RISK ANALYSIS STUDY PROTOCOL CUM REPORT

FOR EVALUATION OF CHILLER PLANT SHUT DOWN

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

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR EVALUATION OF CHILLER PLANT SHUT DOWN

PROTOCOL CUM REPORT CONTENTS

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR EVALUATION OF CHILLER PLANT SHUT DOWN

1.0 PROTOCOL CUM REPORT APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR EVALUATION OF CHILLER PLANT SHUT DOWN

- The objective of this Protocol Cum Report is to evaluate the impact of shutdown of Ciller plant on different activities of plant:

  Quality:
  - Warehouse
  - Production
  - Packing
  - Quality Control

3.0 SCOPE:

- Risk analysis study Protocol cum Report is applicable for all Blocks.

4.0 RESPONSIBILITY:

Department	Responsibility
Production Team	• Assure proper planning to avoid any low RH product at shop floor.
Quality Assurance Team	• Monitor & record the temperature & RH. • Review the QC report for any impact on product quality.
Engineering Team	• Assure the proper shut down.
Quality Control	• Bio-burden analysis of the products & environment monitoring. • Assure proper planning for analysis to avoid any failure.

5.0 REASON FOR RISK ANALYSIS:

- To mitigate & monitor the risk on the product quality & QC analysis during chiller shut down period.

6.0 SITE OF STUDY:

…….

7.0 RISK COMMUNICATION & TRAINING:

- The Risk analysis team shall be authorized by the Head-QA or his/her designee.
- Quality Risk Management Team shall be cross functional team comprised of expert from different areas.
- Training shall be imparted to the concerned team.

8.0 RISK IDENTIFICATION, EVALUATION & MITIGATION:

Introduction: At …… facility HVAC system (Heat Ventilation and Air Conditioning System) is used for air conditioning of core areas. HVAC system consists of Chiller, Cooling Tower, Boiler and Air Handling Unit. Here only those components will be discussed which are having direct impact.

- **Chiller System:** There are total 06 chillers for all Blocks.

  (i). **Chiller 01:** 300 TR
  (ii). **Chiller 02:** 300 TR
  (iii). **Chiller 03:** 325 TR
  (iv). **Chiller 04:** 300 TR
  (v). **Chiller 05:** 150 TR
  (vi). **Chiller 06:** 350 TR

