



QRA No.:

Name of Facility/Equipment/Utility/System/Activity/Procedure

Unit Operation: Liquid vial Filling and Stoppering machine

Post Risk Risk Recommend-Potential Effect of Item/ Potential S. Potential Cause/ **Priority** ended **RPN** D Function Failure Mode Failure **Current Control** Reference S 0 S No. Mechanism of Failure Number Actions 0 D S*0* (Failure Mode) (Effect) (S*O*D) (if any) D 1. Vial Size Equipment is not ▶ Filling process will Different Vial sizes Filling machine is 4 2 1 8 Adequate NA NA NA NA OQ& PQ of I Stoppering suitable be interrupted and may not be processed suitable for filling of for procedure different size of filling with same equipment. different sizes of Vials process & PQ of Filling An opering machine no Vials continue changing format cannot by recommend further. (change) parts ation Change parts for required. different Vial size with Hence risk marking provided is accepted. by ; And vendor, along with the equipment, as per requirement. Machine has been qualified with different Vial size. Vial transport > Overturned/ Vial jamming, Vial Design of the system The design of the system 3 1 3 Adequate NA NA NA NA 2. 1 OQ& PQ of Filling Stoppering machine fallen Vials on damage or breakage is not adequate to the is adequate to procedure infeed may take place. Vials. positioning and transfer the no conveyor belt. Continuous filling Positioning of Vials of Vials via a conveyor recommend operation will on infeed conveyor belt with SS side guides. ation effected. belt is not up to the Overturned Vials not required. point. enter in the convevor. Hence risk Functioning of the Functionality has been is accepted. system not verified verified during qualification activities. properly. 3. Transfer > Depyrogenated \triangleright Particle The transfer of Vials The transfer of Vials, OQ& PQ of Filling And Stoppering 4 1 4 Adequate NA NA NA NA of 1 machine filling & stoppering is Vials from Vials travel contamination of to filling & stoppering procedure tunnel to filling through unclean Vial. is performed under the performed under no non classified area. unidirectional air flow station. (unclassified) Micro-biological recommend contamination Classification unit (Grade A). environment level ation possible. hasn't verified. Classification level has required. been verified during the Hence risk qualification study. is accepted.

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S. No.	Function	Failure Mode (Failure Mode)	Failure (Effect)	Potential Cause/ Mechanism of Failure	ntial Cause/ nism of Failure Current Control		S	0	D	Priority Number (S*O*D)	ended Actions (if any)	S	0	D	RPN S*O* D
4.	Transfer of Vials	Improper positioning of Vials during transfer to filling station.	 Filling shall not be proper Product spillage may occur. 	 Design of the system is not adequate to the Vials. Positioning of Vials on to filling station is not up to the point. Functioning of the system not verified properly. 	 The design of the system is adequate that individual Vials are transferred and positioned properly below the filling needles at filling station. Functionality has been checked during qualification activities 	OQ of Filling And Stoppering machine.	3	1	2	6	Adequate procedure no recommend ation required. Hence risk is accepted.	NA	NA	NA	NA
5.	Transfer of product	Contamination of product while transfer from holding vessel.	Product failure	 No proper & safe transfer line available for transfer the product to filling & stoppering machine. The product transfer system not properly sterilized. 	 The product transferred through a closed system wherein sterile product has been transferred through Nitrogen gas pressure, from holding vessel to buffer tank (placed on filling machine), through sterilizable grade filter (0.2 μm), whenever applicable. The complete transfer system has been sterilized routinely through SIP, before every batch, as per SOP. 	SOP for CIP& SIP of Vessels.	4	1	1	4	Adequate procedure no recommend ation required. Hence risk is accepted.	NA	NA	NA	NA





