Risk Analysis Study Protocol cum Report

For

Filter Integrity Testing

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR FILTER INTEGRITY TESTING

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RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR FILTER INTEGRITY TESTING

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 FILTER INTEGRITY TESTING

2.0 OBJECTIVE:

- To provide the documented evidence that there are sufficient controls to avoid any risk in case of Filter Integrity Tester malfunctioning installed in Injection block.

3.0 SCOPE:

- This risk analysis study Protocol cum Report is applicable for performing risk analysis study for Filter Integrity Tester installed in Injection block.

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR FILTER INTEGRITY TESTING

4.0 RESPONSIBILITY:

Department	Responsibility
Quality Assurance	• Shall prepare & review the Risk analysis Protocol cum Report. • Execution of the Risk analysis Protocol cum Report with Production Quality Control and Engineering. • Shall compile the data & prepare summary report • Risk analysis Protocol cum Report shall be approved by the QA prior the execution. • Shall review the executed Protocol cum Report 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 cum Report for correctness, completeness and technical excellence. • To provide support for execution of Risk analysis Study as per Protocol cum Report. • Post approval of Risk analysis Protocol cum Report after execution.

5.0 REASON FOR RISK ANALYSIS:

Filter-integrity testing is an essential step for a batch release. A false-passed integrity test (e.g., a conforming test result even though a filter is broken) could risk the patient health if it is not detected through required sterility testing. A false-failed integrity test (a failing test result despite filter integrity) would require drug quarantine, incurring a negative financial impact for the manufacturer. Worse, it could risk patient health by disturbing supplies of an essential medicine. Hence a Risk Analysis shall be done to evaluate the controls in place to avoid any critical condition during malfunctioning of Filter Integrity Tester.

6.0 SITE OF STUDY:

Filter Integrity Tester installed at Injection Block.

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 experts from different areas such as QA and Production.
- Training shall be imparted to the team members before execution of Protocol cum Report for proper understanding of the procedure. Training shall be recorded in Training attendance Record.

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.					

Name of the Trainer: _____

Inference:

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……
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Reviewed By_____
Manager QA
(Sign & Date)

8.0 REFERENCE DOCUMENTS/DRAWINGS

S.No.	Document Title	Document Number
1.	Quality Risk Management	
2.	Operation and Cleaning of Integrity Tester Machine	
3.	Integrity Tester Machine, Servicing And Calibration Record	
4.	Operation & Cleaning Record of Filter Integrity Tester	
5.	Standard Operating Procedure for Issuance, Usage, Replacement and Integrity Testing of Filters	
6.	Integrity test value if filters	
7.	Filter Sterilization Cycle Record	
8.	Filter Receiving & Issuance Record	
9.	Product wetted filter integrity test value of filter for specific Products	
10.	Filter Physical Verification Record during Receiving from Store	
11.	Planner for Vent Filter Integrity	

9.0 EQUIPMENT/SYSTEM DESCRIPTION:

Filter Integrity Machine (Palltronic Flowstar IV), is 21 CFR compliance machine installed in Grade D of the Ampoule Section is 21 CFR compliance machine that stores all the data and also have audit trail system. The equipment is commonly used for testing of filters such as Product filters, Vent filters and Compressed gases (Nitrogen & Compressed air) filters of I block & Q Block.

Integrity testing is a critical operation, especially for sterilizing grade filters used in pharmaceutical processing. When performed correctly, an integrity test is a fast, definitive, non-destructive way to assure filter retention performance. Fortunately, there are few ways a non-integral filter will pass the integrity test, eliminating the possibility a non-retentive filter is used undetected. Unfortunately, there are a lot of ways an integral filter can fail the integrity test, resulting in retests, lost time, lost productivity and potentially lost product.

