RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR REDUCING TESTING OF COMPRESSED AIR USER POINTS (G AND F BLOCK)

DATE OF RISK ANALYSIS	
SUPERSEDE PROTOCOL CUM REPORT No.	**NIL**

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RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR REDUCING TESTING OF COMPRESSED AIR USER POINTS

1.0 PROTOCOL CUM REPORT APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR REDUCING TESTING OF COMPRESSED AIR USER POINTS

2.0 OBJECTIVE:

- To provide documented evidence that there is no risk in reducing test from selected user points of Compressed Air in manufacturing area (Granulation & Coating).

3.0 SCOPE:

- This risk analysis study Protocol is applicable for performing risk analysis study for reducing test from selected user points of Compressed Air in manufacturing area (Granulation & Coating).

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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 Quality Control and Engineering. • 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.
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.
Engineering	• Reviewing of Risk analysis Protocol for technical excellence. • Post approval of Risk analysis Protocol after execution.
Quality Control	• Reviewing of Risk analysis Protocol for correctness and completeness. • To provide support for execution of Risk analysis Study as per Protocol.

5.0 REASON FOR RISK ANALYSIS:

- To evaluate the risk in reducing tests of selected user points of Compressed Air in manufacturing area (Granulation & Coating).

6.0 SITE OF STUDY:

Manufacturing area (Granulation & Coating).

7.0 RISK COMMUNICATION & TRAINING:

- The Risk analysis team shall be authorized by Head-QA or his/her designee.
- Quality Risk Management Team shall be cross functional team comprised of expert from different areas such as QA, QC, Engineering and Production.
- Training shall be imparted to the team members before execution of Protocol for proper understanding of the procedure. Training shall be recorded in Training attendance Record.

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7.1 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 PROTOCOL CUM REPORT FOR REDUCING TESTING OF COMPRESSED AIR USER POINTS

8.0 RISK IDENTIFICATION & EVALUATION:

- Compressed air is used to operate valves of equipments. In some equipments Compressed air comes in direct contact of product during the operation while in other it helps in opening & closing of pneumatic valves. On the basis of its usage, distribution of compressed air have been categorized as Critical & Non-Critical.