- **Chiller system consists of 03 parts:**

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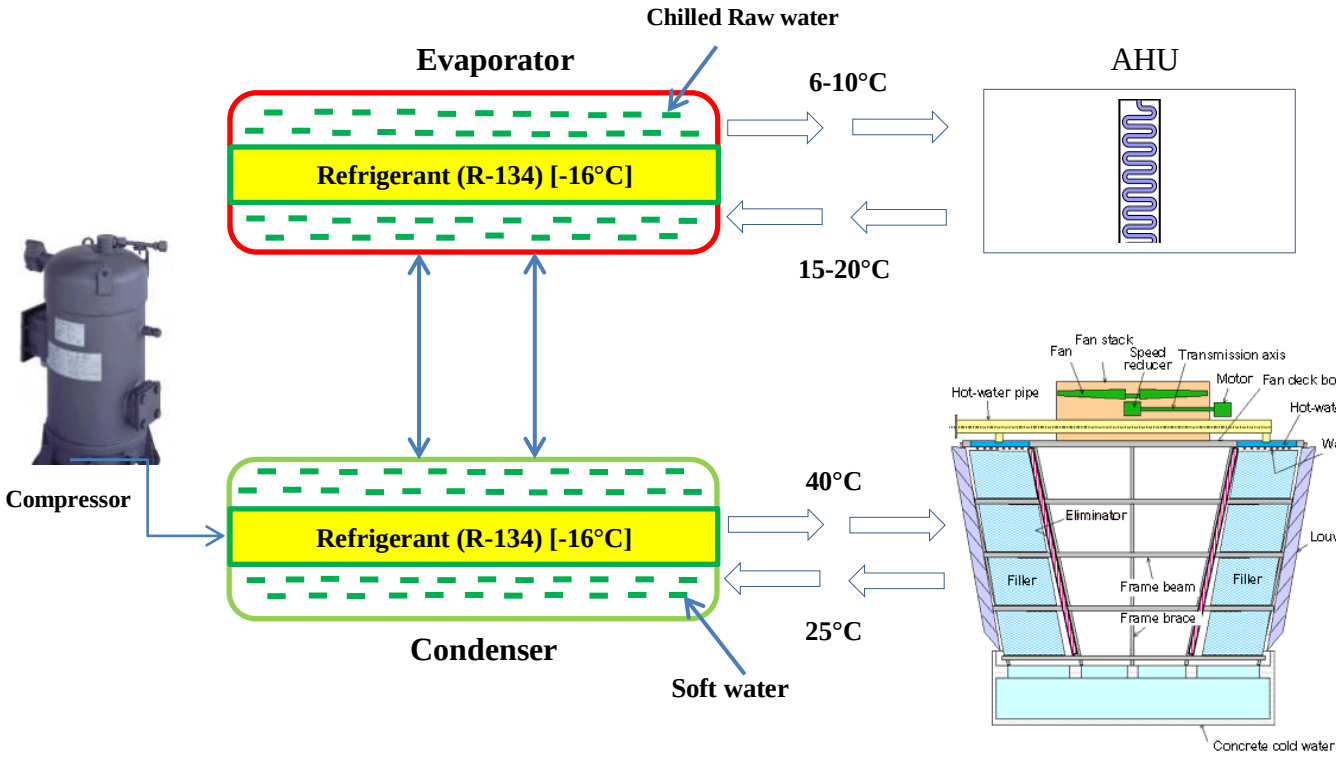
(i). **Evaporator:** The part of the chiller system where cool liquid refrigerant absorbs heat from the chilled water circuit.
(ii). **Condenser:** The part of a chiller system where the refrigerant Vapor is converted to liquid as it rejects heat.
(iii). **Compressor:** The main component in a chiller system, the compressor is used to increase the pressure & temperature of the refrigerant Vapor.



A chiller works on the principle of vapor compression or vapor absorption. Chillers provide a continuous flow of coolant to the cold side of a process water system at a desired temperature of about 10°C. The coolant is then pumped through the process, extracting heat out of one area of a facility (e.g., machinery, process equipment, etc.) as it flows back to the return side of the process water system.
A chiller uses a vapor compression mechanical refrigeration system that connects to the process water system through a device called an evaporator. Refrigerant circulates through an evaporator, compressor, condenser and expansion device of a chiller. The evaporator functions as a heat exchanger such that heat captured by the process coolant flow transfers to the refrigerant. As the heat-transfer takes place, the refrigerant evaporates, changing from a low-pressure liquid into vapor, while the temperature of the process coolant reduces.
The refrigerant then flows to a compressor, which performs multiple functions. First, it removes refrigerant from the evaporator and ensures that the pressure in the evaporator remains low enough to absorb heat at the correct rate. Second, it raises the pressure in outgoing refrigerant vapor to ensure that its temperature remains high enough to release heat when it reaches the condenser. The refrigerant returns to a liquid state at the condenser.
Water-cooled chillers feature a water-cooled condenser connected with a cooling tower. A typical water-cooled chiller uses recirculating condenser water from a cooling tower to condense the refrigerant. A water-

cooled chiller contains a refrigerant dependent on the entering condenser water temperature (and flow rate), which functions in relation to the ambient wet-bulb temperature.

AHU SYSTEM: An encased assembly consisting of a fan or fans and other necessary equipment to perform one or more of the functions of circulating, cleaning, heating, cooling, humidifying, dehumidifying and mixing of air".

An Air Handling Unit Some AHU components shown are
1 – Supply duct
2 – Fan compartment
3 – Vibration isolator ('flex joint')
4 – Heating and/or cooling coil
5 – Filter compartment
6 – Mixed (recirculated + outside) air duct

From chiller, the chilled raw water (6-10°C) is circulated to different blocks, whereby the chilled water is passed through the cooling coil of the AHU system, resulting into cooling of the air which further enters the clean room through HEPA filter. This cooled filtered air helps in maintaining the required temperature & RH of the area.
In case of any shut down of the chiller plant, the cooling of the coil hampered resulting into disturbance of the temperature & RH of the area. This may further leads to impact on:

- Product quality, if persist for longer duration.
- Analysis issues in HPLC, FTIR, Low RH QC areas.
- Disturb Environment of quarantine area.
- Disturb microbial analysis.

