



**RISK ASSESSMENT FOR THE MOVEMENT OF DISPENSED RAW MATERIALS**

**1. Risk Assessment:**

**Risk Assessment related to Movement of Dispensed Raw Materials from Dispensed Materials Staging area to Production Area**

A.	Risk Identification				Risk Analysis/ Evaluation				
S. No.	Item or Process Step	Potential risk and/or Failure mode	Probable impact of potential risk and/or failure mode	Current control measures	S	O	D	RPN	Risk Level
1.	Dispensing and transfer of Dispensed Materials to Dispensed Materials Staging area	Dispensing and Transfer of wrong Material	<p>Non-conforming product may produce and it may impact to patient health.</p> <p>Product Recall or Market complain may happen</p> <p>Production Target impact or Business loss may occur</p>	<p>Procedure for Dispensing Activity is in effective.</p> <p>Trained personnel are executing the Dispensing activity.</p> <p>Line clearance Procedure is in effective. Every batch is being dispensed after Line Clearance from QA. Only Approved Materials are dispensed with double lined virgin polybag with proper air tight closing through Nylon Tie.</p> <p>Dispensing of materials is being carried out under RLAF and in controlled environmental condition to avoid any contamination.</p>	4	2	2	16	Low Risk



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				Dispensed Materials are transferred to Dispensed Material Staging area through Pass box using Material Trolley. This activity is being performed by Trained Personnel. Procedure for Training to respective Personnel is in effective.					
		Exposure of Material during transfer or spillage of Materials	Contamination of Materials, which may lead to produce Non-conforming product & Loss of Materials.	Procedure for “Dispensing of Raw Materials is in effective, which includes ‘the dispensed materials will be kept in double polybags along with dispensed label in-between and will be transferred to Dispensed Material staging area through Pass Box’.					
		Dispensed Materials may mix up at area meant for staging dispensed material.	May Lead to Batch Mixup, which may lead to non-conforming product.	Procedure to store the dispensed Materials at staging area is in effective. This includes ‘All dispensed material will be kept on pallets / cages with batch wise segregation and updated status label’.	3	2	3	18	Low Risk



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				<p>Dispensed Material label is affixed on each storage cage.</p> <p>Entry to Dispensed Material Staging area is under control of Trained Production Personnel. The area is kept under lock and key to control the unauthorized entry</p> <p>Procedure for receiving and movement of dispensed Raw Material and Packaging materials is in effective. This activity is performed by trained Production personnel.</p>					
		Impact of Environment on Dispensed Materials during staging at Dispensed Material Staging area.	<p>Stability of Product may be impacted</p> <p>Market complain may receive</p> <p>Physical &amp; chemical Parameters may not comply during Batch Production period.</p>	<p>All dispensed material are kept in double poly bags and tied with Nylon tie.</p> <p>HVAC system is in place to facilitate the required Temperature and Humidity at the Dispensed Material staging area.</p>	3	2	3	18	Low Risk



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S. No.	Item or Process Step	Potential risk and/or Failure mode	Probable impact of potential risk and/or failure mode	Current control measures	S	O	D	RPN	Risk Level
				Procedure to monitor and record the Temperature and humidity is in effective and executed as per defined frequency. Hold Time Study has been performed through Protocol to establish the time duration for keeping the dispensed materials.					
2	Movement of Dispensed Materials to Production area	Damage or Spillage of Materials during the movement of dispensed materials from Warehouse (Dispensed Material Storage area) to Production Material Air Lock.	Loss of materials  Exposure of Material to environment may lead to microbial contamination	Materials are transferred in Storage container / Cage Trolley and all the dispensed materials are transferred in double lined polybags.  Trainer personnel are only authorized to carry these Cage trolleys and the procedure for this activities is in place.	3	2	2	12	Low Risk
		Movement of Dispensed Materials from Dispensed Material staging area (Classified area) to Production material Air Lock	Exposure of Dispensed Materials to unclassified environment during transferring.	The Raw Materials are dispensed in double polybags followed by Tied with Nylon tie and are transferred in cage trolley. The Dispensed Raw	3	5	1	15	Low Risk



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		(Classified area) through Corridor (un Classified area)		<p>Materials are not exposed to environment directly during the movement. The materials are exposed only in Production processing area (classified area)</p> <p>In addition to the existing material movement procedure / practice, the Dispensed Materials will transfer through the closed suitable Containers.</p>					

B.	Risk Reduction/ Acceptance					Risk Review					
S.No.	Potential risk and/or Failure mode	Risk level	Risk Acceptance Yes / No	Justification	Any action/ Mitigation plan for reduction	S	O	D	RPN	Final Risk Level	Residual Risk
1	-	-	-	-	-	-	-	-	-	-	-



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**2. Conclusion:** Risk Assessment carried out related to movement of dispensed material from dispensed material staging area to Production material air lock through corridor. The Risk Assessment was done by the cross functional team and the risk evaluation done. All the Risks are found as Lower Risk, so no Risk Mitigation plan is required. However in addition to existing procedure, the dispensed materials will be transferred through suitable closed container along with double lined polybags and cage trolley.

**3. Risk Review and Approval:**

S.No.	Name	Designation	Department	Sign/Date
1.				
2.				
3.				