Flow diagram of Compressed air

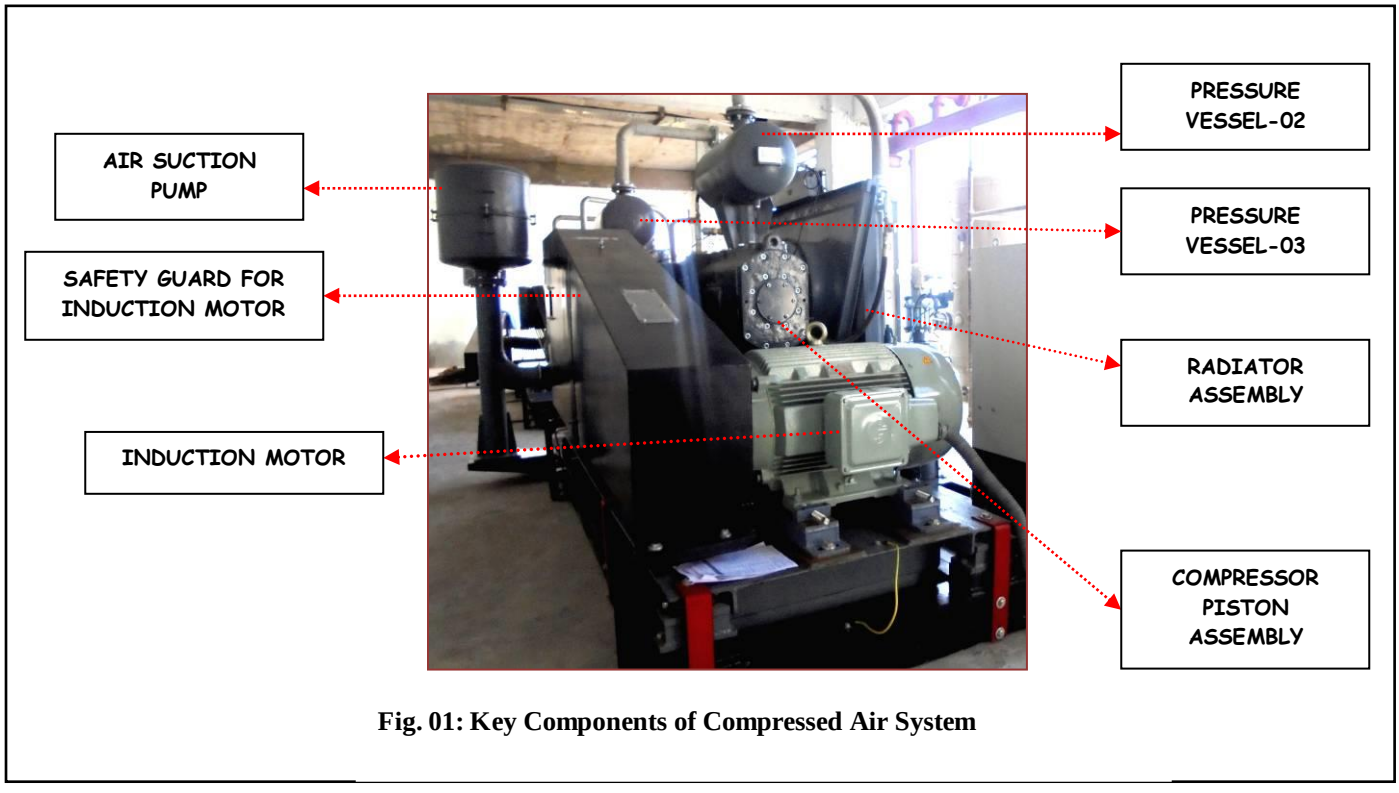

Fig. 01: Key Components of Compressed Air System

Air Compressor 644 CFM	Air Compressor 644 CFM	Air Compressor 644 CFM	Air Compressor 819 CFM

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8.1 COMPRESSED AIR PROCESSING STEPS:

Step 1: Air received (1 kg/cm^2) from atmosphere through suction pump (20µ filter).
Step 2: With the help of piston, air got compressed upto 7 kg/cm^2.
Step 3: The collected compressed air further forwarded to Radiator.
Step 4: Further cooled air got collected in Header (maintains pressure).
Step 5: Compressed air then collected in Receiver Tank.
Step 6: Where by the moisture extracted out through the drain outlet (After every 10 minute).
Step 7: Moisture free compressed air further transferred through Refrigerant Dryer.
Step 8: In Dryer the Dew point maintains upto 3-7°C.
Step 9: The dried Compressed air passed through 5 µ, 1µ and 0.01 µ filter.
Step 10: Compressed Air transferred through the SS316L pipe to the G Block service floor whereby through the Header transferred to user points.
Step 11: The equipments which are in direct contact of Compressed air are considered to be critical.

8.2 RISK IDENTIFIED:

Risk 1: Dew point may increase during generation.
Risk 2: Non-viable particle count may increase.
Risk 3: Pressure Drop.
Risk 4: Leakage problem.
Risk 5: Filters may choke.
Risk 6: Corrosion may develop due to excess moisture.
Risk 7: Bio-burden may increase.
Risk 8: Temperature increases.

