PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

QRA No.:

Name of Facility/Equipment/Utility/System/Activity/Procedure **Risk in reducing Swab & rinse testing**	**Date of Quality Risk Assessment:**

Sr. 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
1.	**Cleaning Verification**	Rinse Sample not send to Quality control Dept.after each product to product change over.	May leads to contamination	➢ Product Failure ➢ Product recall ➢ Product quality	➢ Cleaning process has been validated for practically insoluble API (**Nandrolon Decanoate Injection in Ampoule line, Ondansetron injection in Liquid Vial line , Hydrocortisone Sodium Succinate Injection in Dry powder injection** ➢ Cleaning validation already done for Ampoule ,Liquid Vial & Dry Powder injection. ➢ Cleaning method is robust (Previous trend of swab & rinse). ➢ Visual inspection is the part of line clearance. ➢ Testing done online at shop floor and instrument is dedicated ➢ pH & Conductivity test shall be done by IPQA .	➢ SOP No.: SOP/QA/066 “Procedure for swab/Rinse Sampling”. ➢ Cleaning validation protocol of DPI, Ampoule & Liquid vial: …..	4	2	2	16					

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		Improper sampling	Inattentiveness or Lack of training	➢ Procedure failure. ➢ Product failure. ➢ Contamination.	➢ Cleaning validation already done for Ampoule ,Liquid Vial & Dry Powder injection. ➢ Cleaning method is robust (Previous trend of swab & rinse). ➢ Training is given as per OJT schedule.	➢ SOP No.: SOP/QA/066 “Procedure for swab/Rinse sampling”. ➢ Cleaning validation protocol of DPI,Ampoule & Liquid vial: …									
		Improper Visual inspection	Residue contamination may occur	➢ contamination may pass on to next batch leading to failure in description. ➢ Cleaning agent residue may leads to toxicity ➢ Impurity may pass on to next batch leading to batch failure.	➢ Cleaning validation already done for Ampoule ,Liquid Vial & Dry Powder injection. ➢ Cleaning method is robust (Previous trend of swab & rinse). ➢ Light intensity of critical areas is verified & recorded during HVAC/Area qualification .	➢ Cleaning validation protocol of DPI,Ampoule & Liquid vial: …					Cleaning validation Shall be performed of cleaning agent				

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2.	**Cleaning Verification**	Cleaning Verification not done	Worst case not selected	May leads to contamination	➢ Cleaning validation completed for Ampoule ,Liquid Vial & Dry Powder injection.. ➢ Testing done online at shop floor and instrument is dedicated ➢ pH & Conductivity test shall be done by IPQA .	➢ SOP No.: SOP/QA/066 "Procedure for swab/Rinse sampling". ➢ Cleaning validation protocol of DPI,Ampoule & Liquid vial: …..					Cleaning validation to be evaluated periodically (Yearly). SOP of cleaning validation to be revised.				
		Cleaning Verification not effective	➢ Worst case changed ➢ Deviation in cleaning method ➢ Proper evaluation not done	May leads to contamination	➢ Evaluation of new API done ➢ SOP of cleaning followed and verified by QA	➢ "Evaluation of new product for cleaning validation" ➢ SOP's of equipment cleaning									
3.	**Swab/Rinse Sampling**	Sampling method not adequate	➢ Untrained person ➢ Sampling method not followed.	➢ May leads to contamination ➢ False results generated	➢ SOP of sampling already distributed ➢ Sampling done by trained QA personnel	➢ SOP no.: "Procedure for Swab/Rinse Sampling".									
		Untrained person	➢ New person ➢ Negligence	May leads to contamination	➢ Training given to every new joinee. ➢ OJT training given to IPQA personnel.	➢ Employee training card									

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												S	O	D	RPN S*O
		Sampling/location procedure wrongly selected	➢ Untrained person ➢ New person ➢ Negligence ➢ Sampling procedure not available.	May leads to contamination	➢ Cleaning validation completed for Ampoule ,Liquid Vial & Dry Powder injection ➢ SOP of cleaning strictly followed and verified by QA. ➢ OJT training given to IPQA personnel. ➢ SOP of sampling is in place	➢ SOP No.: "Procedure for swab/Rinse sampling". ➢ Cleaning validation protocol of DPI, Ampoule & Liquid vial: ……									
		Sample hold for long period	➢ Hold time not defined ➢ Negligence ➢ UV scanner out of service ➢ Workload	False results generated	➢ Hold time defined in Analytical Method validation Protocol ➢ Testing done online at shop floor and instrument is dedicated										
4.	**SOP not validated**	Cleaning method of equipment not validated	➢ Evaluation of new equipment.	Cross contamination chance	➢ Procedure for new equipment evaluated after installation is in place. ➢ Change control initiated and shared to QA by Engineering Dept.	➢ "Evaluation of new equipment for cleaning validation"									

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												S	O	D	RPN S*O
5.	**Visual Inspection**	Visual inspector not fit for inspection	➢ Weak eye sight of person. ➢ Untrained person.	Cross contamination chance	Eye sight tested as per schedule	Medical examination certificate.									
6.	**Light Intensity**	Light intensity not suitable	Area not qualified	Cross contamination chance	Procedure for check light intensity during area qualification is in place.	Validation master plan									
7.	**New Formulation**	➢ New API not evaluated	➢ Worst case might change & SOP's need to be revalidation of API evaluation not performed. ➢ Procedure for evaluation of new API not available.	Cross contamination chance	➢ Provision for new API evaluation in CVMP ➢ Batch Offer sheet verified daily with current list.	…									
8.	**API sticky in nature**	Sticky API not identified	New API not evaluated	➢ Cross contamination chance ➢ Product failure.											

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Sr. 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
9.	**Method of Analysis**	Analysis method not proper	SOP not followed	➢ Effectiveness of method	Procedure of AMV SOP is in place	➢ "Reason of revalidation"									

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 : Media Fill Activity	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.:

Quality Risk Management Team			Reviewed By Head Production Sign & Date	Approved By Head QA Sign & Date
Name	**Department**	**Sign & Date**		

QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

QRA No.:

Name of Facility/Equipment/Utility/System/Activity/Procedure **Risk in reducing Swab & rinse testing**	**Date of Quality Risk Assessment:**

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Facility/Equipment/Utility/System/Activity/Procedure/Unit Operation : Media Fill Activity

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