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S.	Item/ Eunation	Potential Failura Mada	Potential Effect of	Potential Cause/	Current Control	Deference	G	0	n	Priority	ended				RPN
No.	Function	(Failure Mode)	(Effect)	Mechanism of Failure	Current Control	Kelerence	3	U	υ	Number	Actions	S	0	D	S*O*
		(Fallure Mode)	(Effect)							(S*O*D)	(if any)				D
12.	Product Dosing	Different range of filling volume could not be achieved.	Incorrect dosage may leads to market recall.	 No provision for different range of filling volume Fill volume set point adjustment not possible. 	 Different rotary piston pump sets are provided by vendor for different range of filling volume, to ensure accurate volume. PLC Based Servo drive available for volume adjustment and product volume has been set accordingly. 	Operation of filling machine.	3	2	1	6	Adequate procedure no recommend ation required. Hence risk is accepted.	NA	NA	NA	NA
13.	Filling processes	Presence of headspace oxygen	 Chance of product degradation. Microbial contamination due to presence of air. 	 No provision of nitrogen flushing. 	 Provision for Pre and post nitrogen purging is available in machine. Control system available to set the pre and post nitrogen purging time and the pressure for the same. 	Cleaning and Sanitation of Aseptic/Vial Stoppering Area.	4	1	1	4	Adequate procedure no recommend ation required. Hence risk is accepted.	NA	NA	NA	NA
14.	Nitrogen Gas Purging	Purging pressure too high/ cannot be adjusted.	Chances of product spillage in case of too high pressure.	 Nitrogen flow can't be monitored. No provision is there of alarm in case of High pressure. 	 Flow regulator has been installed on nitrogen gas flow line for regulate the purging gas flow. High purging of Nitrogen Show red alarm and machine Stop challenge test has been done. 	SOP for Operation of Nitrogen Gas Plan	4	1	2	8	Adequate procedure no recommend ation required. Hence risk is accepted.	NA	NA	NA	NA





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17.	Filling	Product level in the buffer tank could not be monitored	Low level or no product inside buffer tank may produce wrong fill in Vials.	 Level sensor is not provided. No provision for alarm in case of low level of product. 	 Product level sensor is Available to monitor the product level inside the buffer tank. In case of low level of product inside buffer tank, alarm will be generated and filling will be stopped. 	Operation & Cleaning of Filling & Stoppering	3	1	1	3	Adequate procedure no recommend ation required. Hence risk is accepted.	NA	NA	NA	NA
18.	Filling	Filling speed could not be adjusted or maintained.	Variation in output	 No provision for counting the Vials from filling machine. No provision for adjust & maintain the rate of Vial filling. 	 Counters are placed at infeed and out feed to count number of filled Vials. The equipment control system is suitable to adjust & maintain the rate of Vial filling (number of Vials/ minute). 		3	1	1	3	Adequate procedure no recommend ation required. Hence risk is accepted.	NA	NA	NA	NA
19.	Filling	Position of the filling needles could not be adjusted.	 Spillage of product may possible. Generation of air bubbles due to gap between needle and Vial surface, which might lead to product contamination. 	 Nozzle alignment & Dropping test not performed. Machine is not suitable for filling of different sizes of Vials. Filling needle height can't adjustable based on different format parts. 	 Nozzle alignment & Dropping test has been performed during PQ. Machine is suitable for filling of different sizes of Vials by adjusting height of the filling needle automatically as per different Vial size with different set of dosing pump & needle. Filling needle height shall be adjustable based on different format parts, so as to be close to the Vial mouth. 	OQ &PQ of Filling & Stoppering machine	3	2	1	6	Adequate procedure no recommend ation required. Hence risk is accepted.	NA	NA	NA	NA





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	I dame /	Detertial	Detertial Effect of							Risk	Recommend-		Post	Risk	
S. No.	Function	Failure Mode (Failure Mode)	Failure (Effect)	Potential Cause/ Mechanism of Failure	Current Control	Reference	ice S	0	D	Priority Number (S*O*D)	ended Actions (if any)	s	0	D	RPN S*O* D
42.	LAF (over Filling & discharge conveyor)	HEPA Filter leakage/ Choking	In case of leakage may lead to product contamination.	 There is no extra precaution in case of HAPA choking/leakage to prevent direct load of particles on HEPA filter. There is no provision to monitor pressure across all HEPA filters of LAF. Filter integrity test of HEPA filters didn't carry out during qualification. 	 Pre-filter is installed at the upstream of HEPA filters to prevent direct load of particles on HEPA filter Differential pressure switch/ transmitter are provided to monitor pressure across all HEPA filters of LAF, along with alarm in case of high or low DP. Integrity test of HEPA filters shall be performed during qualification and routinely as per SOP. 	IQ ,OQ & PQ of Filling & Stoppering Machine	4	2	2	16	Adequate procedure no recommend ation required. Hence risk is accepted.	NA	NA	NA	NA
43.	LAF (over Filling & discharge conveyor)	Choking/ Damage of Pre- filter	Particulate matter load directly on the HEPA filter, may lead to frequent replacement of HEPA filter.	 There is no provision for indicating choking or leakage of pre-filters. In case of low or high DP there is no provision for alarm system. Cleaning frequency of pre filers is not defined. 	 Differential pressure switch/ gauge are provided for indicating choking or leakage of pre-filters with alarm provision in case of high or low DP. Pre-filters are also be cleaned regularly as per SOP. 	IQ ,OQ & PQ of Filling & Stoppering Machine	3	2	1	6	Adequate procedure no recommend ation required. Hence risk is accepted.	NA	NA	NA	NA