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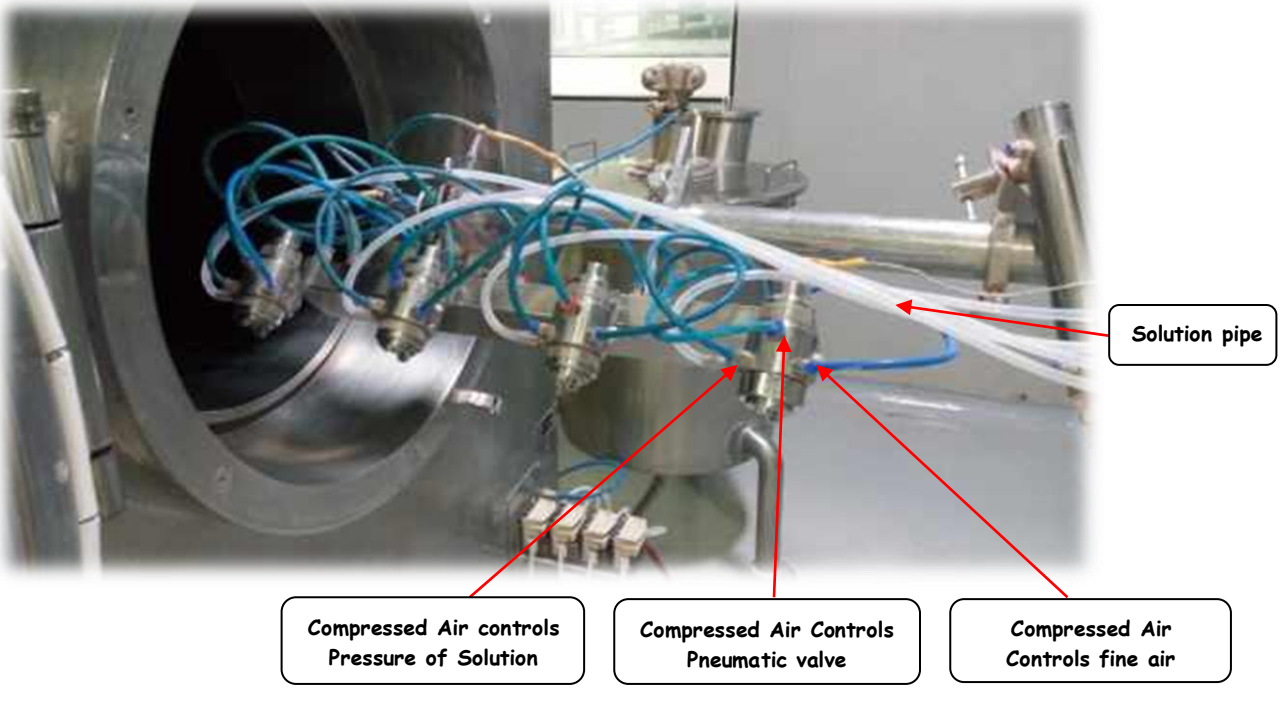
- Equipments which are in direct contact of the Compressed air are the most susceptible to the contamination.

RAPID MIXER GRANULATOR (CRITICAL)

- **At Impeller end & at Chopper end:** Compressed air is in direct contact of powder & controls the accumulation of powder.

AUTO-COATER (CRITICAL)



- Compressed air comes in direct contact of solution during coating through spray gun. Compressed air creates pressure for the solution to pass through the needle valve (in fine form).

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR REDUCING TESTING OF COMPRESSED AIR USER POINTS

8.3 RISK EVALUATION:

- Following are the reasons which may deteriorate the product if comes in contact:

S.no.	Risk Identification	Risk Evaluation
1.	**Bio-burden may increase**	Increase in particle count may increase in bio-burden may leads to product contamination, as the compressed air comes in direct contact during mixing in RMG & Coating.
2.	**Dew point may increase during generation**	Temperature increases as the air compressed through compressor, which resulted into increase in temperature (approx. 50°C). Further as the compressed air passes through distribution and the temperature decreases (40°C), it releases its moisture in the form of condensate which further increases the dew point.
3.	**Non-viable particle count may increase**	During the initial air suction, fresh air passes through 20µ filter, air particles less than 20 µ are entered into generation system which further may transfer to Distribution system resulting into cross contamination.
4.	**Pressure Drop**	Leakage in line & chocked filters may result into Pressure Drop. Pressure drop may lead to discrepancy in opening & closing of pneumatic valves of water system & equipments.
5.	**Leakage problem**	Wear & tear in generation and distribution line may result into leakage which further results into pressure drop.
6.	**Filters may choke**	Increase in particle count may result into filter choke which further results into pressure drop at user points.
7.	**Corrosion may develop due to excess moisture**	As the moisture increases corrosion may increase itself resulting into increase in particle count & microbial count.
8.	**Other Gases (Carbon Di-oxide, Carbon mono-oxide, Sulphur Dioxide, Nitrous Oxide, Hydrocarbons, Oil content)**	Increase in air contamination may lead to increase in level of other gases which may act as pollutants for the product.
9.	**Temperature Increases**	Temperature increases as the air compressed through compressor, which resulted into increase in temperature (approx. 50°C). Which further indirectly results into increase in dew point.

