ANNEXURE 3

TEMPORARY CHANGE /PLANNED DEVIATION FORM

SECTION A:

Deviation No.				Date of issuance	
Applicable to	☐ Area ☐ Utility ☐ Product ☐ System ☐ Document ☐ Equipment ☐ Material ☐ Instrument ☐ Other			T.C.D.	
				Ext. I	
Title of Change				Ext. II	
Product / material / Document / Instrument/ Equipment/ Area/Utility /Other		Reference Batch No./ AR No. / Doc. No./ Equipment ID /Instrument ID/Area		Name of mfg. block/ Area	
Product Stage		Associated product/ area/ equipment		Number of Batches involved	
Previous change control form No.(if any)					
Initiated By (Name)		Logged By QA (Name)			
Department					
CHANGE DETAILS					
Existing system					
Proposed change					

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Deviation No.

Reason/Justification			
Root Cause for planned deviation			
CAPA details			
Initiated by (Sign & Date)		Approved by HOD/Designee (Sign & Date)	

SECTION B:

IMPACT ANALYSIS				
Items	Impact (Yes/No)	Task No.	Recommendation of Impacted Dept. HOD/ Designee	Concerned HOD (Sign & Date)
Process				
Quality Parameter				
Calibration Schedule				
Stability				
Process Validation				
Cleaning Validation				
Training				

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Deviation No.

Information (As per annexure 7)				
Hold time Sampling				
Regulatory Approval				
Mfg. product Lic./COPP				
Marketing Approval				
DCGI				
Product list				
Cleaning/ Passivation/ Sanitation				
Preventive Maintenance Schedule				
Equipment / Instrument Master List				
Layout/ Drawing/ Diagram				
Segregation of the Area/ Caution Display				
Items	Impact (Yes/No)	Task No.	Recommendation of Impacted Dept. HOD/ Designee	Concerned HOD (Sign & Date)
Utility Impact				
Spec./ATP (RM, PM,FP, stability)				
MBMR / Mfg. BOM				
MBPR / Pkg. BOM				
SOP / Protocol				
LIMS / METIS/SAP				
Qualification				
Calibration				

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Deviation No.

Packing Material/ Pack style				
Change parts / tooling				
Artwork				
Rejection / Destruction				
Price, equipment list				
E.H.S.(If yes annexure)				
Risk Assessment				
Cross function investigation report				
CAPA				
MSTG/FDD Comment				
Any Other				
Dep. Head (Sign & Date)				
Impact Analysis Review by QA Head /Designee (Sign and Date)				

Notification	Comment	Sign & Date
Plant Head		

SECTION C:

APPROVAL FOR EXECUTION
To be filled by QA Head/Designee
☐ Approved ☐ Rejected **Deviation Category :**

Approved By	Comment	Sign & Date
Department Head / Production Head		
Q.A. Head		
Site Quality Head		

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SECTION D:

ACTION ITEM CLOSURE DETAILS				
Task No. Number	Task No. Completion Date	Initiator/Designee Sign and Date	Reference Document Details	Reviewed By QA Sign and Date
Task No. Number	Task No. Completion Date	Initiator/Designee Sign and Date	Reference Document Details	Reviewed By QA Sign and Date

TASK NUMBER CLOSURE EVALUATION		
Department	**Comments**	**Sign & Date**
Department Head		

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Quality Assurance		

SECTION E:

IMPLEMENTATION AND CHANGE CLOSURE DETAILS	
☐ **Change implemented** ☐ **Change not implemented**	
Closure comments:	
Checked by QA Head (Sign & Date)	**Approved by Site Quality Head (Sign & Date)**
Deviation closure status: ☐ **Closed** ☐ **Not implemented**	**Sign and Date**

SECTION F:

POST CHANGES AND EFFECTIVENESS MONITORING DETAILS				
Mode : APQR / Protocol / Self Inspection / CAPA		**Reference Tracking No.:**		
		Target Date		
		Date & Sign		
Date	Observation	Final conclusion	Ref. Doc. No.	Checked by Sign and Date

ANNEXURE 3

TEMPORARY CHANGE /PLANNED DEVIATION FORM
Deviation No.

Associated documentation along with file attachment:

1.
2.
3.
4.
5.