	Reference SOP NO. : QA-XXX/NN
Company Name	**Company Logo**

Change Control Form

1) Do not retain this form and forward to the next after completion of review.
2) Put N/A where not applicable.
3) Attach an additional sheet if required as annexure.
4) Please specify the details in case of "others".

Name of Initiating Department :

Put a √ on area affected and X mark if not.

Change requested for: **Temporary change:** ☐ **Permanent change:** ☐

Manufacturing Process	☐	Specification	☐
Equipment	☐	Analytical Instrument	☐
Instrument	☐	Analytical Method	☐
Facility (Building / Layout)	☐	Service pipelines	☐
Utilities	☐	SOP / Formats	☐
Raw Material/Packing Material	☐	Any other	☐

Document No. :

Existing System :

Proposed Changes :

Reason / Justification for Change :

Reference / Supporting Data (If Applicable) :

Change Implementation Details:

Tentative Implementation Date: From Batch No. :

	Prepared By	**Checked By**	**Approved By**
Name			
Designation			
Signature			
Date			

Issued by : (Sign/date)	Copy No. :

	Reference SOP NO. : QA-XXX/NN
Company Name	**Company Logo**

Change Control Form

Initiator Name :	Designation :	Sign/ Date :
Concurrence From Department Head :		
Name :	Designation :	Sign/ Date :
Initial Assessment By Quality Assurance Department :		
Change Control No. : CC-XXX-NNN/YY *		Assigned By (Sign/ Date):
Proposed Document No.:		Revision No.:
(Put √ mark in the block provided with department Name if assessment required and if not then put X mark in a box provided.		
Name :	Designation :	Sign/ Date :
Impact Assessment By Quality Control : ☐		
Name :	Designation :	Sign/ Date :
Impact Assessment By Regulatory Affairs : ☐		
Name :	Designation :	Sign/ Date :
Impact Assessment By Engineering & Utility : ☐		
Name :	Designation :	Sign/ Date :

	Prepared By	**Checked By**	**Approved By**
Name			
Designation			
Signature			
Date			

Issued by : (Sign/date)	Copy No. :

Reference SOP NO. : QA-XXX/NN	
Company Name	**Company Logo**

Change Control Form

Impact Assessment By Production : ☐		
Name :	Designation :	Sign/ Date :
Impact Assessment By Stores (RM & FP) : ☐		
Name :	Designation :	Sign/ Date :

Impact Assessment By Personnel & Administration : ☐		
Name :	Designation :	Sign/ Date :
Impact Assessment By Environment Health & Safety : ☐		
Name :	Designation :	Sign/ Date :
Impact Assessment By Others : ☐		
Name :	Designation :	Sign/ Date :
Impact Assessment By Quality Assurance: Are the changes likely to affect the following? (Put √ mark if yes and X mark if not)		

	Prepared By	Checked By	Approved By
Name			
Designation			
Signature			
Date			

Issued by : (Sign/date)	Copy No. :

	Reference SOP NO. : QA-XXX/NN
Company Name	**Company Logo**

Change Control Form

Training status		GMP / regulatory requirements	
Validation Status		Changes are to be inform to drug authorities/ Regulatory authorities	
Qualification Status		Changes are to be informed Customer	
Stability of product		Others	

Category of Change : Major ☐ **Minor** ☐

Comment from Quality Assurance :

Action to be Taken :

Name : Designation : Sign/ Date :

Approval By Head Quality Operations :

Comment:

Changes are Approved /Not Approved.

Name : Sign/ Date :

POST IMPLEMENTATION REVIEW

Comment from head initiating department:

Name : Sign/ Date :

	Prepared By	**Checked By**	**Approved By**
Name			
Designation			
Signature			
Date			

Issued by : (Sign/date)	Copy No. :

	Reference SOP NO. : QA-XXX/NN
Company Name	**Company Logo**

Change Control Form

Review of compliance to planned actions by Quality Assurance : Comment:		
Change is approved as temporary change / permanent change.		
Change need to make permanent. / not needed to make permanent.		
Name :	Designation :	Sign/ Date :
CLOSURE OF CHANGE CONTROL		
Changes Effective Date :	Batch No.:	
Revised Document Name :	Revised Document No.:	
Comment:		
Name :	Designation :	Sign/ Date :
Regulatory submission / Notification detail:		
Name :	Designation :	Sign/ Date :

* Where CCT stands for Temporary Change Control & CCP stands for Permanent CC,

XXX stands for Dept. Code, for ex. QA, QC, PRD, ADM, WH etc.

NNN stands for sequential no. of change control

YY stands for last two digits for the current year, for ex. 19 for 2019

	Prepared By	**Checked By**	**Approved By**
Name			
Designation			
Signature			
Date			

Issued by : (Sign/date)	Copy No. :