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9.0 RISK MITIGATION:

S.No.	CONTROLS	DESCRIPTION
1.	**20µ filter**	Four 20 µ filters are installed at initial of each compressed air system which controls the particle counts above 20 µ.
2.	**Coolant**	Premix cool named coolant is used for cooling the radiator which further controls the temperature of compressed air.
3.	**Radiator & Exhaust Fan 01**	Radiator & exhaust fan maintains the temperature of compressed air.
	Radiator & Exhaust Fan 02	
	Radiator & Exhaust Fan 03	
	Radiator & Exhaust Fan 04	
5.	**FRL**	Filter Regulator Lubricator controls the oil particles entering into the system.
6.	**Common Header 01**	Header collects the generated air and helps in maintaining the required air pressure throughout the distribution system.
	Common Header 02	
	Common Header 03	
7.	**Pressure Gauge 01**	Pressure gauges installed at required locations helps to verify the pressure drop throughout the system.
	Pressure Gauge 02	
	Pressure Gauge 03	
	Pressure Gauge 04	
8.	**Manual Drain 01**	Manual drains are installed at different critical locations, after every 10 minutes the whole generation system is flushed out to avoid any possibility of moisture in line.
	Manual Drain 02	
	Manual Drain 03	
	Manual Drain 04	
9.	**Auto Drain 01**	Auto drains are installed at different critical locations, after every 02 minutes for 10 seconds the whole generation system is flushed out to avoid any possibility of moisture in line.
	Auto Drain 02	
	Auto Drain 03	
	Auto Drain 04	
9.	**Refrigerant Dryer 01**	04 Refrigerant Dryers are installed to trap remaining moisture and for maintaining dew point upto -18°C at user point.
	Refrigerant Dryer 02	
	Refrigerant Dryer 03	
	Refrigerant Dryer 04	
10.	**5µ filter**	Different micron sized filters are installed after dryer to filter compressed air to control non-viable & viable particle count.
	1 µ filter	
	0.01 µ filter	
	0.2 µ filter	
11.	**Receiver**	Two receiver tanks are installed for receiving & distribution of compressed air.
12.	**SS 316L Distribution line**	Whole distribution line is made up of SS line which controls corrosion throughout the system.
13.	**Qualification as per schedule**	Qualification done every year to monitor the critical parameters.
14.	**Preventive Maintenance**	Operational parameters are monitored through Preventive Maintenance on quarterly basis.

