PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR ADDITIONAL MATERIAL TAKEN DURING PROCESS

Name of Procedure: Additional material has been taken during process of said product:

- Colloidal Silicon Dioxide IP (1.100 kg),
- Cross Povidone XL 10 (2.125 kg)
- Talcum IP (0.775 kg) in batch
- Blend for 3 min at 12 RPM in Octagonal Blender.
- Compression done at average weight of 178 mg and thickness 3.53-3.71 mm.

Quality Risk Assessment Date: ……

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	RPN (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
1.	Colloidal Silicon Dioxide IP	• Variations in description of Granules, Tablets, • Fail in process parameter. • Product failure during in process. • Not suitable for compression. • Batch failure in the Finished • Product. Batch might not be stable as per the storage condition.	• Product not meets FG specification • Market complaint	Addition of Colloidal Silicon Dioxide added against the BMR.	• In process testing at granulation and Compression stage as per BMR. • Finished product analysis by QC as per applicable specification. • Batch should be released based on QC testing. • Batch should be released by QA based on FG COA.	BMR No.:	5	2	2	20	Risk is low but stability of batch to be charged due to high severity.	5	2	1	10
2.	Cross Providence INF10	• Variations in description of Granules, Tablets, • Fail in process parameter. • Batch failure in process testing. • Batch failure in the Finished Product. • Batch might not be stable as per the storage condition.	• Product not meets FG specification • Market complaint	Addition of Cross providence INF10 added against the BMR.	• In process testing at granulation and Compression stage as per BMR.	BMR No.	5	2	2	20	Risk is low but stability of batch to be charged due to high severity.	5	2	1	10
3.	Talcum IP	• Variations in description of Granules, Tablets, • Fail in process parameter. • Batch failure in process testing. • Batch failure in the Finished Product. • Batch might not be stable as per the storage condition.	• Product not meets FG specification • Market complaint	Addition of Talcum added against the BMR.	• In process testing at granulation and Compression stage as per BMR.	BMR No.	5	2	2	20	Risk is low but stability of batch to be charged due to high severity.	5	2	1	10
4.	Compression done at average weight of	• Variations in description of Granules, Tablets, • Fail in process parameter. • Batch failure in process (Average weight, DT,	• Product not meets FG specification	In process parameter should be	• In process testing at granulation and Compression stage as per BMR.	BMR No.	4	2	2	16	Risk is low hence no action plan	NA	NA	NA	NA

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR ADDITIONAL MATERIAL TAKEN DURING PROCESS

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	RPN (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
	178 mg	Hardness) • Batch failure in the Finished Product as per applicable specification.	• Market complaint	deviated	• Finished Product testing as per FG specification.						is required				
5.	Thickness 3.53-3.71 mm.	• Variations in description of Granules, Tablets, • Fail in process parameter. • Batch failure in process (Average weight) testing. • Batch failure in the Finished Product as per applicable specification. • Batch might be not suitable for packing.	• Product not meets FG specification • Market complaint	In process parameter should be deviated	• In process testing at granulation and Compression stage as per BMR. • Finished Product testing as per FG specification.	BMR No.	4	2	2	16	Packing suitability should be check	NA	NA	NA	NA

Rating Scale – Severity	**Rating Scale - Occurrence**	**Rating Scale - Detection**	**Acceptance Criteria**
1= No Effect	1= Unlikely	1= Always Detected	51 to ≤ 125 = High Categories
2= Minor Effect	2= Very Rare	2= Will Detect Failure	26 to 50 = Medium Categories
3= Moderate Effect	3= Possible	3= Might Detect Failure	Upto25 = Low Categories
4= Serious Effect	4= Likely	4= Almost certain not to Detect Failure	
5= Hazardous Effect	5= Almost Certain (every time)	5= Lack of Detection Control	

Where: S=Severity; O=Occurrence Probability; D=Detection.

CONCLUSION: Observed sticking and improper flow problem during compression. To mitigate sticking and improper flow we have added

S.No.	Recommended Action	Responsible Person	Target Date of Completion
1.	Stability to be charged of FG batch and batch shall be monitored for any discrepancy observed during stability study.		

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

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN FOR ADDITIONAL MATERIAL TAKEN DURING PROCESS

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: Additional material taken during process

Verification of Recommended Action:

Remarks (if any):

Verified By
Officer/Executive QA
(Sign & Date)

Approved By
Head QA
(Sign & Date)