Filter integrity tests are primarily based on capillary forces that hold liquid in the pores of wet membranes. The smaller the pores, the stronger the capillary forces. The “bubble point” test measures the force in gas pressure required to overcome the capillary forces, and therefore provide an assessment of pore size. The “Diffusion” type tests measure gas flow across the wet membrane at a pressure below the bubble point. If gas flow is below an established specification the assumption is capillary forces have not been exceeded and therefore, all the pores are small enough to meet retention requirements. Test errors come from any phenomena impacting capillary forces, gas diffusion, or gas flow or pressure measurement accuracy. It is a common assumption that false integrity failures are the result of incomplete membrane wetting. Incomplete wetting is certainly a common problem, but it is not the only potential problem. Simply rewetting and retesting may or may not produce a passing result and may not reveal the root cause of the problem.

10.0 RISK IDENTIFICATION, EVALUATION & MITIGATION:

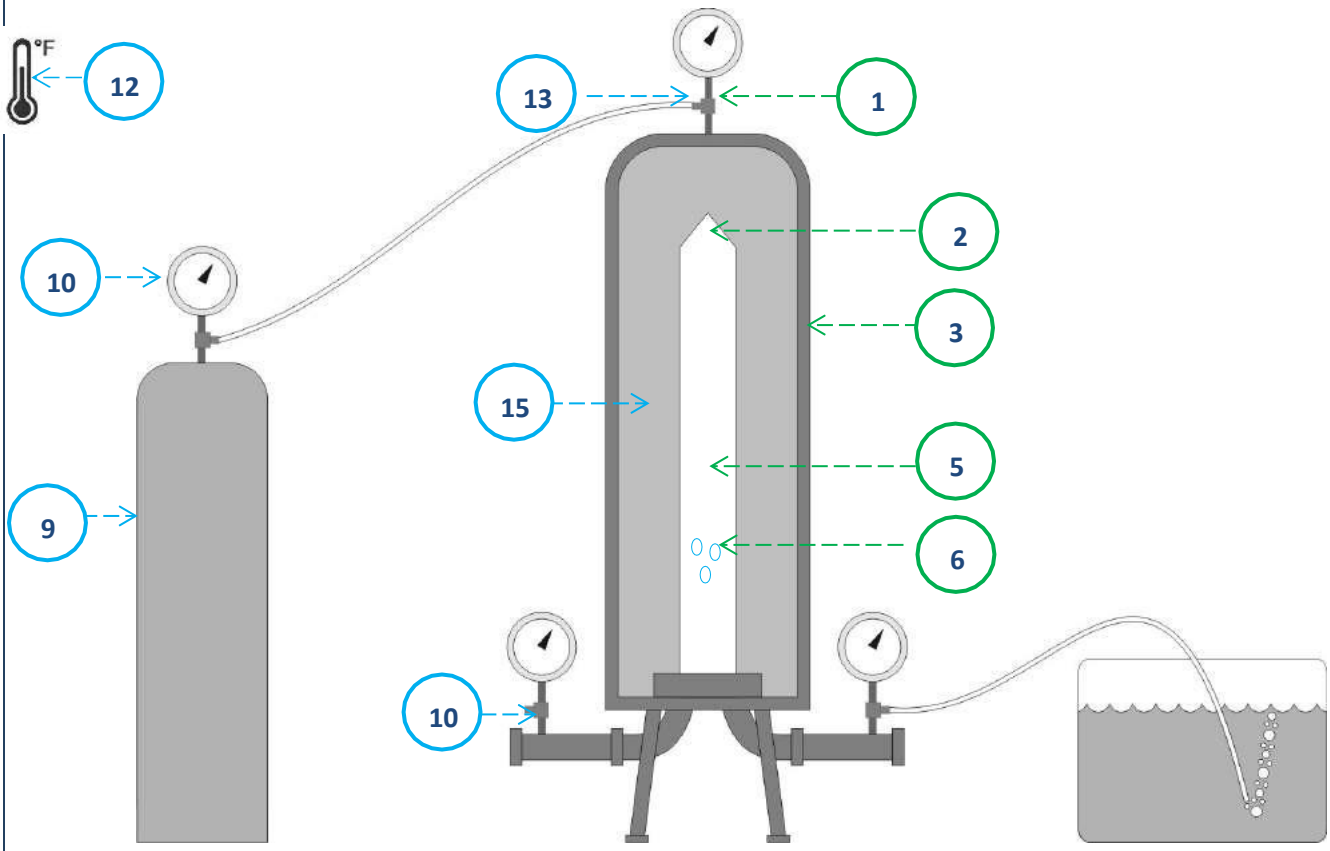


Figure 1

Following are the Risk identified & to be evaluated:

S.No.	Filter Related Failure Modes	S.No.	Test Method Failure Modes
1	O-ring damage	8	Wrong test selected
2	Membrane damage	9	Wrong test gas used
3	Device damage	10	Leaks
4	Surface tension suppression	11	Instrument/gauges out of calibration
5	Poor wetting	12	Temperature change
6	Air lock	13	Valves improperly open or closed
7	Wrong membrane	14	Untrained operator
		15	Wrong wetting fluid

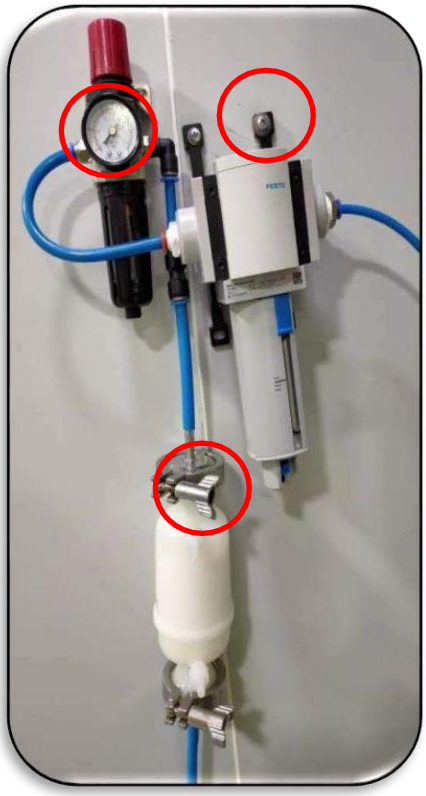
Table 1

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR FILTER INTEGRITY TESTING

At the very basic stage of design, the Risk Assessment is carried out to verify that all features are taken into consideration to avoid the risk of failure of critical GMP and EHS parameter in the equipment. During study, all GMP, EHS and operational parameters will be identified and assessed for the risk, appropriate mitigation will be proposed and verification point will be identified and defined. The Risk Assessment report is produced to provide the documented evidence that design concepts or requirement are complete in considering all GMP, EHS and operational risks.

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR FILTER INTEGRITY TESTING

11.0 ERRORS & ALARMS:



Line pressure low due to certain factors

Cause of Error:

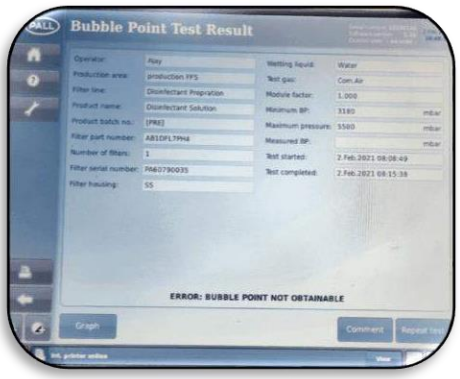
1. Leakage
2. Valve improperly closed
3. Nozzle Opened
4. Clamp not tightly closed
5. Incoming compressed air with low pressure

Mitigation:

1. Trained Operator
2. Clamps, Valves & Nozzles properly closed /opened as per requirement
3. Pressure verified

Error 1: Line pressure too low

Error 2: Leak test failure



Error 3: Bubble Point not obtainable

Error 4: Pressure not obtainable

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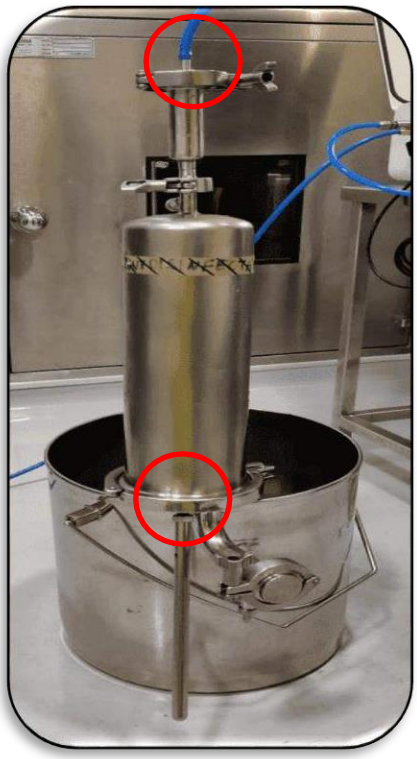
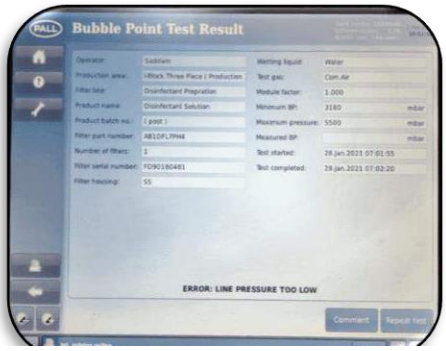
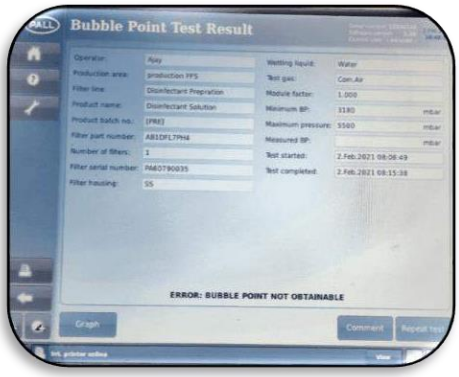


Assembly settings



Error 1: Line pressure too low

Error 2: Leak test failure



Error 3: Bubble Point not obtainable

Error 4: Pressure not obtainable

Cause of Error:

1. Leakage
2. Valve improperly closed
3. Nozzle Opened
4. Clamp not tightly closed

Mitigation:

4. Trained Operator
5. Clamps, Valves & Nozzles properly closed /opened as per requirement
6. Pressure verified

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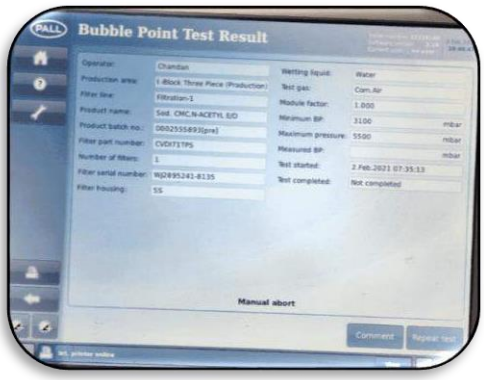
Setting Parameters



Manual Abort: Improper setting

Cause of Error:

1. Wrong Product name
2. Wrong Batch number
3. Wrong setting parameters

Mitigation:

1. Trained Operator
2. Trained Chemist
3. SOP in place

12.0 RISK ANALYSIS TOOLS, RE-RISK ANALYSIS CRITERIA:

12.1 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 2: Instruction for each column given above

The purpose of FMEA for Filter Integrity Testing is to establish documentary evidence to assure that the manufacturing process is capable of producing the pre-determined quality specifications when using a specific tester for integrity testing of filters, while guaranteeing the safety of the operator.