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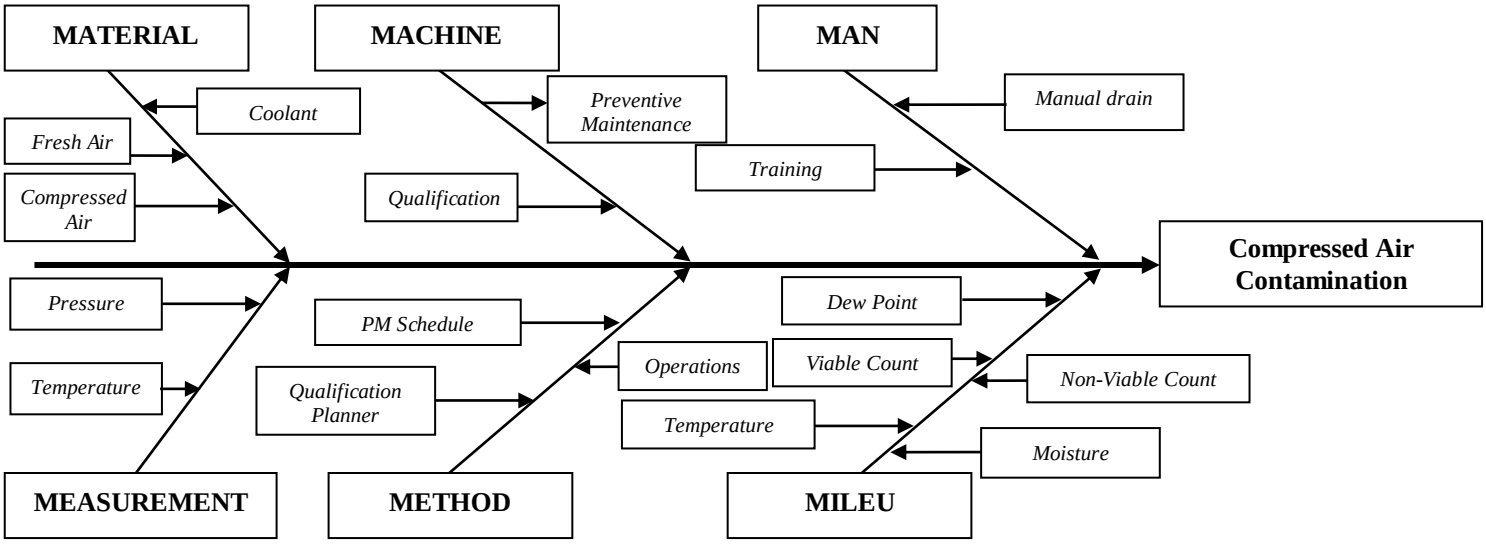
10.0 RISK ANALYSIS TOOLS, RE-RISK ANALYSIS CRITERIA:

10.1 Fish bone:



Fish bone tool used for risk assessment, area of concern are:

1. **Mileu :** Environment seems have direct impact on compressed air quality, Increase in any of the contaminants may leads to system failure.

2. **Method:** All operational parameters shall be done as per the SOP along with timely scheduled qualification & preventive maintenance.

3. **Measurement:** Certain critical parameters shall be monitored regularly.

4. **Man:** Persons doing operations shall be trained in their respective jobs.

5. **Machine:** Compressed air system shall be qualified regularly.

6. **Material:** All input raw material shall be monitored for its quality.

10.2 Failure Mode Effect Analysis:

In the following section a table is produced for the risk analysis using FMEA tool. The significance or instruction for each column is described in the following paragraph.

Column 1:	**Serial number** of Risk Analysis item
Column 2:	**Item/Function:** Identify the process step or component associated with the risk.
Column 3:	**Potential Failure Mode:** Identify the type of risk associated with the process or component.
Column 4:	**Effect of Potential Failure/Cause:** Verify that whether risk have **GMP impact.**
Column 5/6/7/8/9:	**Severity/Occurrence/Detection/Risk level/Risk Acceptance:** Risk Priority Number to be calculated by taking Severity, Occurrence & Detection of potential failure into consideration.
Column 10:	**Risk Mitigation**: Write the risk mitigation strategy as considered in design.
Column 11/12/13/14/15:	**Severity/Occurrence/Detection/Risk level/Risk Acceptance:** Risk Priority Number to be calculated after mitigation by taking Severity, Occurrence & Detection of potential failure into consideration.
Column16:	**Recommended action:** Recommended actions should be given for controlling failure occurrence.

Table 1: Instruction for each column given above

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR REDUCING TESTING OF COMPRESSED AIR USER POINTS

Procedure: Risk in reducing testing of compressed air user points	**Quality Risk Assessment Date:**

