



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## QUALITY RISK ASSESSMENT & MITIGATION PLAN

### FAILURE MODE EFFECT ANALYSIS FOR NEW PACKING LINE

Reference Document No.:

Risk Assessment No.:

QRA No.: .....

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

Quality Risk Assessment Date: ...

New Packing Line

S.No.	Item/ Function	Potential Failure Mode (Failure Mode)	Potential Effect of Failure	Potential Cause/ Mechanism of Failure	Current Control	Reference document No.	S	O	D	Risk Priority Number (SxOxD)	Recommended Actions (if any)	Post Risk Evaluation			
												S	O	D	RPN SxOxD
<b>MAN</b>															
1.	Manpower	Equipment not operated properly	Equipment breakdown	Untrained machine operator	Recruitment of employees SOP available		3	2	1	6	Risk is low hence no action plan required	NA	NA	NA	NA
			Product quality failure	Equipment not working.	Equipment Qualification SOP available										
		Area & AHU not qualified as per GMP	Product quality failure	Area/facility qualification Not Done	Area/Facility Qualification SOP available		3	1	1	3	Risk is low hence no action plan required	NA	NA	NA	NA
			Area not design as per GMP	Area/facility is not designed as per Approved layout	Approved layout available										
			AHU not working	AHUs Not working properly	AHU qualification SOP available										
		Equipment not qualified as per its limits	Equipment not Qualified	Equipment not qualified as per GMP	Equipment qualification SOP available		3	2	1	6	Risk is low hence no action plan required	NA	NA	NA	NA
			Equipment not working	Equipment Preventive maintenance not available	Equipment Preventive Maintenance SOP available										
Improper cleaning of area & equipment	Environmental Failure	Area Cleaning & sanitization procedure not adequate	Area Cleaning & sanitization procedure SOP available		3	2	1	6	Risk is low hence no action plan required	NA	NA	NA	NA		



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												S	O	D	RPN SxOxD		
		Unhygienic practices	Environmental Failure Product Quality Failure	Inadequate Personal Hygiene Product Contamination	Personal hygiene policy available. Personal hygiene SOP available												
<b>MATERIAL</b>																	
2.	Utility	Electricity failure	Product quality failure Personal safety Environmental failure Material safety	DG not available Light cut Proper voltage not Available Short circuit in electricity	DG Available DG SOP available Fire Fighter System Available MCB Trip provision available in case of short circuit.		2	2	1	4	Risk is low hence no action plan required	NA	NA	NA	NA		
		Chilled water line not available	Equipment not working as per GMP	Overheating of Sealing plate	Chilled water pipe line available												
		Compressed Air not available	Equipment not working as per GMP	Equipment not working	Compressed air SOP available												
3.	SS Almirah	SS Almirah not available	Product quality failure Product Contamination	Gowning & De-gowning process Not effective Cleaned & to be cleaned garment not separated	As per approved drawing SS Almirah available Cleaned & to be cleaned separate available						Risk is low hence no action plan required	NA	NA	NA	NA		
4.	Cross over bench	Cross over bench not available	Environmental failure	Product Contamination	As per approved drawing Cross over bench available		3	1	1	3	Risk is low hence no action plan required	NA	NA	NA	NA		
5.	Mirror	Mirror not available	Personal safety	Improper Gowning	As per approved drawing Mirror available		2	1	1	2	Risk is low hence no action plan required	NA	NA	NA	NA		
6.	Dispenser	Dispenser not available	Product Safety	Contamination of product	As per approved drawing dispenser available		3	2	1	6	Risk is low hence no action plan required	NA	NA	NA	NA		



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												S	O	D	RPN SxOxD		
		Disinfectant solution (IPA 70%) not changed on daily basis	Product Safety	Microbial Growth not inhibit.	Sanitization SOP available												
7.	<b>Secondary gowning</b>	Available gowning not cleaned	Contamination	Use Gowning cleaning process not available	Garment cleaning SOP available		2	1	1	2	Risk is low hence no action plan required	NA	NA	NA	NA		
8.	<b>Equipment</b>	Equipment not qualified	Product quality failure personal safety	Machine not validated lack of training Safety interlocking /features not available	Equipment qualification SOP available		3	2	1	6	Risk is low hence no action plan required	NA	NA	NA	NA		

**METHOD**

9.	<b>Standard Operating Procedures</b>	SOP of operation not available	Product quality failure personal safety material safety	Machine not validated lack of training Safety interlocking /features not available	Equipment qualification SOP available Equipment Preventive maintenance SOP available		3	1	1	3	Risk is low hence no action plan required	NA	NA	NA	NA		
		SOP of Cleaning not available	Area Not clean	Area Cleaning not adequate	Area Cleaning & sanitization SOP available		3	2	1	6	Risk is low hence no action plan required	NA	NA	NA	NA		
			Equipment not clean	Cleaning of equipment not adequate	New Equipment cleaning SOP available												
			AHU Not Working	Cleaning of AHUs not adequate	Cleaning of AHU SOP available												
AHU filter Cleaning not adequate	AHUs Dampers & Return Riser filter Dampers filter SOP available																



