

CHANGE CONTROL FORM

CCR No		DATE OF INITIATION	
<i>PART-I: INITIATION OF CHANGE CONTROL</i>			
<i>(Section 1.0)</i> Initiator Department	<input type="checkbox"/> Production <input type="checkbox"/> Engineering & Utility <input type="checkbox"/> PDL <input type="checkbox"/> Purchase <input type="checkbox"/> Quality Control <input type="checkbox"/> Quality Assurance <input type="checkbox"/> Warehouse <input type="checkbox"/> Others <input type="checkbox"/> Personnel & Adm. <input type="checkbox"/> Safety <input type="checkbox"/> Packaging Development		
<i>(Section 2.0)</i> Change Requested for	<input type="checkbox"/> Documented procedure <input type="checkbox"/> Facility <input type="checkbox"/> Equipment <input type="checkbox"/> Process <input type="checkbox"/> Software Specify _____		
<i>(Section 3.0)</i> Details of Change(s) (Proposed)			
<i>Attach supporting document as applicable based on the change proposed</i>			
<i>(Section 4.0)</i> Reason for change (s)			
<i><u>(Section 5.0) Documents Affected by the Change</u></i>			
S.No.	Document No.	Document Title.	Effective Date
1			
2			
3			
<i>(Section 6.0)</i> Temporary Change Period (upto) _____		<i>(Section 7.0)</i> Permanent Change	
<i>Tick whichever is applicable & if temporary, specify the period</i>			
<i>(Section 8.0)</i> Tentative date of Implementation		<i>(Section 9.0)</i> Write B. No if applicable	
<i>(Section 10.0)</i> Request for the document nature	<input type="checkbox"/> To be Amended <input type="checkbox"/> To be Cancelled		

CHANGE CONTROL FORM

	CHANGE INITIATED BY <i>(Representative of initiating department)</i>	AUTHORIZED BY <i>(Head/Deputy of initiating department)</i>
NAME		
SIGN		
DATE		

PART-II (A) CHANGE CONTROL CONSENT & REVIEW

<i>(Section 11.0)</i> Consent of other Departments (write NA if not applicable)			
Department	Review Comments <i>(Attach additional sheet for more details if required)</i>	Change Accepted/ Not accepted	Reviewed by (HOD/Deputy)

PART-II (B) CHANGE CONTROL ASSESSMENT BY QA

Scope of Change <i>(Tick whichever is applicable)</i>	<input type="checkbox"/> C01 <input type="checkbox"/> C02 <input type="checkbox"/> C03 <input type="checkbox"/> C04 <input type="checkbox"/> C05
--	--

<i>(Section 12.0)</i> Level of change <i>(Tick whichever is applicable)</i>	Type-A: Minor changes who do not have any detectable impact on the quality attributes of the product and having no regulatory impact	<input type="checkbox"/>
	Type-B: Changes that are likely or may have minor impact on the quality attributes of the product and requires intimation to registration agency.	<input type="checkbox"/>
	Type -C: Changes that are having significant impact on the quality attributes of the product and requires pre-approval from the registration agency.	<input type="checkbox"/>

CHANGE CONTROL FORM

<i>(Section 13.0) QA Assessment checklist</i>				
S.No.	Document type	Review	Existing Ref No	Revised Ref No
1	SOP	<input type="checkbox"/> Yes <input type="checkbox"/> No		
2	GTP/STP/ Specification	<input type="checkbox"/> Yes <input type="checkbox"/> No		
3	Master Formula Record	<input type="checkbox"/> Yes <input type="checkbox"/> No		
4	Batch Processing & packaging record	<input type="checkbox"/> Yes <input type="checkbox"/> No		
5	Validation Protocol /Validation Master Plan	<input type="checkbox"/> Yes <input type="checkbox"/> No		
6	Stability Protocol	<input type="checkbox"/> Yes <input type="checkbox"/> No		
7	Site Master File	<input type="checkbox"/> Yes <input type="checkbox"/> No		
8	Formats (Specify)	<input type="checkbox"/> Yes <input type="checkbox"/> No		

<i>(Section 14.0) Action to be carried out for the proposed change</i>		
Action	Details	Proposed Time frame
Qualification (DQ /IQ/OQ/PQ)		
Validation (Process/Cleaning/Others) specify		
Action	Details	Proposed Time frame
Stability study –specify no. of batches & batch no to be kept in stability		
Training		
Drawing (pre-approval/notification to registration body/business partner/key customer(s))		
Prior approval/information/Notification to regulatory body/business partner/key customer(s)/Internal information to other departments /corporate Regulatory Affairs		
Information to Annual update		
Change effected & intimation to registration body		

	CHANGE EVALUATED BY <i>(Representative of QA department)</i>	
NAME		
SIGN		
DATE		

REGULATORY AFFAIRS DEPARTMENT ASSESSMENT & APPROVAL FOR CHANGE
<i>Only applicable for Type -B & Type-C changes</i>

CHANGE CONTROL FORM

<p><i>(Section 15.0)</i> Review Comments</p>	
--	--

Change Requires	<input type="checkbox"/> Pre-approval supplement	<input type="checkbox"/> Change being effect supplement
-----------------	--	---

Conclusion	<input type="checkbox"/> Approved	<input type="checkbox"/> Not Approved
-------------------	-----------------------------------	---------------------------------------

	EVALUATED BY FROM REGULATORY AFFAIRS	APPROVAL FROM REGULATORY AFFAIRS <i>(HOD/Deputy of RA department)</i>
NAME		
SIGN		
DATE		

PART-III: FINAL APPROVAL OF CHANGE CONTROL BY QA

(Section 16.0) Approval checklist

S.No.	Action	Check point		
1	Whether all related documents are drafted and evaluated.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
2	Whether all actions proposed are taken.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
3	All related departments are intimated.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA

<i>(Section 17.0) Change Approval</i> <i>(Put tick which ever applicable)</i>	Approved		Not Approved	
Head of QA Department				
Name	Signature	Date		

PART-IV: MONITORING & CLOSING OF CHANGE CONTROL

(Section 18.0) Approval checklist

S.No.	Action	Check point		
1	Whether all applicable documents are revised, distributed and implemented	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
2	All the superseded documents are retrieved, made obsolete and destroyed.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA

CHANGE CONTROL FORM

3	The change is implemented as proposed.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
4.	Old system is practiced after the recommended period of temporary changes (applicable only for temperature change)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
5.	Training is completed and evaluated to all concerned	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
6.	The qualification /validation/stability as applicable is initiated as recommended	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA
7.	Others, Specify _____	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> NA

	CHANGE MONITORED BY <i>(Document change control incharge)</i>	CHANGE CLOSED BY <i>(Head-Quality Assurance)</i>
NAME		
SIGN		
DATE		