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)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN S*O*D
1.	**Compressed air Generation System**	Dew point	Cross Contamination	Product may deteriorate.	• Drain points available • Qualification • Auto drain • Dryer available	• As per SOP • As per ISO8573 • As per DQ, IQ,OQ & PQ	4	3	1	12	NA	NA	NA	NA	NA
2.		Non-viable particle count	Increase in microbial load	Product may deteriorate.	• SS Pipeline • Filters installed • Qualification	• As per SOP • As per ISO8573 • As per DQ, IQ,OQ & PQ	4	3	1	12	NA	NA	NA	NA	NA
3.		Pressure Drop	Opening & closing of pneumatic valves of water system & equipments	• Water system operational parameters got disturbed. • Equipment will not operate.	• Header availability after compressor & dryer • Receiver available • No leakage should observed • Pressure gauge installed	• As per SOP • As per ISO8573 • As per DQ, IQ,OQ & PQ	3	3	1	9	NA	NA	NA	NA	NA
4.		Leakage	May leads to pressure drop	• Water system operational parameters got disturbed. • Equipment will not operate.	• Qualification • Pressure gauge installed	• As per SOP • As per ISO8573 • As per DQ, IQ,OQ & PQ	3	3	1	9	NA	NA	NA	NA	NA
5.		Filters choke	May results into pressure drop	• Water system operational parameters got disturbed. •Equipment will not operate.	• Pressure gauge installed	• As per SOP • As per ISO8573 • As per DQ, IQ,OQ & PQ	3	3	1	9	NA	NA	NA	NA	NA
6.		Corrosion	May leads to increase in non-viable particle count.	Product may deteriorate.	• SS Line in distribution • Auto drains • Manual drains	• As per SOP • As per ISO8573 • As per DQ, IQ,OQ & PQ	4	1	3	12	NA	NA	NA	NA	NA
7.		Bio-burden	Product deterioration	Product may deteriorate.	• Filters available at different stages	• As per SOP • As per ISO8573 • As per DQ, IQ,OQ & PQ	4	1	1	4	NA	NA	NA	NA	NA
8.		Temperature	Temperature fluctuation may leads to increase in moisture content & Dew point.	Moisture fluctuation	• Coolant used • Radiator & exhaust fan available • Dryer available	• As per SOP • As per ISO8573 • As per DQ, IQ,OQ & PQ	2	2	1	4	NA	NA	NA	NA	NA

Table 2: The above table shows Potential failure mode, effect of potential failure along with Risk Probable Number, Risk Mitigation & Recommended Actions.

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***The Risk Priority Number (RPN/Overall Risk) changes based upon the risk. The Risk Assessment team shall decide the acceptance criteria. For example the risk priority number is categorized as below:**

Risk Priority Number (RPN)	Risk levels
Upto 25	Low
26-50	Medium
51 to ≤ 125	High

RPN = Severity x Occurrence x Detection

Remark 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			

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Facility			
S.No.	Recommended Action	Responsible Person	Target Date of Completion
1.			

Verification of Action Plan:

All the above agreed actions completed, Not Completed.

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

Remark if any:

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Verified By
(QA)
Sign & Date……..

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

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR REDUCING TESTING OF COMPRESSED AIR USER POINTS

11.0 CONCLUSION:

Risk analysis data shall be written on Risk Analysis Study Protocol cum Report for reducing or testing compressed air user points alternately clearly stating the achievement or non-compliance of the acceptance criteria, effect of the deviations made during the Risk analysis and in case of failure, investigation carried out and their findings.

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12.0 RECOMMENDATION:

Recommendation shall be written on the Risk Analysis Study Protocol cum Report for reducing or testing compressed air user points alternately, clearly stating that there is no impact/adverse impact on the product quality& personnel.

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RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR REDUCING TESTING OF COMPRESSED AIR USER POINTS

13.0 REFERENCES:

SOP **"Quality Risk Management".**

14.0 DOCUMENTS TO BE ATTACHED:

- Reference SOP.

15.0 DEVIATION FROM PRE DEFINED SPECIFICATION, IF ANY:

Deviations from pre-defined procedures & specification during use of containers for manufacturing shall be investigated in accordance with QA SOP **"Handling of Deviations"**, and shall be documented in the Risk analysis Protocol cum report.

16.0 CHANGE CONTROL, IF ANY:

Change control during use of containers for manufacturing shall be authorized in accordance with QA SOP **"Change Management"**, and shall be documented in the Risk analysis Protocol cum report.

17.0 ABBREVIATIONS:

FMEA : Failure Mode Effect Analysis
GMP : Good Manufacturing Practices
RPN : Risk Priority Number

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR REDUCING TESTING OF COMPRESSED AIR USER POINTS

18.0 PROTOCOL CUM REPORT POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			