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Procedure: Filter Integrity Testing											**Quality Risk Assessment No.: …..**				
S.No.	**Item/Function**	**Potential Failure Mode**	**Potential Cause/Mechanism of Failure**	**Potential Effect of Failure**	**Current Control**	**Reference document no.**	**S**	**O**	**D**	**Risk Priority Number (S x O x D)**	**Recommended action (If any)**	**Post Risk Evaluation**			
												S	**O**	**D**	**RPN**
1.	**Manpower**	• Filter Damage • Filter Housing opened during operation • Filter Specification not followed • Improper wetting • SOP not followed • Valves not closed properly	• Mishandling • Untrained Operator • Pressure not achieved • Vendor specific set parameters not followed • Failure not addressed through QMS tool	• Bubble Point Failure • Filter got leakage • Inappropriate results • Bubble Point failure • Filter got damaged • Results not achieved • No effect on product quality	• Training report available • SOP in place • Pre & Post filter integrity performed and detected before manufacturing activity	• Training record • SOP No.: …..	5	3	3	**45** **Severity** is high, as the failure if not addressed through QMS tool can result into data integrity **Occurrence** of the incident is possible, as wetting is a manual process Failure might be **Detected** and depends on the training of the concerned person	• Gasket & Valves to be verified before the start of the activity • Valves to be opened slowly • Robust training to be given on QMS & concerned SOP. • Audit trail review checklist to be introduced.	5	1	1	5
2.	**Filters Shelf life**	Filters expired	• Improper filtration • Chocked filters • Pressure not maintained	• Bubble Point failure	• Filters replaced after maximum sterilization cycle	• Filters Specification • Record of Sterilization cycle available	5	2	1	**10** **Severity** is high, as the expired filter results into Bubble Point failure As vendor specification is available with its expiry & filters sterilization cycle is recorded hence	• Calibration to be done for Gauges	NA	NA	NA	NA

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S.No.	Item/Function	Potential Failure Mode	Potential Cause/Mechanism of Failure	Potential Effect of Failure	Current Control	Reference document no.	S	O	D	Risk Priority Number (S x O x D)	Recommended action (If any)	Post Risk Evaluation			
												S	O	D	RPN
										chance of **Occurrence** is very rare. Due to availability of Specification & sterilization cycle, shelf life of filters is always **Detected**					
3.	**Wetting Solvent (Water for Injection/Iso Propyl Alcohol)**	Improper wetting of filters	Air got trapped	• Wrong result interpretation • Bubble Point Failure	• Dedicated mBAR values available for specific products. • SOP of Operation of Filter Integrity Tester is in place	SOP No.: "Issuance, Usage, Replacement and Integrity Testing of Filters", Annexure IV "Product wetted filter integrity test value of filter for specific Products"	5	3	1	**15** **Severity** of the improper wetting is high, as it can result into Bubble Point Failure or wrong results **Occurrence** is possible, as the process of wetting depends on trained manpower working accuracy Failure will be always **Detected**, as failure results are displayed in printout		NA	NA	NA	NA

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S.No.	Item/Function	Potential Failure Mode	Potential Cause/Mechanism of Failure	Potential Effect of Failure	Current Control	Reference document no.	S	O	D	Risk Priority Number (S x O x D)	Recommended action (If any)	Post Risk Evaluation			
												S	O	D	RPN
4.	**Pressure Gauge**	Defective Pressure gauges	Pressure Gauges not calibrated	Bubble point not achieved	Yearly Calibration as per schedule	Calibration Planner in place	5	3	1	**15** **Severity** is very high, as defective pressure gauge may result into air pressure fluctuation which further result into Bubble point failure **Occurrence** of defective Pressure Gauge is possible Defected Pressure Gauge can always be **Detected**		NA	NA	NA	NA
5.	**Filter Regulator Lubricator**	• FRL not working • Air pressure fluctuation	Excess moisture or dust particles ma contaminate the filters	Filters got chocked due to dust accumulation	Display pressure over gauge monitored regularly		5	3	1	**15** Failure of FRL can be **Severe** in case of dust accumulation **Occurrence** might be possible Any failure in FRL can be easily **Detected**		NA	NA	NA	NA
6.	**Valves**	Air pressure fluctuation	Valve not properly closed	Filter get ruptured or damaged	• External valve is	SOP No.:	5	3	1	**15**		NA	NA	NA	NA

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S.No.	Item/Function	Potential Failure Mode	Potential Cause/Mechanism of Failure	Potential Effect of Failure	Current Control	Reference document no.	S	O	D	Risk Priority Number (S x O x D)	Recommended action (If any)	Post Risk Evaluation			
												S	O	D	RPN
			External valve not opened	Pressure increased	verified before every operation • Pressure monitoring	Issuance, Usage, Replacement and Integrity Testing of Filters") in place				Improper closing of valves can cause serious concern to filters, hence increase **Severity** **Occurrence** of valves improper closing might be possible Valves opening or closing can be easily **detected** during instrument operation.					
7.	**Tube fittings**	Leakage in tube fitting	Pressure required for bubble point not achieved	• Wrong interpretation • Bubble Point Failure	Pressure monitoring	SOP "Issuance, Usage, Replacement and Integrity Testing of Filters") in place	5	3	1	**15** Leakage in tube fittings is a serious concern and can have **Severe** impact on instrument performance **Occurrence** of tube fitting leakage might be possible Leakage can be easily **detected** by touching the joints		NA	NA	NA	NA