There are several mitigation programs which shall be implemented before initiating this activity (shut down of the chiller plant).

- Chiller shall be shut down in phase wise manner.
- Optional chiller can be utilized for Parenteral & QC Block.
- DX system shall be utilized for low RH area.
- AC shall be used for QC & Micro areas.
- Chiller is PLC based, hence trip off, if operating parameters fluctuates.

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S.No.	RISK IDENTIFICATION	RISK EVALUATION	RISK MITIGATION
1.	**Warehouse**	• During the chiller shutdown, only cooling coil of the AHU system will get impacted. As Cooling Coil is used to cool and dehumidify the air hence unavailability of chilled water from Chiller plant will directly impact the temperature & RH of the dedicated area. While increase in RH of warehouse area does not directly impact the API quality. There may be the possibility that the API may deteriorate.	• Continuous temperature & RH monitoring shall be done. • RH is not required in warehouse.
2.	**Production**	• As per the planning, shut down will be for approx. 24 hours, if in any case shut down time increases, will pose more risk to products which are already under hold. Low RH products may get deteriorated if extended their hold time.	• Continuous temperature & RH monitoring shall be done. • Hold time already validated for different dosage form. • DX system installed in parallel for low RH products.
3.	**Quality Control**	• In QC working standard preparations are done in Low RH area which is maintained under 25°C/15% RH. Chiller shut down may hamper the activity & working standard may gain moisture resulting into false potency results. • While in Micro section, increase in temperature & RH may affect the incubator efficiency, resulting into condensation, which further contaminate the inverted plates kept inside.	• Air conditioning system in parallel. • Proper planning to be done. • Block chiller can be used as optional.
4.	**Engineering**	• Chiller shut down shall be initiated in phase wise manner. Sudden shut down may increase the ampere load on remaining transformers & operating parameters may get disturbed. hence all Operating & Chemical parameters shall be monitored & recorded. While faulty tapping & valves may result into leakage.	• PLC based system will trip, if any parameter fluctuated. • Safety valves are installed.

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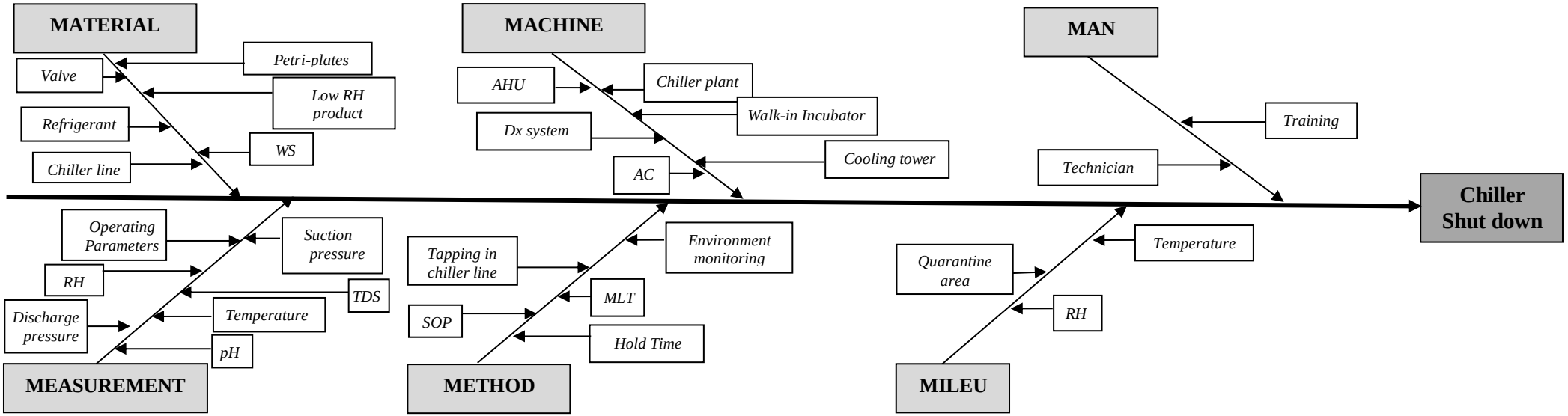
9.0 RISK ANALYSIS TOOLS, RE-RISK ANALYSIS CRITERIA:

9.1 Fish bone/6M/Ishikawa diagram:



Fish bone tool used for risk assessment, area of concern along with their sub-categories:

1. **Method**
2. **Machine**
3. **Material**
4. **Man**
5. **Measurement**
6. **Milieu**

9.2 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

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Procedure: Risk analysis for Chiller shut down	**Quality Risk Assessment Date:……..** **QRA No.: ……..**

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			
												S	O	D	RPN S*O*D
WAREHOUSE AREA															
1.	**Low RH API**	• Description failed (NMT 25℃ & RH NMT 22%) • API Gain moisture	• Increase in temp. • Increase in RH.	• API may deteriorate. • Microbial count may increase	• Separate quarantine area for storage of products. • Chillers to be shut down in phase wise manner. • AHU system will run, only cooling of some areas hamper. • Some specific areas may got impacted. • Hold time of general product is 07 days while for Low RH product is 05 days. • Separate DX unit used for maintaining temperature	• Hold time study • Risk Management	5	3	1	15	• Severity is high as it affects the product quality, occurrence may be possible while it is always detectable. • Before the start of the shutdown activity. Separate DX system shall be verified for its effectiveness.	NA	NA	NA	NA
2.	**Temperature**	• Moisture content decrease	• Increase in temperature.	• API may fail in parameters	• Separate DX unit used for maintaining temperature • AHU/DHU will run only cooling coil will not work resulting into increase in temperature, RH will not be impacted.	• Monitoring of Temperature, Relative Humidity & Differential Pressure • Risk Management	5	3	1	15		NA	NA	NA	NA
3.	**RH**	• Moisture content increases with increase RH	• Increase in RH.				5	3	1	15		NA	NA	NA	NA
4.	**Quarantine areas**	• Moisture gain	• Temperature & RH fluctuation.		• Quarantined products shall be kept in closed containers with double polybag. • DX system shall be used for low RH products. • AHU runs without cooling coil, temperature will be impacted, RH will not. • Temperature & RH shall be monitored & recorded regularly.		5	3	1	15		NA	NA	NA	NA

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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)	Recommended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
5.	**Hold time of material**	• Validated Material hold time may exceed.	• Increase in shut down time period.	• Material gain moisture	• All API & excipients are kept in closed containers. • RH is not the concern of warehouse area. • Only temperature to be monitored & recorded regularly.	• Hold time study • Risk Management	5	3	1	15	• Severity is high as it affects the product quality, occurrence may be possible while it is always detectable. • Hold time shall not exceed the pre-defined criteria.	NA	NA	NA	NA
	MANUFACTURING AREA														
6.	**Quarantine areas**	• Moisture gain	• Temperature & RH fluctuation.	• Product deteriorate	• Quarantined products shall be kept in closed containers with double polybag. • DX system shall be used for low RH products.	• Monitoring of Temperature, Relative Humidity & Differential Pressure. • Risk Management	5	3	1	15	• Severity is high as it affects the product quality, occurrence may be possible while it is always detectable. • Before the start of the shutdown activity. Separate DX system shall be verified for its effectiveness.	NA	NA	NA	NA
7.	**Hold time of material (Bulk)**	• Validated Material hold time may exceed.	• Increase in shut down time period.		• Paste preparation can be hold for maximum 08 hours at controlled conditions, hence shall be used after preparation. • Hold time for bulk, uncoated & coated is 30 days in controlled conditions, only temperature will fluctuate, RH will not be affected. Hence product shall be closed tightly to avoid moisture. • Pressure differential, Air velocity & ACPH will remain maintained.	• Hold time study • Risk Management	5	3	1	15	• Severity is high as it affects the product quality, occurrence may be possible while it is always detectable. • Hold time shall not exceed the pre-defined criteria.	NA	NA	NA	NA
8.	**Hold time for coating suspension**		• Microbial load increases		• Suspension hold time is 72 hours, hence shall be used immediately.		5	3	1	15		NA	NA	NA	NA