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												S	O	D	RPN SxOxD
		Gowning De-gowning procedure not available	Contamination	Inadequate Gowning /DE Gowning Procedure	Gowning/DE Gowning system made and SOP available		3	2	1	6	Risk is low hence no action plan required	NA	NA	NA	NA
		Unhygienic practices	Contamination	Hand sanitization not done	Dispenser available all area		3	2	1	6	Risk is low hence no action plan required	NA	NA	NA	NA
	Face mask not used			Gowning & De-gowning SOP available											
	Beard not trimmed			Good Hygiene practices SOP available											
	Personal Hygiene														
10.	Sanitization	Procedure not available	Contamination	Sanitization method not followed	Preparation of Cleaning & sanitization SOP available		3	1	1	3	Risk is low hence no action plan required	NA	NA	NA	NA
		Not effective	Contamination	Dilution improper (70%)	Sanitization SOP available										
11.	Man movement	Man movement layout not in place	Man entry wrong place	Man movement approved layout not available	Man Entry Layout available		3	1	1	3	Risk is low hence no action plan required	NA	NA	NA	NA
		Entry exit procedure not followed	Contamination	Lack Of Tanning of procedure	Entry & Exit SOP available										
		Gowning procedure not followed	Cross- contamination	Without gowning & De-gowning person enter in area	Gowning & De-gowning SOP available										
12.	Material movement	Material movement layout	Material safety	Material movement layout not available	Approved Material Movement layout available		2	1	1	2	Risk is low hence no action plan required	NA	NA	NA	NA
		Static Pass Box not	Material movement	Material movement layout available	Approved Layout available										



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												S	O	D	RPN SxOxD			
		available																
13.	Qualification not done	Unqualified area	Area not design GMP	Area qualification SOP not available	Area qualification SOP available		3	2	1	6	Risk is low hence no action plan required	NA	NA	NA	NA			
		Unqualified AHU	Environmental failure in area	AHU Qualification SOP not available	AHU Qualification SOP available													
		Unqualified equipment used for commercial batches	Equipment Safety Personal safety Material safety	Equipment qualification SOP available	Equipment Qualification SOP available													
				Equipment preventive maintenance SOP not available	Equipment preventive maintenance SOP available													
<b>MILEU</b>																		
14.	Environment condition	AHU not qualified	Environmental failure in area	AHU Qualification SOP not available.	AHU qualification SOP available		3	2	1	6	Risk is low hence no action plan required	NA	NA	NA	NA			
				AHU preventive maintenance SOP not available	AHU preventive SOP available													
		Temperature, Relative humidity and DP Not maintain	Environmental failure Product quality failure Personal safety Material safety	AHU's Not working properly	AHUs Operation, cleaning, SOP available													
				Preventive maintenance of AHUs Not Done.	AHUs Operation, cleaning, preventive maintenance SOP available													
				AHU Filter Cleaning SOP not available	Pre filter, fine filter. riser filter Cleaning SOP available													
				Viable count, nonviable count	Environmental failure	Area Cleaning & sanitization procedure not										Area Cleaning & sanitization SOP		



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												S	O	D	RPN SxOxD	
		increased	Product quality failure Personal safety Material safety	adequate, AHU's Not working properly AHUs Operation, cleaning SOP available. Preventive maintenance of AHUs Not Done Cleaning of AHUs Dampers & Return Riser filter Dampers filter not adequate Inadequate Gowning /DE Gowning Procedure Inadequate Return riser Cleaning Inadequate Personal Hygiene	available AHU Qualification SOP available AHUs preventive maintenance SOP available Pre filter, fine filter riser filter Cleaning SOP available Gowning/De Gowning system made and SOP available Return Riser SOP available Personal Hygiene SOP available											
15.	Facility Design	Facility not design as per cGMP	Environmental failure Product quality failure Personal safety Material safety	Layout not available & Approved	Layout is available Room data sheet SOP annexure available		3	1	1	3	Risk is low hence no action plan required	NA	NA	NA	NA	
16.	Return riser blocked by keeping material	Air flow pattern disturbed	NVPC & VPC uncontrolled in area	AHU Qualification process not available Machine Block riser	AHU Qualification SOP available Area Qualification SOP available RDS available		3	2	1	6	Risk is low hence no action plan required	NA	NA	NA	NA	