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S.No.	Item/Function	Potential Failure Mode	Potential Cause/Mechanism of Failure	Potential Effect of Failure	Current Control	Reference document no.	S	O	D	Risk Priority Number (S x O x D)	Recommended action (If any)	Post Risk Evaluation			
												S	O	D	RPN
8.	**Filter Assembly Set up**	• Wrong filter size is being tested • Filter installed in wrong direction	Incorrect setup	• Inappropriate results • Filter got damaged	• SOP of operation in place • Trained operator		5	1	1	**5** **Severity** of wrong filter set up is high **Occurrence** of wrong filter setup is very rare Wrong filter setup can be easily **detected**		NA	NA	NA	NA

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S.No.	Item/Function	Potential Failure Mode	Potential Cause/Mechanism of Failure	Potential Effect of Failure	Current Control	Reference document no.	S	O	D	Risk Priority Number (S x O x D)	Recommended action (If any)	Post Risk Evaluation			
												S	O	D	RPN
9.	**Temperature**	• Temperature too high • Error observed during machine operation	• Proximity to heat source (Autoclave /Steam lines) • Poor ventilation by HVAC system • Steam sterilizing surrounding equipment • By exposure to direct sunlight	Inaccurate results	• Activity performed in controlled area • Regular monitoring of temperature & RH	Temperature/ RH monitoring log book	3	1	1	**3** **Severity** is moderate as filters are installed in an SS assembly & are away from direct environment **Occurrence** is not possible as the Is performed within the controlled environmental conditions & regular monitoring of temperature is done& recorded. Can be easily **detected**		NA	NA	NA	NA

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S.No.	Item/Function	Potential Failure Mode	Potential Cause/Mechanism of Failure	Potential Effect of Failure	Current Control	Reference document no.	S	O	D	Risk Priority Number (S x O x D)	Recommended action (If any)	Post Risk Evaluation			
												S	O	D	RPN
10.	**Filter Wetting**	• Improper Dilution of IPA (70%) • Improper wetting of filters membrane • Improper dipping in product solvent	• Wetting time (10-15 minutes) not followed • Product solvent not used	• Bubble point not achieved • Filters got chocked	• Robust wetting • Trained operator	SOP No.: "Issuance, Usage, Replacement and Integrity Testing of Filters") in place	5	3	5	**75** **Improper filter wetting can have Severe effect on results** **Occurrence** of improper wetting is possible **Detection** cannot be done for improper wetting		**5**	**1**	**1**	**5**
11.	**Storage for filters**	Damaged filters	Storage condition (Temperature/RH) not maintained	Product Sterility failure	Stored in lock & key under controlled conditions	SOP No.: Issuance, Usage, Replacement and Integrity Testing of Filters") in place	5	2	1	**10** **Severity** is maximum if filters stored under inappropriate conditions **Occurrence** is very rare, as filters are stored under controlled conditions Can be easily **detected** is not maintained properly		NA	NA	NA	NA
12.	**Pre-Filter**	Product failure	Not performed	Product Sterility	SOP in place	HPD/038	5	1	1	**5**		N	N	N	NA

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S.No.	Item/Function	Potential Failure Mode	Potential Cause/Mechanism of Failure	Potential Effect of Failure	Current Control	Reference document no.	S	O	D	Risk Priority Number (S x O x D)	Recommended action (If any)	Post Risk Evaluation			
												S	O	D	RPN
	integrity & Post filter integrity			failure		"Issuance, Usage, Replacement and integrity testing of filters				**Severity** is very high, if the activity not performed **Occurrence** is unlikely **Detectability** is always detected		A	A	A	
13.	**Line pressure**	Required pressure (5000-6000 mbar not achieved	• Line pressure too low or fluctuation in the compressed air supply • Improper Storage • Wrong results interpretation • Improper flushing	• Error in transcription • Improper wetting	• Check/increase the line pressure • Qualified compressed air available	SOP "Issuance, Usage, Replacement and Integrity Testing of Filters") in place	5	1	1	**5** Improper line pressure may leads to **Severe** impact if not maintained **Occurrence** is unlikely, as line pressure is monitored before the start of the activity Can be easily **detected**		NA	NA	NA	NA