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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)	Recommended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
9.	**Gelatin mass**	• Physical appearance may change	• Microbial load increases	• Gelatin may get hard or soft • Fail in Specification	• Gelatin is hold at constant temperature (50-55°C) hence temperature & RH does not have any impact on its quality. • Hold time already validated for 03 days.		5	3	1	15		NA	NA	NA	NA
10.	**Drying of Soft Gelatin**	• Soft gelatin may gain moisture Temperature (NMT 25°C & RH NMT 22%).	• Increase in temperature & RH	• Moisture will not get removed & capsules may get soft, resulting into leakage during packing.	• DX system required in parallel during drying.	• Monitoring of Temperature, Relative Humidity & Differential Pressure. • Risk Management	5	3	1	15	• Severity is high as it affects the product quality, occurrence may be possible while it is always detectable. • Before the start of the shutdown activity. Separate DX system shall be verified for its effectiveness.	NA	NA	NA	NA
	QUALITY CONTROL														
11.	**Microbial Section**	• Cross contamination	• Environmental Microbial load increases	• Microbial count increases • Deterioration of media in petri plates	• Separate Air conditioning system already installed. • All critical activities are done under LAF. • Upto 27°C temperature & 60% RH is acceptable.	• Procedure for Monitoring of Temperature and Relative Humidity in Microbiology Laboratory. • Risk Management	5	3	1	15	• Severity is high as it affects the analysis results, occurrence may be possible while it is always detectable. • AC system shall be verified for its effectiveness.	NA	NA	NA	NA
	MLT Section						5	3	1	15		NA	NA	NA	NA
	Sterility room						5	3	1	15		NA	NA	NA	NA

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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)	Recommended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
	BET room	• Cross contamination				• Procedure for Monitoring of Temperature and Relative Humidity in Microbiology Laboratory. • Daily Temperature Monitoring of Walk-In Type Incubator. • Risk Management	5	3	1	15		NA	NA	NA	NA
	Incubator room (20-25°C & 30-35°C).		• Increase in temperature may result into condensation which further results into microbial load over lid of the inverted petri-plates.	• Condensed contaminated water over the lid may result into MLT failure.	• Air conditions are installed in one incubator room. • In case of emergency, plates can be transferred to another incubator room of same specification (20-25°C). • Proper planning shall be done before shut down.		5	3	1	15		NA	NA	NA	NA
12.	**HPLC & FTIR Section**	• High environmental moisture may affect the instrument efficiency.	• Increase in temperature & RH may affect the integrity of instrument & bulk used for analysis. Temperature NMT 27°C for all QC & RH for FTIR 30-65%	• Result variation	• Proper planning shall be done before shut down.	• Monitoring of Temperature and Relative Humidity in Quality Control Laboratory • Risk Management	5	3	1	15	• Severity is high as it affects the product quality, occurrence may be possible while it is always detectable. • Proper planning shall be done before shut down.	NA	NA	NA	NA
13.	**Low RH (Working Standard)**	• Working standard may gain moisture	• Increase in temperature may increase the moisture content of surrounding environment. (Temperature limit NMT 15°C).	• Working standard potency got impacted.			5	3	1	15		NA	NA	NA	NA

