



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MATERIAL STAGING AFTER DISPENSING (OSD)

Reference Document No.:

Risk Assessment No.:

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation for: Material Staging after dispensing (OSD)

Date Of Quality Risk Assessment:

S. No.	Item / Function	Potential Failure Mode	Potential Effect of Failure (Effect)	Potential Cause/ Mechanism of Failure	Current Control	Reference	Risk with Current control Measure				Recommended Actions (if any)	Risk after control measure			RPN (S*O*D)
							S	O	D	Risk Priority Number (S*O*D)		S	O	D	
1.	Material Staging after dispensing	Cross Contamination	Product Failure	<ul style="list-style-type: none"> ➤ During the transfer sugar bag opens and sugar transfer activity is performing. ➤ There is no physical segregation available ➤ No over gowning procedure is available for sugar transferring area as the person is directly come in contact with material. 	<ul style="list-style-type: none"> ➤ Dispensed material is kept in tightly closed double polybags. ➤ Segregation and Controlled area provided for storage of material. Only authorized persons allowed in the area. ➤ Secondary gowns and Gowning procedure is available for all person 	SOP	4	3	1	12	NA	NA	NA	NA	NA



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MATERIAL STAGING AFTER DISPENSING (OSD)

Reference Document No.:

Risk Assessment No.:

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

Remarks (if any):

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



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSMENT & MITIGATION PLAN

FAILURE MODE EFFECT ANALYSIS FOR MATERIAL STAGING AFTER DISPENSING (OSD)

Reference Document No.:

Risk Assessment No.:

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation:	Material Staging after Dispensing (OSD)
--	---

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

Verification of Action Plan:

All the above agreed actions completed, Not Completed.

(*incase any recommendations Not completed, to be tracked through CAPA System)

Remarks (if any):

Verified By
QA
Sign & Date

Approved By
Head QA
Sign & Date