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S.No.	Item/Function	Potential Failure Mode	Potential Cause/Mechanism of Failure	Potential Effect of Failure	Current Control	Reference document no.	S	O	D	Risk Priority Number (S x O x D)	Recommended action (If any)	Post Risk Evaluation			
												S	O	D	RPN
14.	**Filter Integrity tester not calibrated**	Results not achieved	• Wrong data generated • Outside party not available	Error observed during performance	• Calibration report available • Replace filter if needed	Calibration Planner	5	1	1	5 **Severity** is high if not calibrated as per schedule **Occurrence** is low as calibration is done yearly **Detectability** can be easily done		NA	NA	NA	NA
15.	**Flow unstable**	Fast increase in flow during the measurement due to a leak filter de-wetting during the test	• Fluctuating pressure • Fluctuating temperature	• Error observed during performance • Filter ruptured	• Check test systems • Check for temperature conditions	SOP "Issuance, Usage, Replacement and Integrity Testing of Filters") in place	5	1	1	5 Unstable flow can be **severe** and may result into Bubble Point failure & filter rupture **Occurrence** might be possible **Detectability** is very high, as flow can be monitored		NA	NA	NA	NA
16.	**Gaskets between the clamp**	Damaged	Low pressure maintained	Joints leakage	Trained operator	"Operation and Cleaning of Integrity Tester Machine"	5	1	1	5 **Severity** is high as decreased line pressure may lead to low pressure error		NA	NA	NA	NA

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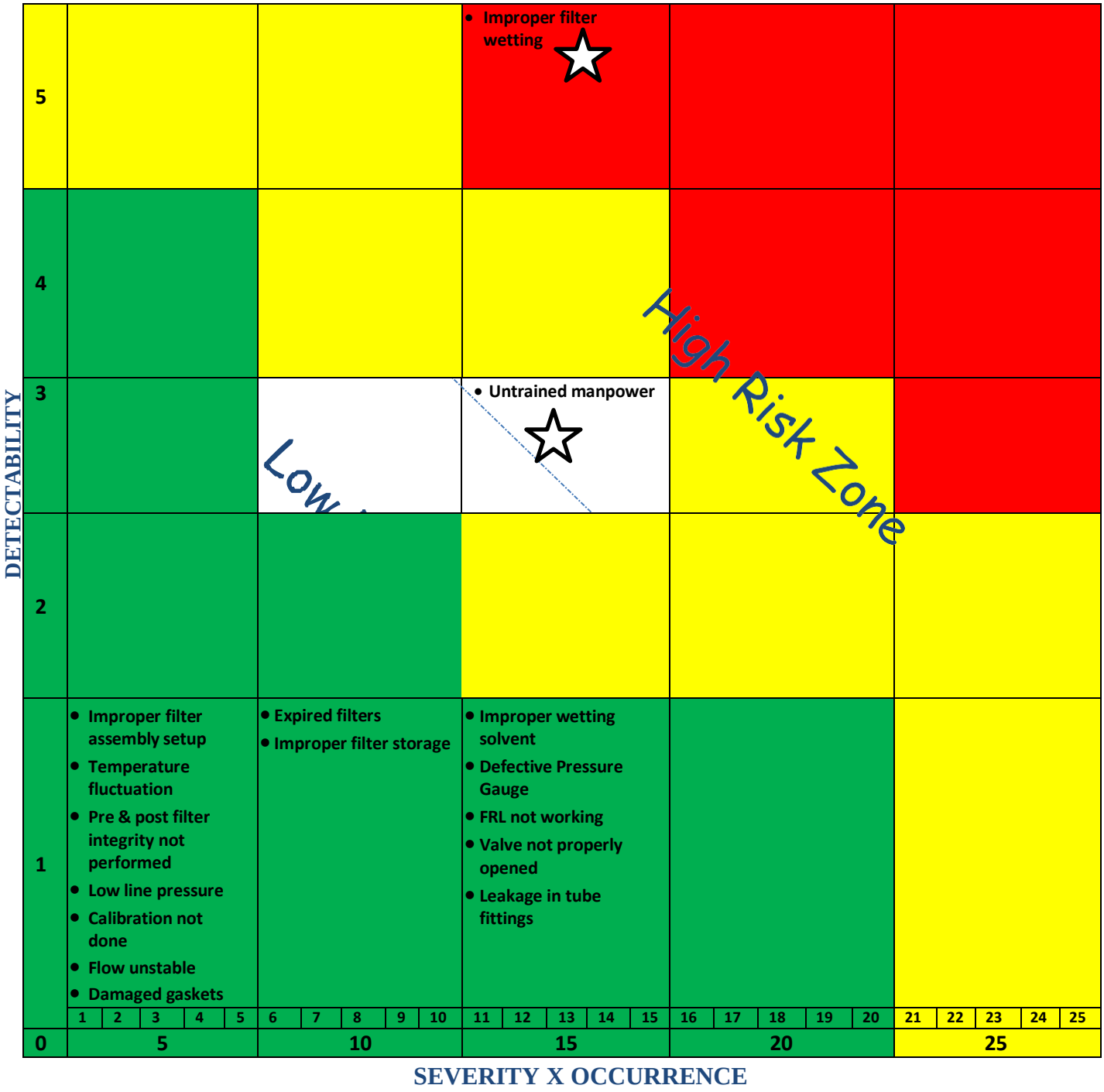
												S	O	D	RPN
										Occurrence might be possible **Detectability** is high					