CHILLER PLANT

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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)	Recommended Actions (if any)	Post Risk			
												S	O	D	RPN S*O*D
14.	**Operating parameters**	Operating parameters may fluctuate (Chilled Water Temperature, Chilled Water Pressure, Condenser Water Pressure, Cond. Water Temp.)	• Sudden shut down may fluctuate the pressure resulting into deviation in critical parameters.	• Wrong results may generate during daily verification	• Chiller is PLC based; any deviation in operating parameters may result into trip off. • Safety valve will open , if pressure increases. • Sensors are installed to monitor any fluctuations.	• SOP for Operation of Chiller plant • SOP for Risk Management	5	3	1	15	• Severity is high as it affects the critical parameters , occurrence may be possible while it is always detectable. • Chiller plant shut down shall be taken in phase wise manner. • Operating parameters shall be monitored closely.	NA	NA	NA	NA
15.	**Suction of Evaporator**	• Evaporator may choke	• Decrease in suction Pressure (NLT 180 kpa) increases the ice flakes.	• Evaporator may get choked.			5	3	1	15	• Severity is high as it affects the critical parameters , occurrence may be possible while it is always detectable.	NA	NA	NA	NA
16.	**Discharge of Condenser**	• Condenser may burst	• Increase in discharge of pressure more than 1080 kpa may increase pressure inside condenser.	• May result into bursting of condenser.			5	3	1	15	• Chiller plant shut down shall be taken in phase wise manner. Operating parameters shall be monitored closely.	NA	NA	NA	NA
17.	**Tapping of Chiller line**	• Leakage in chiller line	• Improper tapping.	• Leakage may result into area contamination.	• Verification done for nay leakage.	• SOP for Operation of Chiller plant • SOP for Risk Management	5	3	1	15		NA	NA	NA	NA
18.	**Valve replacement**	• Leakage in joints	• Improper valve adjustment.		• Trained technicians. • Testing certificates of valves.		5	3	1	15		NA	NA	NA	NA
19.	**Ampere Load**	• Transformer may shut down	• Shut down of chillers will result into sudden increase in ampere load.	• Transformer may trip down.	• Shut down to be done in phase wise manner.		5	3	1	15		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
Up to 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		

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

Name of Facility		…….	
S.No.	Recommended Action	Responsible Person	Target Date of Completion
1.			
2.			

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
(QA)
Sign & Date……..

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

RISK ANALYSIS STUDY PROTOCOL CUM REPORT
FOR
EVALUATION OF CHILLER PLANT SHUT DOWN

10.0 CONCLUSION:

Risk of Chiller Shut Down on Product Quality & QC Analysis at facility.

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11.0 RECOMMENDATION:

Recommendation shall be written on the Risk Analysis Study Protocol cum Report for evaluation of Chiller Shut Down risk, clearly stating that there is no impact/adverse impact on the product quality & QC analysis.

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RISK ANALYSIS STUDY PROTOCOL CUM REPORT FOR EVALUATION OF CHILLER PLANT SHUT DOWN

12.0 REFERENCES:

- Reference SOP of Risk Assessment.
- Deviation.
- Operation of Ciller System.
- Hold time study.
- Monitoring of Temperature, Relative Humidity & Differential Pressure.
- Procedure for Monitoring of Temperature and Relative Humidity in Microbiology Laboratory.
- Daily Temperature Monitoring of Walk-In Type Incubator.
- Monitoring of Temperature and Relative Humidity in Quality Control Laboratory.

13.0 DOCUMENTS TO BE ATTACHED:

- Annexures related to Photographs.
- Related documents.

14.0 DEVIATION FROM PRE DEFINED SPECIFICATION, IF ANY:

Deviations from the pre-defined acceptance criteria observed in accordance with QA SOP **"Handling of Deviations"**, shall be documented in the Risk analysis Protocol cum report.

15.0 CHANGE CONTROL, IF ANY:

Change control observed in accordance with QA SOP **"Change Management"** shall be documented in the Risk analysis Protocol cum report.

16.0 ABBREVIATIONS:

FMEA	: Failure Mode Effect Analysis
GMP	: Good Manufacturing Practices
RPN	: Risk Priority Number
DX	: Direct Expansion
CAPA	: Corrective action preventive action
WHO	: World health organization
HPLC	: High pressure liquid chromatogram
FTIR	: Fourier-transform infrared spectroscopy
RH	: Relative Humidity
TR	: Ton of Refrigeration
AHU	: Air Handling Unit
HEPA	: High Efficiency Particulate Air Filter
PLC	: Programmable logic controller
API	: Active Pharmaceutical Ingredient
TDS	: Total Dissolved Solids
MLT	: Microbial Limit Test

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17.0 PROTOCOL CUM REPORT POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (QUALITY CONTROL)			
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			