PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT FOR PACKING OPERATIONS

QRA No.: ……

Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation: Packing Operation	**Quality Risk Assessment Date:……**

S.No.	Item / Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure (Effect)	Potential Cause/ Mechanism of Failure	Current Control	Reference document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
1	Labeling	1)Mix-up of Labels 2)Wrong labeling 3)Wrong printing over labels	1) Product may lose the identity. 2)Market complaint	1)Dispensing of two batches at the same time 2)Two different batches packing material is in the same area 3)Wrong data feed in PLC software	1)Dispensing of one batch at one time and issuance slip generated through SAP 2) Verification of packing material according to item code by QA during line clearance. 3) Only one batch of packing material kept in cubical. 4) In case of extra material, packing material taken in cubical only after verification from QA and slip generated through SAP. 5) Coded packing material is kept in lock and key condition. 6) PLC is password protected and Specimen check by production and after that QA verify this	1) SOP and BPCR 2)SOP of Dispensing of packing material 3) SOP for Operation and cleaning of automatic high speed self-	4	2	2	16	NA	NA	NA	NA	NA

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												S	O	D	RPN SxOxD
						adhesive labeling machine									
		1)Probability of mix-up of stereos during product change over	1)Market complaint 2) Product may lose the identity.	1)Handling of stereos not proper	1)Stereo is kept in lock and key system 2) Issuance and destruction record is maintained in logbook. 3)After completion of batch stereos are destroyed and record is attached with BPR 4)QA verify the stereo indent form against the batch record 5)On receipt of stereo production checked the details by taking impression and verified by IPQA	1) SOP for Receipt and handling of rubber stereos and BPCR	4	2	2	16	NA	NA	NA	NA	NA
		1)Probability of packing of unlabeled bottles with un-coded labels	1)Market complaint	1)Inspection of labeled bottles not performed	1)100% inspection of labeled bottles performed	SOP for Visual inspection of fill and seal LDPE bottle	4	2	2	16	NA	NA	NA	NA	NA
2	Online visual inspection of filled and sealed bottles	1)Defected bottles packed 2)Skipping of the inspection	1)Market complaint	1)Inspection of filled and sealed bottles not formed	1) 100% inspection of filled and sealed bottles performed.	1) SOP for Visual inspection of fill and seal LDPE bottle) and BPCR	4	2	2	16	NA	NA	NA	NA	NA

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												S	O	D	RPN SxOxD
				2)Procedure not follow by person 3) Light facility not proper.	2) Adequate area & Light facility provided for visual inspection of defected bottles.										
3	Specimen verification	1)Wrong verification of specimen of carton and label	1)Market complaint	1)Inadequate training 2)Batch coding details and price not as per provided list and BPCR	1)Batch coding details and price list provided 2) Verification of specimen from QA after production check	1)SOP for In-process of packing operation 2)Price list 3)BPCR	4	3	2	24	NA	NA	NA	NA	NA
4	Batch packing operation	1)Mix-up 2)Environ-mental monitoring 3)Improper status labeling	1)Market complaint 2)Product may be degrade 3) Product may lose the identity.	1)If area not properly segregated 2)Fails to follow SOP 3)AHU breakdown 4)There is no labeling procedure available	1)Separation between individual secondary packing lines for proper segregation of material 2)Only one product/ batch packing takes place on one line at a time 3)Procedure of Environmental monitoring 4) Procedure of preventive maintenance 5) There is a labeling procedure Labeling procedure 6)Procedure of line	1)SOP for Plant equipment preventive maintenance 2)SOP for Dispensing of packing material 3) SOP for Line clearance for product manufactured in injectable facility 4)SOP for Plant equipment preventive maintenance	4	2	2	16	NA	NA	NA	NA	NA

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												S	O	D	RPN SxOxD
		4)Improper functioning of packing machine	4)Market complaint	5)Break down in machine	clearance 7)There is a procedure of preventive maintenance 8)Camera for coding checks 9)Sensors on conveyer for auto rejection of vial which have improper coding 10)Weighing balance for weight of shipper with graph (date ,tare wt., net wt., gross wt and person name is mentioned on the graph for better traceability) 11)BOPP taping machine 12)HI-CART for automated carton and insert packing and sensors are also there for auto rejection of carton , if carton is empty. 13) If there are three continue rejection of	5) Graph 6)Operation and cleaning of Hi-cart plus machine									

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												S	O	D	RPN SxOxD
					bottles then machine automatically stopped.										
5	Packed material transfer from packing to finished goods	1)Wrong quantity transfer. 2)Damage during transfer 3)Temperature is not maintained in finished good area	1)Market complaint 2)Product may be degrade	1)Inadequate training 2)Lack of facility 3)Procedure is not available	1) Material transfer through transfer ticket which is cross verified by QA after check of production & also checked by finished good personnel. 2)For material transfer sufficient trolley are there & Lift system is also 3)Procedure of Environmental monitoring	1)Transfer ticket 2)BPR	4	2	2	16	NA	NA	NA	NA	NA

Where: S=Severity; O=Occurrence Probability; D=Detection:, Risk category upto 25 is low risk, 26-50 is medium risk, 51 -125 high
Remarks(if any); All the above failure mode and their severity, Occurrence, Detectability rating done & found risk is Low

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

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

RISK ASSESSMENT FOR PACKING OPERATIONS

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 Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation: Packing operation	Packing operation

Verification of Recommended Action: NA

Remarks (if any): All the above failure mode and their severity, Occurrence, Detectability rating done & found risk is Low, hence current controls are appropriate to ensure the packing operation.

Verified By
Officer/Executive QA
(Sign & Date)

Approved By
Head QA
(Sign & Date)