PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

FAILURE MODE EFFECT ANALYSIS FOR PROCESSING OF EYE DROP

S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure (Effect)	Potential Cause/ Mechanism of Failure	Current Control	Reference	S	O	D	Risk Priority Number (S*O*D)	Recommend-ended Actions (if any)	Post Risk			
												S	O	D	RPN S*O
Product Processing:															
1.	Qualified Packers	➢ Packers are not qualified to check the overprinting of the labels.	➢ In case of wrong or no overprinting on vial / ampoule there might be a chance of packing of without printed labels, which may cause may leads to market complaint in future. ➢ Incorrect or illegible printed matter will mislead the patient lead to market complaint.	➢ Non-qualified visual inspectors verify the vial/ampoule coding. ➢ Casual approach of visual inspectors during visual inspection.	➢ During labeling operation of vial/ampoules, visual inspectors continuously verify the vial/ampoules coding. ➢ The visual inspectors are rotate after every two hours. ➢ SOP of sticker labeling is available.	As per SOP.	3	2	1	6 Low category & Risk Accepted	Adequate procedure no recommendation required.	N A	NA	NA	N A
2.	Label sensors	➢ Presence of label can't be checked automatically during labeling.	➢ Unlabelled and mislabeled vials /ampoules will mix with good ampoule/vial. ➢ Product may be produced with incomplete information. ➢ There might be a chance of packing of without labeled vial/ampoule followed by market complaint in future.	➢ "No label" sensor is available to check the presence or absence of label.	➢ "No label" sensor is available to check the presence or absence of the label during labeling. ➢ At starting of batch or any after any break the sensor is challenged and recorded the details in its log book.	As per SOP.	3	2	1	6 Low category & Risk Accepted	Adequate procedure no recommendation required.	N A	NA	NA	N A

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3.	Air Filters	➢ Filter Chocking / leakage ➢ Filter integrity test not possible.	➢ Without filtered air directly impacted to Product Sterility & Quality. ➢ Product contaminated. ➢ Environmental contamination of product	➢ Filter use more than recommended cycle ➢ Filter Use without Integrity testing.	➢ Filter use as per recommended cycle & maintained in log book for their cycle. ➢ Air filters filter integrity done according to the frequency; Manufacturing tank- Monthly, Holding Tank: - 15 days, Buffer Vessel: - 15 Days, Filling Machine: - Daily, Pendants: - Monthly. ➢ Pressure gauge available to monitor differential pressure across filter.	As per SOP.	4	2	1	8 Low category & Risk Accepted	Adequate procedure no recommendation required.	N A	NA	NA	N A
4.	Nitrogen Gas	➢ Nitrogen gas quality failure.	➢ Particle and microbial contamination of Vials may leads to product failure.	➢ No provision to filter the nitrogen gas before use. ➢ Sampling and testing of nitrogen for sterility testing is not done periodically. ➢ Purity of nitrogen is not identified. ➢ Nitrogen gas generator didn't qualified.	➢ Nitrogen gas supply to the equipment has been qualified & COA available for purity. ➢ Sampling and testing for sterility of nitrogen gas is done periodically, As PER SOP. ➢ Before pre-purging and post purging station two dedicated 0.2 µ filters are in place and one 0.2 µ filter is installed at pendent in filling room. ➢ SOP of Integrity checking of Nitrogen filter in place.	As per SOP.	4	1	1	4 Low category & Risk Accepted	Adequate procedure no recommendation required. Hence risk is accepted.	N A	N A	N A	N A

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5.	Power failure	➢ Critical processes stops, like LAF over filling machine, blower of tunnel, HVAC system etc. ➢	➢ Area gets contaminated due to stopped HVAC system. ➢ Vials cannot be depyrogenated properly due to shut down of blower. ➢ Filling area gets contaminated due to LAF stopped. ➢ Process out of specification. ➢ Unsafe if start automatically on restoration of power	➢ Power shut down. ➢ No electricity. ➢ Technical fault. ➢ No UPS supply available. ➢ No DG set available.	➢ Machine is not start automatically without operator intervention after incident. ➢ Provision of UPS is also there to the control the system in case of power failure. ➢ LAF Over the filling machine, blower of tunnel, HMI of all machines have provision of UPS. ➢ 02 DG sets are available which can be started within 30 sec. ➢ Area Recovery study has been performed. ➢ SOP FOR Procedure to be followed in case of power failure is in place.	As per SOP.	3	2	2	12 Low category & Risk Accepted	Adequate procedure no recommendation required. Hence risk is accepted.	NA	NA	NA	NA

Where: S=Severity; O=Occurrence Probability; D=Detection; Risk category 1-25 RPN is Low risk, 26-50 RPN is Medium Risk, 51-125 RPN is High Risk.

Name of Facility/Equipment/Utility/System/Activity/Procedure/Unit Operation: Product Processing of Eye Drop	**Date:**

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

CAPA: Not required

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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**		

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Equipment: Product Processing of Eye Drop

Verification of Action Plan: NA

Remarks (if any): The entire above failure mode and their Severity, Occurrence, Detection rating done and RPN No. is found between 3 to 12. Hence Risk is detected as low which is acceptable.

Verified By
QA
Sign & Date

Approved By
Head QA
Sign & Date