



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK TO PRODUCT QUALITY AS INLET TEMPERATURE FLUCTUATION AGAINST SET VALUE IN AUTO COATER

S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference document No.	S	O	D	Risk Priority Num ber (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
1.	Auto coater – PC/GB/AUC- 016 Risk to product quality as inlet temperature fluctuation against set value and defined limit.	Inlet Temperature of Auto coater fluctuated against defined limit i.e. 55°C to 65 °C and observed 51 °C to 67 °C.	Product Quality may be impacted by means of defect generation or impact on quality specification.	Occurrence of Rough surface/ sticking/ wt. variations	1. In process test (Description, Avg. wt., thickness, length, width, DT and Disso) of coated tablet of respective batch has been performed and found within limit. 2. Acceptance Quality limit inspection after each stage performed and same has been performed in respective batch after coating stage & product complies. 3. Visual inspection of coated tablets also in practice and performed for respective batch and no any major rejection observed. 4. Complete analysis of all finished product is in practice and	BMR	4	1	1	04	During preventive Maintenance all sensor to be checked.	4	2	1	08



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					reviewed finished product COA and found product complies as per IP specification.										

Remarks (if any):- N/A

S. No.	Recommended Action	Responsible Person	Target Date of Completion
1.	Inlet temperature sensor has to be replaced		
2.	During preventive maintenance equipment valve and sensor to be closely verified		

CAPA (Required / Not Required):
If required, mention CAPA No.: NA



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Quality Risk Management Team			Reviewed By Head Operations (Sign & Date)	Approved By Head QA (Sign & Date)
Name	Department	Sign & Date		

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Procedure: Risk to product quality as inlet temperature fluctuation against set value in Auto coater.

Verification of Recommended Action:

Remarks (if any): Based on the above Risk Assessment and current Mitigation Measurement there is no effect on Product , efficacy, quality and purity.

Verified By
Officer/Executive QA
(Sign & Date)

Approved By
Head QA
(Sign & Date)