RISK ANALYSIS STUDY REPORT FOR MERGING OF BLOCK 1 AND BLOCK 2

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

RISK ANALYSIS STUDY REPORT FOR MERGING OF BLOCKS

REPORT CONTENTS

RISK ANALYSIS STUDY REPORT FOR MERGING OF BLOCKS

1.0 REPORT PRE APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

RISK ANALYSIS STUDY REPORT FOR MERGING OF BLOCKS

2.0 OBJECTIVE:

To compile the data of Risk analysis study of Merging of Block 1 & Block 2 corridor.

3.0 SCOPE:

This risk analysis study Report provides information after compilation of risk analysis study data of Merging of Block 1 & Block 2 corridor of General Block.

RISK ANALYSIS STUDY REPORT FOR MERGING OF BLOCKS

4.0 RESPONSIBILITY:

Department	Responsibility
Quality Assurance	• Shall prepare & review the risk analysis report. • Verification of test & Results. • Deficiency (if any) & Corrective Action. • 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 Report for Correctness, Completeness and Technical Excellence. • Analyze the sample as per Protocol. • Post approval of Risk Analysis Report after Execution.
Engineering	• Reviewing of Risk Analysis Report for Correctness, Completeness and Technical Excellence. • Responsible for Trouble shooting (if occurred during execution).
Production	• Reviewing of Risk Analysis Report for Correctness, Completeness and Technical Excellence. • To provide support for execution of Risk Analysis Study as per Protocol. • Post approval of Risk Analysis Report after execution.
Safety	• Reviewing of Risk Analysis Report for Correctness, Completeness and Technical Excellence. • To provide support for execution of Risk Analysis Study as per Protocol. • Post approval of Risk Analysis Report after execution.

RISK ANALYSIS STUDY REPORT FOR MERGING OF BLOCKS

5.0 REASON FOR RISK ANALYSIS:

To evaluate the risk in merging of Block 1 & Block 2 corridor.

6.0 SITE OF STUDY:

General Block

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:

_____

_____

_____

_____

_____

_____

Reviewed By_____
Manager QA
(Sign & Date)

RISK ANALYSIS STUDY REPORT FOR MERGING OF BLOCKS

8.0 RISK ANALYSIS,RE-RISK ANALYSIS RESULTS:

FACILITY: MERGING OF BLOCK 1 AND BLOCK 2 CORRIDOR **QRA No.:**	Reference change control……..

S. No.	Item/ Function	Potential Failure Mode	Effect of Potential Failure/ Cause	Severity	Occurrence	Detection	Risk Priority Number	Risk Acceptance Yes/No	Risk Reduction	Severity	Occurrence	Detection	Risk Priority Number	Risk Acceptance Yes/No	Recommended Actions (If any)
1.	**G-block renovation**	Area	Air will contaminate, due to dust non-viable particle count will get increase	10	4	4	160	Yes	G-block core area to be segregated from F block by maintaining pressure differential & Alupan sheet partition.	4	4	4	64	No	1. Partition to be verified by QA before merging of corridors. 2. Regular monitoring of pressure differential to be done for 07 days before merging of corridors. 3. Proper training on gowning to be given to the personnel involved in merging of corridor to avoid contamination & cross-contamination
			Pressure differential will get disturbed leading to increase in Non-viable count	7	4	4	112	No	Pressure Differential maintained between block 1 & block 2	1	4	4	16	No	
		HEPA filters integrity	Filters may got chocked due to dust collection	7	4	4	112	No	HEPA Filters adjacent to construction area should be covered properly	4	4	4	64	No	
		Return Risers	Filters may got chocked due to dust collection	4	4	10	160	Yes	Return riser filters adjacent to construction area should be covered properly	4	4	4	64	No	
		Environmental monitoring	Viable particle count will increase which leads MLT failure.	10	4	7	280	Yes	Particle count verification to be done before & after merging of corridor and cleaning & sanitization procedure shall be available.	4	4	4	64	Yes	
			Environmental parameters Temperature leads to failure	4	4	4	64	No	Continuous temperature monitoring to be done before & after merging of corridor	1	4	4	16	No	
			Environmental parameters Humidity leads to failure	4	4	4	64	No	Continuous humidity monitoring to be done before & after merging of corridor	1	4	4	16	No	

