



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

QRA No.:

Name of Equipment: De-dusting tunnel										Quality Risk Assessment Date:				
S.No.	Item/ Function	Potential Failure Mode (Failure mode)	Potential Effect of Failure	Potential cause/Mechanism of Effect of Failure	Current control	S	O	D	Risk Priority Number	Recommended Actions (If any)	Post Risk Evaluation			
											S	O	D	RPN SxOxD
1.	Blower	Blower is not able to work properly	1. Inadequate differential pressure. 2. Inadequate air velocity 3. Chances of cross contamination in the area	May be due to any mechanical or electrical problem	1. Verification of differential pressure from the gauge. 2. During OQ de-dusting tunnel has successfully passed the differential pressure & air velocity test. 3. Differential pressure is recorded daily as per SOP format. 4. All the raw materials are packed in tight, intact containers so the changes of contamination with the RM is negligible. 5. After passing from de-dusting tunnel raw material containers are also physically verified for presence of any dust particles.	4	1	1	4	Current control measures are adequate	NA	NA	NA	NA
2.	Air velocity	Decrease or increase in Air velocity beyond the defined limit	1. Cross contamination 2. Inadequate differential pressure	1. Choking/damage of filters 2. Blower problem 3. Failure of Magnehelic gauge 4. Improper installation of air filters	1. During OQ de-dusting tunnel has successfully passed the air velocity test. 2. Differential pressure is recorded daily as per SOP format. 3. All the raw materials are packed in tight, intact containers so the changes of contamination with the RM is negligible. 4. After passing from de-	4	2	1	8	Current control measures are adequate	NA	NA	NA	NA



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											S	O	D	RPN SxOxD
					dusting tunnel raw material containers are also physically verified for presence of any dust particles.									
3.	Differential Pressure	Decrease or increase in differential pressure beyond the defined limit	1. Inadequate air velocity 2. Cross Contamination	1.Choking/damage of filters 2.Blower problem 3.Failure of Magnehelic gauge 4.Improper installation of air filters	1. During OQ de-dusting tunnel has successfully passed the differential pressure test. 2. Differential pressure is recorded daily as per SOP format. 3. All the raw materials are packed in tight, intact containers so the changes of contamination with the RM is negligible. 4. After passing from de-dusting tunnel raw material containers are also physically verified for presence of any dust particles.	4	2	1	8	Current control measures are adequate	NA	NA	NA	NA
4.	Air Filter	Decrease or increase in differential pressure & air velocity beyond the defined limit	1. Inadequate differential pressure 2. Inadequate air velocity 3. Chances of cross contamination	1.Choking 2.Damage of filters 3.Improper installation of air filters	1. Differential pressure is recorded daily as per SOP format. 2. During OQ de-dusting tunnel has successfully passed the differential pressure & air velocity test.	4	1	1	4	Current control measures are adequate	NA	NA	NA	NA
5.	Brushes	Brushes not able to clean the	1. Chances of contamination of area	Brushes are not installed properly	1. After passing of containers from de-dusting tunnel	4	2	1	8	Current control	NA	NA	NA	NA



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											S	O	D	RPN SxOxD
		containers properly	with dust	or not adequate for operation	cleaning is also physically verified by store person. 2. SOP is in place for de-dusting tunnel & training has been imparted to all concerned personal. 3. All the raw materials are packed in tight, intact containers so the changes of contamination with the RM is negligible.					measures are adequate				

Where: S=Severity; O=Occurrence Probability; D=Detection; Risk category 1-25 RPN is Low risk, 26-50 RPN is Medium Risk, 51-125 RPN is High Risk.

S.No.	Recommended Action	Responsible Person	Target Date of Completion
NA	NA	NA	NA

CAPA: Not required

If required, mention CAPA No.: NA

Quality Risk Management Team			Reviewed By Concerned Department Head Sign & Date	Approved By Head QA Sign & Date
Name	Department	Sign & Date		
	QA			
	WAREHOUSE			
	ENGG.			



QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Equipment: De-dusting tunnel

Verification of Action Plan: NA

Remarks (if any): The entire above failure mode and their Severity, Occurrence, Detection rating done and RPN No. is found between 4 to 8. Hence Risk is detected as low which is acceptable.

Verified By
Quality Assurance
Sign & Date

Approved By
Head QA
Sign & Date