

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. No.	Following checkpoints to be considered for data audit trail / electronic data review	Observation (Yes/No/NA)							
		1.	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?								

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COPY OF MASTER FORMAT

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#: In these cases, data available electronically in the system shall be referred for review.

Mention if review is Complying / Not Complying.									
Performed By User Department	Sign. / Date	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__
	Time	__:__	__:__	__:__	__:__	__:__	__:__	__:__	__:__
Reviewed By Quality Assurance	Sign. / Date	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__
	Time	__:__	__:__	__:__	__:__	__:__	__:__	__:__	__:__

Summary:

Reviewed the Data audit trail and are found satisfactory / not satisfactory	
Reference Document/ QMS Number if Review is not Satisfactory	
Reviewed By User Department (Sign. / Date)	
Reviewed By Quality Assurance (Sign. / Date)	