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ANALYSIS STUDY REPORT FOR MERGING OF BLOCKS

S. No.	Item/ Function	Potential Failure Mode	Effect of Potential Failure/ Cause	Severity	Occurrence	Detection	Risk Priority Number	Risk Acceptance Yes/No	Risk Reduction	Severity	Occurrence	Detection	Risk Priority Number	Risk Acceptance Yes/No	Recommended Actions (If any)
		Cross-contamination	Material movement will get disturbed leading to cross-contamination.	10	4	10	400	Yes	As partition of Alupan sheet will be done before merging of wall, hence material movement will not get disturbed leading to contamination.	4	4	4	64	No	
		Personnel	Man movement will increase. Personnel involved in merging of corridors may lead to contamination	4	4	10	160	Yes	As partition of Alupan sheet will be done before merging of wall, hence man movement will not get disturbed leading to contamination.	1	4	4	16	No	
		Gowning	Improper gowning cause contamination	10	4	10	400	Yes	Proper secondary gowning to be done before entering the core area	1	4	4	16	No	
		Air flow pattern change	Return riser may get chocked	4	4	10	160	Yes	Partition during merging of corridors will reduce chances of riser chocking	1	4	4	16	No	
		Power Failure recovery	Environment monitoring get disturbed	10	4	1	40	No	Power failure backup will be given to that particular AHU system to avoid any discrepancy	1	4	1	4	No	

Remarks (if any):……

……

……

……

……

……

……

……

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ANALYSIS STUDY REPORT FOR MERGING OF BLOCKS

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

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Facility			
S.No.	**Recommended Action**	**Responsible Person**	**Target Date of Completion**
1.	All Renovation activity will plan in phase manner		
2.	Fumigation frequency shall be increase in adjacent applicable areas		
3.	Area qualification and Effective environmental monitoring shall be done of renovated Area		
4.	Man Movement of renovation area shall be separate		

Verification of Action Plan:

All the above agreed actions completed, Not Completed.

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

RISK ANALYSIS STUDY REPORT FOR MERGING OF BLOCKS

Remarks (if any):……..…..

……..…

……..……

……..…..

……..…..

……..…..

……..…..

……..…..

Verified By
QA
Sign & Date……...

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

RISK ANALYSIS STUDY REPORT FOR MERGING OF BLOCKS

9.0 DIFFERENTIAL PRESSURE RECORD

Magnehelic Gauge Id. No.	
Date of Calibration	
Calibration due date	
Acceptance Criteria	

Date	Differential Pressure Corresponding To Adjacent Area	Observation					
		Morning		Afternoon		Evening	
		Time	Pressure (Pa)	Time	Pressure (Pa)	Time	Pressure (Pa)

Checked By:
(Engineering)
Sign & Date _____

Verified By:
(Quality Assurance)
Sign & Date _____

Inference:……

……

……

……

……

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

RISK ANALYSIS STUDY REPORT FOR MERGING OF BLOCKS

10.0 DOCUMENTS TO BE ATTACHED:

……

……

……

……

……

……

11.0 DEVIATION FROM PRE DEFINED SPECIFICATION, IF ANY:

……

……

……

……

……

……

12.0 CHANGE CONTROL, IF ANY:

……

……

……

……

……

……

RISK ANALYSIS STUDY REPORT FOR MERGING OF BLOCKS

13.0 CONCLUSION:

……

……

……

……

……

……

……

……

……

……

……

……

14.0 RECOMMENDATION:

……

……

……

……

……

……

……

……

……

……

……

……

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
AHU : Air Handling Unit
HEPA : High Efficiency Particulate Air Filter
MLT : Microbial Limit Test
RPN : Risk Priority Number

16.0 REPORT POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			