			OR THE REAL PROPERTY.
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CADILA HEALTHCARE LIMITED			Zydus Cadila
Annexure No.	0301-SOP-QA-00213-08	Version No.	3.0, CURRENT
Annexure Title	Review of Audit Trails Data Record	,	

Sr.no	Name of Equipment	ID NO	Stage	Product name	Batch Number
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					

Sr.	Following checkpoints to be considered for data audit trail / electronic data review		Observation (Yes/No/NA)								
No.			2.	3.	4.	5.	6.	7.	8.		
1.	Are Batch Number / Product Recipe selected as per defined batch document?										
2.	Is generic recipe (recipe ABC, ABC 123 etc.) used to run the batch?										
3.	Are changes in process parameters during initial equipment set up within validated operating range of product (As per approved batch record)?										
4.	Are changes in the critical process parameters during manufacturing process within specified limit (As per approved batch record)?										
5.	Are date and time of electronic data generation, processing (where applicable), reporting and entries in equipment usage log books / batch document concurrent?										

COPY OF MASTER FORMAT

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Annexure No.	0301-SOP-QA-00213-08	Version No.	3.0, CURRENT
Annexure Title	Review of Audit Trails Data Record		

Sr.	Following checkpoints to be considered for data audit trail	Observation (Yes/No/NA)								
No.			2.	3.	4.	5.	6.	7.	8.	
6.	Have users (operators, supervisors) used their own user accounts in equipment with PLC SCADA/HMI/IPC to run the batch? Note: This point is not applicable for systems with group / common user ID.									
7.	Are there multiple reports generated against the batch number or any trial is taken related to batch operation? # (If yes, record how many reports are generated; and record report numbers of each report in summary section)									
8.	Are all the reports, including trial reports considered for batch decision? #									
9.	Is any event of data deletion logged in Audit Trail? If yes, initiate and mention the appropriate QMS document number in summary section.									
10.	Is paper record submitted for review identical with data available electronically? #									
11.	Is there Any other audit trail event/log or critical error message, which can impact accuracy and integrity of the electronic data generated?									
12.	Other, if any:									
13.									X	

CADILA HEALTHCARE LIMITED									Zydus Cadila		
nnexure No.	0301-SOP-QA-00213-08						Version I	No.	3.0, CU	RRENT	
nnexure Title	Review of Audit Trails Data Reco	ord									
#: In these cases	s, data available electronically in th	e system shall b	e referred	for review	<i>I</i> •						
Mentio	on if review is Complying / Not Com	plying.									
	Performed By User Department	Sign. / Date				//_	//_	!!_	!!_		
		Time	:_	:	:	:	:	:	:	:	
	Reviewed By Quality Assurance	Sign. / Date		//_	//_	//_		//_	//_	//_	
		Time	:	:	:	:	:	:	:	:	
Summary:											
Reviewed the Da	ata audit trail and are found satisfacto	ory / not satisfacto	ory								
Reference Docum	ment/ QMS Number if Review is not	Satisfactory									
Reviewed By Us	ser Department (Sign. / Date)										
Reviewed By Qu	uality Assurance (Sign. / Date)										