PHARMA DEVILS

QUALITY ASSURANCEDEPARTMENT

RISK ANALYSIS STUDY FOR TABLET INSPECTION

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	Risk Priority Number (SxOxD)	Recomme--nded Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
1.	Tablet Inspection.	• Capping in tablets may pack. • Color Variation may pack. • Broken Tablets may pack. • Spotted Tablets may pack. • Twins Tablet may pack. • Chipped may pack. • Blistering in tablets may pack. • Laminated Tablet may pack. • Orange Peel Tablet may pack. • Soft Tab Tablet may pack.	• Market Compline	• Tablet inspection done in high speed. • Tablets send for packing without inspection.	➢ **Tablet Inspection.** • Set the distance of finger & speed of belt as per size of tablet. • Inspect the tablet from both side & sort out defective tablets in separate polythene bag. • Collect the good tablets in labeled double polythene lined HDPE containers. • After completion of process switch "OFF" the Inspection belt. • Record the operation details as per **"Machine Utilization Record".** • Weigh the defective tablets, good tablets & record in BMR.	SOP no.	4	2	3	24	Low Risk category	4	2	2	16
				• Checking Person not Proper Qualified as per requirement.	➢ **Visual inspector qualification** • In case of new joining of personnel or any personnel to be deputed to work as visual inspector, concern department In-Charge shall intimate to IPQA for visual inspector qualification as per **Annexure-I,** Titled **"Intimation for Visual Inspector Qualification"**. • Production In-Charge shall ensure that eye test of Visual Inspector has been completed and reports are available as per SOP **"Medical Examination of Employees".** • In-Charge IPQA shall arrange for training program on Defective Sample with elaboration of Defect Modules as per Annexure-IV, V, XII and XIV for **Oral Solid Dosage** • Visual inspector shall be qualified in the presence of IPQA personnel by providing a kit of Defective Sample. Also as per the Defect modules Show in Annexure mentioned above. • Three trails shall be taken for qualification of	SOP no.	4	2	3	24	Low Risk category	4	2	2	16

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												S	O	D	RPN SxOxD
					visual inspector for respective production line. Then identify the kit in sample by visual inspector and Officer/Executive Production shall fill the document as annexure shown as Annexure-VI, VII, IX, XI, XIII and XV • IPQA Officer/Executive shall evaluate or verified the activity and documents fill by the production Officer/Executive. • Qualification of Visual Inspector for Packing and Manufacturing during inspection shall be completed by visually identifying of defective tablets and capsules are recorded in annexure as shown in **Annexure-VI, VII, XIII and XV** respectively. • After successful evaluation, Mark **"C"** on the front and Back side of the Identity Card of qualified Checker and list of qualified visual inspector shall be prepared and displayed in respective packing area as per **Annexure-II**, • Visual Inspector List shall be updated every six month or whenever required. • If there is a change in employee code number, mention the new employee code number in remark column in black ink pen with sign & date by line In-charge. • In case of any deletion, mention the word **"Left"** in remark column in black ink pen with sign & date by line In-charge.									
				• Improper Light in area.	• During facility qualification Luminance in Area was Perform NLT 2000-3750 Lux at Working Level. • Frequency of Luminance in Area initially (During Operational Qualification) and After Major	SOP no.	4	2	2	16	Low Risk category	4	1	2	8

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												S	O	D	RPN SxOxD
					Modification										

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

Conclusion:- On the basis of above risk assessment the tablet inspection leads to low risk, all evaluated risk during assessment of all concern department like manufacturing area and packing area, department which can be lower down after follow above mentioned controls.

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

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

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

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RISK ANALYSIS STUDY FOR TABLET INSPECTION

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Procedure: Tablet Inspection

Verification of Recommended Action: NIL

Remarks (if any): NA

Verified By
Officer/Executive QA
(Sign & Date)

Approved By
Head QA
(Sign & Date)