RISK ANALYSIS STUDY REPORT

FOR

DISCONTINUATION OF RINSE & SWAB SAMPLING AFTER TYPE B CLEANING (ONLY FOR WATER SOLUBLE API's)

DATE OF RISK ANALYSIS	
SUPERSEDE REPORT No.	**Nil**

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REPORT CONTENTS

RISK ANALYSIS STUDY REPORT FOR DISCONTINUATION OF RINSE & SWAB SAMPLING AFTER TYPE B CLEANING (ONLY FOR WATER SOLUBLE API's)

1.0 REPORT PRE APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

RISK ANALYSIS STUDY REPORT FOR DISCONTINUATION OF RINSE & SWAB SAMPLING AFTER TYPE B CLEANING (ONLY FOR WATER SOLUBLE API's)

2.0 OBJECTIVE:

To provide documented evidence that there is no risk in discontinuation of Rinse & Swab samples of water soluble API's (Tablets & Capsules) of ……...

3.0 SCOPE:

This risk analysis study Protocol is applicable for performing risk analysis study for discontinuation of Rinse & Swab samples of water soluble API's (Tablets & Capsules) of ……..

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4.0 RESPONSIBILITY:

Department	Responsibility
Quality Assurance	• Shall prepare & Review the Risk analysis Protocol. • Execution of the Risk analysis Protocol with Production and Quality Control. • Shall compile the data & Prepare Summary Report • Risk analysis Protocol shall be approved by the QA prior the execution. • Shall review the executed Protocol to check the compliance and corrective action for any discrepancies found. Also shall prepare the summary and conclusion of the Risk analysis Study.
Quality Control	• Reviewing of Risk analysis Protocol for Correctness, Completeness and Technical Excellence. • Post approval of Risk analysis Protocol after Execution.
Production	• Reviewing of Risk analysis Protocol for Correctness, Completeness and Technical Excellence. • To provide support for execution of Risk analysis Study as per Protocol. • Post approval of Risk analysis Protocol after execution.

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5.0 REASON FOR RISK ANALYSIS:

To evaluate the risk in discontinuation of Rinse & Swab samples of water soluble API's (Tablets & Capsules) of ……..

6.0 SITE OF STUDY:

Manufacturing area (Granulation/Compression/Coating and Packing).

7.0 TRAINING OF EXECUTION TEAM:

S.No.	Name of Trainee	Department	Designation	Signature of Trainee	Checked by QA (Sign & Date)
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					

Name of the Trainer: _____

Inference:

_____

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Reviewed By_____
Manager QA
(Sign & Date)

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8.0 RISK ANALYSIS,RE-RISK ANALYSIS RESULTS:

FACILITY: DISCONTINUATION OF RINSE & SWAB SAMPLES (ONLY WATER SOLUBLE API's)	Reference Change Control:

S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Cause/ Mechanism of Failure	Potential Effect of Failure (Effect)	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*D
1.	**Cleaning Verification**	Practically insoluble swab sampling not done	May leads to contamination	• Product failure • Product recall • Product quality	• API's are water soluble, hence will be cleaned easily. As the cleaning process has been validated for practically insoluble API (Alprazolam). • Cleaning validation already done for Tablets & Capsules. • Cleaning method is robust (Previous trend of swab & rinse).	• SOP "Procedure for sampling & testing of Swab & Rinse water". • Cleaning validation protocol of Tablets:	7	10	10	700	• List of Water soluble API's to be distributed to all cluster heads. • Training given to all concerned persons. • Visual inspection SOP to be prepared • Cleaning procedure to be monitored.	7	1	5	35
		Improper sampling due to Negligence	Lack of training	• False analysis report may generate	• Cleaning validation already done for Tablets & Capsules. • Cleaning method is robust (Previous trend of swab & rinse).	• SOP "Procedure for sampling & testing of Swab & Rinse water". • Cleaning validation protocol of Tablets:	7	5	10	350	• Visual inspection SOP to be prepared • Cleaning procedure to be monitored.	7	1	5	35
		Improper Visual inspection	Residue contamination may occur	• Colour 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 Tablets & Capsules. • Cleaning method is robust (Previous trend of swab & rinse). • Cleaning validation of cleaning agent (Extran MA02) already validated. • Cleaning agent is water soluble, hence less chance of remains.	• Cleaning validation protocol of Tablets. • Cleaning validation protocol of Cleaning agent.	10	5	5	250	• Visual inspection SOP to be prepared • Cleaning procedure to be monitored.	1	1	1	1

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RISK ANALYSIS STUDY REPORT FOR DISCONTINUATION OF RINSE & SWAB SAMPLING AFTER TYPE B CLEANING (ONLY FOR WATER SOLUBLE API's)

