planning**	
☐**Acceptable**	☐**Not Acceptable**	**Sign**		**Date**	

Reviewer's Name:			**Dept.**	**Technology Transfer**	
☐**Acceptable**	☐**Not Acceptable**	**Sign**		**Date**	

Reviewer's Name:			**Dept.**	**Plant head**	
☐**Acceptable**	☐**Not Acceptable**	**Sign**		**Date**	

Reviewer's Name:			**Dept.**	**Quality Assurance**	
☐**Acceptable**	☐**Not Acceptable**	**Sign**		**Date**	

Reviewer's Name:			**Dept.**	**Site Training Coordinator**	
☐**Acceptable**	☐**Not Acceptable**	**Sign**		**Date**	

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Reviewer's Name:			**Dept.**	**(Any other)**_____	
☐**Acceptable**	☐**Not Acceptable**	**Sign**		**Date**	

Regulatory Approval
Impact of the proposed change over the submission:
Regions/ country impacted:
Type of variation required: (Tentative date for required for approval)
Validation requirement:

CHANGE CONTROL FORM	
Change Control No.	

Note: Attach additional sheets wherever required

Stability requirement:
Documentation requirement:
When can be the change implemented at Site:
Revision of Registered product details (RPD) required/ Not required:
Other comments (if any):

☐**Acceptable** ☐**Not Acceptable**	**Sign**		**Date**	

5. Compilation of actions for Change implementation: *(To be filled by change control coordinator)*

Reviewer by change control coordinator prior to compilation of actions	
Is impact assessment from all required dept. completed?	Yes ☐ No ☐
Is regulatory approval available?	Yes ☐ No ☐ NA ☐
Are all comments reviewed and found appropriate?	Yes ☐ No ☐ NA ☐

Sr. no.	Actions	Responsibility	Target completion date	Completion date	Sign/ Date (after completion)

Overall target completion date:
***TCDfor complete changes 90 days or based on TCD defined in above section** ****TCD for CCF initiated against CAPA, should have the TCD of CAPA.**

Change Control Coordinator sign		**Date**	

Approval by Head-QA/ Designee		**Name:**	
Is overall assessment of change control form appropriate?		Yes ☐ No ☐	
Are all action items captured for implementation?		Yes ☐ No ☐	
☐**Approved** ☐**Rejected**	**Sign**		**Date**

Approval by Head-CQA/ Designee		**Name:**	
☐**Approved** ☐**Rejected**	**Sign**		**Date**

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CHANGE CONTROL FORM

Change Control No.	

Note: Attach additional sheets wherever required

CCF sent for Customer/QP approval/ Notification on date	

Customer/ QP Approval (Mandatory for all product related major change controls)					
Does the change have any impact over the existing TA?Yes ☐ No ☐					
Does the change have any impact over the existing MA?Yes ☐ No ☐					
Reviewer's Name			**Designation**		
☐**Approved** ☐ **Rejected**		**Sign**		**Date**	

6. Addendum for additional changes:

Addendum attached for additional actions: ☐Yes ☐No
Addendum no:

7. Closure(to be completed by the initiating dept)**:**

All Actions completed as per section 5☐Yes ☐No
Actions partially completed ,if any (Please mention):
Reason for partial completion of actions:
All Actions completed as per addendum ☐Yes ☐No ☐NA
Does the implementation of the change/s had any deleterious impact over the product quality ☐Yes ☐No☐NA

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8. CCF rejection/ cancellation:				
CCFrejected/ cancelled		Yes ☐	No ☐	
Reason for rejection/ cancellation:				
Site QA head/ CQA/Designee	**Sign**		**Date**	

9.Closure comments:				
Initiator	**Sign**		**Date**	
Department head	**Sign**		**Date**	

CHANGE CONTROL FORM

Change Control No.	

Note: Attach additional sheets wherever required

Review and Closure by QA:					
Closed within the timeframe	☐ Yes	☐No			
Extension form filed-1	☐ Yes	☐No	☐NA		
Extension form filed-2	☐ Yes	☐No	☐NA		
Quality Risk assessment complete	☐ Yes	☐No	☐NA		
Effectiveness check required	☐ Yes	☐No	☐NA		
Change control form closed	☐ Yes	☐No			
Change control Coordinator		Sign		Date	

10. : Review of effectiveness check of implemented changes:				
Site QA head/ CQA/Designee	Sign		Date	

Attachment/ Annexure no.	List of Annexure/ Attachments(Attach all supporting documents including e- mail communications)	Number of pages
	Total No. of pages.	

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