DEVIATION APPROVAL FORM

Deviation No.	

Note: Attach additional sheets if required

Initiator		**Location/site**	
Date of Reporting		**Department**	
Product/Material			
Scope/Market		**Customer**	
Batch No./Lot No.			
Date of discovery		**Time of discovery**	
Stage of processing of product			

1. Description of Deviation : (To be filled by initiator)			
Initiator sign		**Date**	

2. Immediate action taken: (To be filled by responsible department)

3. Risk & impact assessment for deviation (To be filled by responsible department)

Responsible person sign		**Date**	
Head of Responsible dept. sign		**Date**	

4. Similar type of deviation repeated in the past one year (To be filled by QA)		☐ **Yes**	**No** ☐
If yes Specify Deviation No. :			
Categorization of deviation	☐ **Minor**	☐ **Major**	☐ **Critical**
QA sign and date			
Requirement of Investigation as per Investigation SOP		☐ **Yes**	☐ **No**

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Deviation No.	

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Head QA/Designee Comments		
Approval of Head QA/Designee (Sign/Date)		

5. Investigation (To be filled by responsible department):
Reference investigation No. as per Investigation SOP (if applicable) :
6. Identified root cause (To be filled by responsible department) :

7. Comments by other Departments:			
Name		**Dept.**	
Sign		**Date**	

Name		**Dept.**	
Sign		**Date**	

Name		**Dept.**	
Sign		**Date**	

8. Corrective Actions and Preventive actions (To be filled by responsible department):				
Sr. No.	**CAPA details**	**CAPA number**	**Responsibility**	**TCD**

Responsible person sign		**Date**	

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9. Final Evaluation and Conclusion by Head QA or Designee:			
Sign		**Date**	

10. Comments By Regulatory Affairs : (if necessary)			
Sign		**Date**	

11. Comments and Approval By Customer/Qualified Person/Marketing Authorization Holder:			
Sign		**Date**	

12. Disposition of deviation impacted materials/products by Head QA or Designee :			
Impacted batches to be released	☐ **Yes**	☐ **No**	☐ **NA**
Sign		**Date**	

13. Comments and approval By Corporate Quality Assurance:			
Sign		**Date**	

14. Closure:			
All actions related to investigation are complete: ☐ Yes ☐ No			
Remark:			
Head of Responsible dept. sign		**Date**	
Review by QA:			
All CAPA logged into the CAPA log book : ☐ Yes ☐ No			

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Deviation No.	

Note: Attach additional sheets if required

Remark (if any):			
Deviation Closed on			
Closed within the timeframe	☐ Yes ☐ No		
Extension form filed-1	☐ Yes ☐ No ☐ NA		
Extension form filed-2	☐ Yes ☐ No ☐ NA		
Head-QA/ designee sign		Date	

Annexure no.	List of Annexure or Supporting documents	Number of pages
	Total No. of Pages.	