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Unit Operation: Liquid vial Filling and Stoppering machine

Risk Recommend-Post Risk Item/ Potential Potential Effect of S. Potential Cause/ **Priority** ended **RPN** D Function Failure Mode Failure **Current Control** Reference S 0 S No. Mechanism of Failure Number Actions 0 D S*O* (Failure Mode) (Effect) (S*O*D) (if any) D 44. oRABs access \geq oRABs access Chances of product There is no provision ≻ Security switches/ 3 2 2 12 Adequate NA NA NA NA DQ, IQ & OQ Stoppering sensors are provided at doors door may be contamination by for access the door procedure opened during direct handling of with the interlocking the access doors with no interlock feature with process. operators. system. recommend There is no alarm the operation of ation provision provided. machine i.e. machine required. stops immediately if Hence risk of Filling Machine oRABs access doors are is accepted. opened. ≻ Alarm provision has 80 been also provided for the same. 45. Compressed air ➢ Insufficient ➢ Equipment \succ There is no pressure Pressure gauge/ 2 3 1 6 Adequate NA NA NA NA ≻ pressure operation will be gauge and pressure Pressure switch is procedure DQ & IQ of Filling & Stoppering Machine disturbed. limits are provided. provided at compressed no No alarming system air inlet to monitor & recommend ≻ is there in case of low control compressed air ation air pressure. pressure along with required. No qualification alarm provision in case Hence risk \geq activity has been of low pressure. is accepted. Verification has been performed. performed at the time of qualification studies. 46. User may make a 3 3 NA NA User \geq Operation SOP \geq System operation System operation SOP 1 1 Adequate NA NA DQ,IQ & OQ Filling & Stopp Machine wrong decision. SOP's didn't has been reviewed with procedure does not contain proper through all aspects and reviewed no information concerned personnel. approved. recommend 2 & OQ oI 2 Stoppering There is no technical Vendor and user may \geq provided ation execution support to the support to the user. required. operate system user for completion all Hence risk is accepted. stages of the qualification report.





QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

QRA No.:

Name of Facility/Equipment/Utility/System/Activity/Procedure

Unit Operation: Liquid vial Filling and Stoppering machine

Recommend-Post Risk Risk Potential **Potential Effect of** Item/ S. **Potential Cause**/ Priority ended RPN 0 D Function Failure Mode Failure **Current Control** Reference S No. S **Mechanism of Failure** Number Actions 0 D S*O* (Failure Mode) (Effect) (S*O*D) (if any) D > Unauthorized > Untrained persons There is no security \geq System is not start 3 1 1 3 Adequate NA NA NA NA DQ, IQ & OQ of Filling Stoppering Machine may damage the access system for without password procedure person tries to running the machine. start/stop the system or product no quality may be recommend system. affected. ation required. Hence risk is accepted. 80

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/U	Utility/System/Activity/Procedure/Unit Operation: Liquid vial Filling	and Stoppering machine Date:			
S. No.	Recommended Action	Responsible Person	Target Date of Completion		
1.	NA	NA	NA		
2.	NA	NA	NA		

CAPA: If required, mention CAPA No.: NA





QRA No.: Name of Facility/Equipment/Utility/System/Activity/Procedure Unit Operation: Liquid vial Filling and Stoppering machine

Date Of Quality Risk Assessment:

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

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Facility/Equipment/Utility/System/Activity/Procedure/Unit Operation : Liquid vial Filling and Stoppering machine

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 1-25. Hence Risk is detected as low which is acceptable.

Verified By QA Sign & Date

Approved By Head QA Sign & Date