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR FILTER INTEGRITY TESTING

FMEA MATRIX



1. High Quality Risk due to improper wetting, Severity: 5; Occurrence: 3; Detectability: 5, **RPN = 75**
2. Medium Risk due to untrained manpower, Severity: 5; Occurrence: 3; Detectability: 3, **RPN = 45**

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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:

Severity Ranking:

Severity Effect	Rating
No Effect	1
Minor Effect	2
Moderate Effect	3
Serious Effect	4
Hazardous Effect	5

Likelihood Occurrence Ranking:

Likelihood Occurrence	Rating
Unlikely	1
Very Rare	2
Possible	3
Likely	4
Almost Certain (Every time)	5

Detection Ranking:

Severity Effect	Rating
Always Detected	1
Will Detect failure	2
Might Detect Failure	3
Almost certain not to detect failure	4
Lack of detection control	5

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

RPN = Severity x Occurrence x Detection

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR FILTER INTEGRITY TESTING

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			

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR FILTER INTEGRITY TESTING

13.0 VERIFICATION OF ACTION PLAN:

All the above agreed actions completed, Not Completed.

(*in case any recommendations not completed, to be tracked through CAPA System)

Remark if any:

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Verified By
(Officer/Executive QA)
Sign & Date……..

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

14.0 CONCLUSION:

Risk analysis data shall be written on Risk Analysis Study Protocol cum Report for the equipment, 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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15.0 RECOMMENDATION:

Recommendation shall be written on the Risk Analysis Study Protocol cum Report clearly stating that there is no impact/adverse impact on the product quality & personnel.

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16.0 DEVIATION FROM PRE DEFINED SPECIFICATION, IF ANY:

Deviations observed from the pre-defined procedures, calibration not performed as per the schedule, matter has been investigated in accordance with QA SOP **"Handling of Deviations"**, and has been documented in the Risk analysisProtocol cum report.

17.0 CHANGE CONTROL, IF ANY:

No Change control observed, if observed shall be authorized in accordance with QA SOP **"Change Management"**, and shall be documented in the Risk analysisProtocol cum report.

18.0 ABBREVIATIONS:

FMEA : Failure Mode Effect Analysis

GMP : Good Manufacturing Practices

RPN : Risk Priority Number

19.0 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)			