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												S	O	D	RPN SxOxD		
				Same AHUs Supplied air to multiple area having different product processing	Approved AHU Supply layout available												
19.	Safety	Earthing not provided	Equipment not safe	Equipment qualification SOP not available	Equipment Qualification SOP available		3	2	1	6	Risk is low hence no action plan required	NA	NA	NA	NA		
		Fire system	Product quality failure Personal safety Material safety	Fire Hydrant system not available	Fire Hydrant system available		3	2	1	6	Risk is low hence no action plan required	NA	NA	NA	NA		
				Lack of Mock Drills	Mock Drills SOP available												
				Fire Sensor Alarm not Provided	Fire Sensor Alarm available												
				Fire extinguisher not provided at identified location	NA												
		Area/Facility qualification	Product quality failure Patient safety Material safety Personal safety	Area/facility qualification Not Done	Area/Facility Qualification SOP available		3	2	1	6	Risk is low hence no action plan required	NA	NA	NA	NA		
				Cleaning producers not adequate	Cleaning SOP available												
				Area/facility is not Designed as per Approved layout	Approved layout available												
		Emergency Exit gate	Personal safety	Emergency gate not available	Emergency gate available.		3	2	1	6	Risk is low hence no action plan required	NA	NA	NA	NA		
				Lack of Mock Drills	Mock drills SOP available												
Emergency Exit Layout not available	Approved Emergency Exit Layout not																





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												S	O	D	RPN SxOxD	
				Glow sign arrow for Emergency Exit not provided	NA											
20.	Quarantine area	Temperature Mapping of storage area	Product quality failure Patient Safety	Temperature Mapping Not done of storage area Temperature Mapping Activity failure	Temperature Mapping of storage area SOP available		3	2	1	6	Risk is low hence no action plan required	NA	NA	NA	NA	
				Area temperature not maintained	EQMS SOP available											

**MACHINE**

21.	Equipment	Qualification not done	Product quality failure Personal safety Material safety	Machine not validated	Equipment Qualification SOP available		3	2	1	6	Risk is low hence no action plan required	NA	NA	NA	NA
				Lack of training	All Trained person work										
				Safety interlocking /features not available	Equipment Qualification SOP available										
		Equipment Operation & Cleaning not available	Product quality failure Material safety	Equipment cleaning not adequate	Cleaning procedure SOP for equipment & instrument & other accessories available										
				Preventive maintenance of machine not done	Preventive maintenance of machine SOP available										
		Equipment PM Planner Not available	Equipment not working	Preventive maintenance SOP Not available	Preventive maintenance SOP available										
		Earthing not Provided in Equipment's	Static charge issue	Earthing not given to machine	Preventive maintenance SOP available										

**MEASUREMENT**



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												S	O	D	RPN SxOxD
22.	<b>Temperature mapping</b>	Temperature mapping of quarantine area not performed	Environmental failure Product quality failure Personal safety Material safety	Storage Temperature Mapping not done	Temperature mapping SOP		3	2	1	6	Risk is low hence no action plan required	NA	NA	NA	NA
				Product storage condition not maintained	available EQMS										
23.	<b>Area Design</b>	Area not design as per layout.	Environmental failure Product quality failure Personal safety Material safety	Layout not available & Approved	Layout is available		3	2	1	6	Risk is low hence no action plan required	NA	NA	NA	NA
					Room data sheet available										
24.	<b>Pressure Differential</b>	DP Not maintain	Environmental failure Product quality failure Material safety	AHU's Not working properly	AHUs Operation, cleaning SOP available		3	1	1	3	Risk is low hence no action plan required	NA	NA	NA	NA
				Preventive maintenance of AHUs Not Done.	AHU PM SOP available										
				HVAC Validation not done	HVAC Validation SOP available. Pre filter, fine filter. riser filter Cleaning SOP available										
25.	<b>Lux Intensity</b>	Lighting not available	Personal Safety Product Safety	Proper Light not available in area	Approved RCP layout available		3	2	1	6	Risk is low hence no action plan required	NA	NA	NA	NA
		SOP not available		Light intensity (Visibility) not as per GMP	Area Qualification SOP availability										



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**Where: S=Severity; O=Occurrence Probability; D=Detection**

**Assessment of Severity, Occurrence, Detection**

Severity Effects	Likelihood Occurrence	Likelihood of Detection	Rating
No Effects	Unlikely	Always Detected	1
Moderate Effects	Possible	Might Detect Failure	2
Serious Effects	Almost Certain (Every Time)	Lack of Detection control	3

**Evaluation of RPN**

RPN Rating	Category
12 to 27	High
7 to 11	Medium
Upto 6	low

**CAPA (Required / Not Required):**

**If required, mention CAPA No.:**

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Quality Risk Management Team			Reviewed By Head Operations (Sign & Date)	Approved By Head QA (Sign & Date)
Name	Department	Sign & Date		



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Reference Document No.:

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**QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT**

**Name of Facility / Equipment / Utility / System / Activity / Procedure / Unit Operation:** New Packing Line

**Verification of Recommended Action:**

**Remarks (if any):**

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**Verified By**  
**Operation Person QA**  
**(Sign & Date)**

**Approved By**  
**Head QA**  
**(Sign & Date)**