S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Cause/ Mechanism of Failure	Potential Effect of Failure (Effect)	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*D
2.	**Cleaning Validation**	Cleaning validation not done	Worst case not selected	May leads to contamination	• Cleaning validation completed for both tablet & Capsules • Rinse & Swab sampling after every change over	• Cleaning validation protocol of Tablets • Cleaning validation protocol of cleaning agent	1	5	10	50	Cleaning validation to be evaluated periodically	1	1	10	10
		Cleaning validation 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 strictly followed and verified by QA	• Evaluation of New product for cleaning validation" • SOP's of equipment cleaning	1	1	10	10	NA	NA	NA	NA	NA
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 "Procedure for sampling & testing of Swab & Rinse water".	5	5	10	250	SOP to be revised and location to be defined	1	1	10	10
		Untrained person	• New person • Negligence	May leads to contamination	• Training given to every new joinee	• Employee training card	5	7	10	350	Training frequency to be increased	3	2	10	60
		Sampling/location procedure wrongly selected	• Untrained person • New person • Negligence	May leads to contamination	• Cleaning validation completed for both tablet & Capsules • SOP of cleaning strictly followed and verified by QA	• Cleaning validation protocol of Tablets	10	5	10	500	SOP revised and freeze and more defined	2	2	10	40
		Sample hold for long period	• Hold time not defined • Negligence • UV scanner out of service	False results generated	• Hold time defined in Analytical Method Validation Protocol • Testing done online at shop floor and instrument is dedicated	• AVP	5	1	10	50	NA	NA	NA	NA	NA
		Rinse sample collected in plain clear bottle	• Negligence	False results generated	Amber colored bottles available in stock	SAP System	5	3	5	75	Stock to be verified after every request	1	3	5	15

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S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Cause/ Mechanism of Failure	Potential Effect of Failure (Effect)	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*D
4.	**SOP not validated**	Cleaning method of equipment not validated	• New equipment used	Cross contamination chance	• New equipment evaluated after arrival • Change control initiated and shared to QA by Engineering dept.	"Evaluation of New Equipment for Cleaning Validation"	3	3	3	27	NA	NA	NA	NA	NA
5.	**Visual Inspection**	Visual inspector not fit for inspection	Weak eye sight may lead to failure	Cross contamination chance	No current control	No reference	7	7	10	700	• Visual inspection SOP to be prepared • Medical certificate to be verified.	3	3	5	45
6.	**Light Intensity**	Light intensity not suitable	Area not qualified	Cross contamination chance	Area used after qualification	VMP	1	1	1	1	NA	NA	NA	NA	NA
7.	**Cleaning Agent**	Cleaning agent not validated	Cleaning agent changed	Cross contamination chance	Any change initiated as per change control SOP	Change Control SOP	1	1	1	1	NA	NA	NA	NA	NA
		Wrong dilution used for cleaning	• Untrained person • Negligence	Cross contamination chance	SOP of preparation of cleaning agent	SOP	5	5	10	250	Verification of remaining stock	3	3	3	27
8.	**New Formulation**	New API not evaluated	Process validation missed	Cross contamination chance	New API information shared by Validation team	NA	10	5	5	250	Batch offer sheet to be verified daily with current list	1	1	1	1
9.	**API sticky in nature**	Sticky API not identified	New API not evaluated	Cross contamination chance	New API information shared by Validation team	NA	10	5	5	250	Batch offer sheet to be verified daily with current list along with property	1	1	1	1
10.	**Coloring agent**	Coloring agent not identified	New coloring agent not evaluated	Next product will fail in description	No control	No reference	10	10	5	500	New formulation to be identified initially	1	1	1	1
11.	**Method of analysis**	Analysis method not proper	SOP not followed	False results generation	Method of analysis defined	STP	10	5	5	250	SOP to be verified before every analysis	1	1	1	1

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Remarks (if any):……

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

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QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Facility			
S.No.	**Recommended Action**	**Responsible Person**	**Target Date of Completion**
1.	**Training to be given on Visual inspection**		
2.	**Cleaning procedure to be monitored strictly**		
3.	**Visual inspection SOP to be implemented**		
4.	**Light intensity to be defined each critical area**		
5.	**Cleaning validation to be redefined (Toxicity)**		

Verification of Action Plan:

All the above agreed actions completed, Not Completed.

(*incase any recommendations Not completed, to be tracked through CAPA System)

Remarks (if any):……..…..

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Verified By
(QA)
Sign & Date……..

Reviewed By:
(Manager QA)
Sign & Date……

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9.0 LIGHT INTENSITY FOR VISUAL INSPECTION: NLT 300 Lux

S.No.	Area	Location 01	Location 02	Location 03	Location 04	Location 05	Average
Granulation							
1.	Granulation 01						
2.	Granulation 02						
Compression							
1.	Compression 01						
2.	Compression 02						
Coating							
1.	Coating 01						
2.	Coating 02						
Packing							
1.	Packing Line 01						
2.	Packing Line 02						
Hard gel							
1.	Capsule Filling 01						
2.	Capsule Filling 02						

Remark:……

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Verified By
(QA)
Sign & Date……..

Reviewed By
(Manager QA)
Sign & Date…….

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10.0 DOCUMENTS TO BE ATTACHED:

- Reference SOP's.
- API Checklist.
- Training record.

11.0 DEVIATION FROM PRE DEFINED SPECIFICATION, IF ANY:

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12.0 CHANGE CONTROL, IF ANY:

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13.0 CONCLUSION:

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14.0 RECOMMENDATION:

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15.0 ABBREVIATIONS:

QA : Quality Assurance
QC : Quality Control
No. : Number
Ltd. : Limited
SOP : Standard Operating Procedure
RH : Relative Humidity
CFU : Colony Forming Unit
ISO : International Organization of Standards
FMEA : Failure Mode Effect Analysis
GMP : Good Manufacturing Practices
RPN : Risk Priority Number

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16.0 REPORT POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			