



REPORT FOR RISK ASSESSMENT FOR THE HANDLING OF RAW MATERIAL STORED AT AMBIENT CONDITION IN WAREHOUSE

**REPORT
FOR
RISK ASSESSMENT
& MITIGATION
FOR
THE HANDLING OF
RAW MATERIAL STORED
AT AMBIENT CONDITION
IN
WAREHOUSE**

Location: Warehouse
LOCATION:

| | |
|-------------------------------|----|
| Report No. | |
| Reference Protocol No. | |
| Supersede Document No. | NA |
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REPORT FOR RISK ASSESSMENT FOR THE HANDLING OF RAW MATERIAL STORED AT AMBIENT CONDITION IN WAREHOUSE

PROTOCOL CONTENTS

| S.No. | Section Title | Page No. | | |
|-------|--|--|---|---------------------------|
| 1.0 | Protocol Approval | 3 | | |
| 2.0 | Overview | 4 | | |
| | Objective | | | |
| | Purpose & Scope | | | |
| | Risk Assessment Team | | | |
| | Responsibility | | | |
| 3.0 | Introduction | 4 | | |
| 4.0 | Quality Risk Management Process | 9 | | |
| | Risk Identification | 9 | | |
| | Risk Analysis | 9 | | |
| | Risk Evaluation | 9 | | |
| | Risk Control | 9 | | |
| | Risk Reduction | 9 | | |
| 5.0 | Risk Assessment for Handling the raw material stored at ambient temperature in warehouse | 9 | | |
| | 5.1 | Risk Assessment Legend | 6 | |
| | | A | | Severity |
| | | B | | Probability or Occurrence |
| | | C | | Detection |
| | 5.2 | Risk Assessment Tool – Failure Mode Effect Analysis (FMEA) | 6 | |
| | | 5.2.1 | | Risk Identification |
| 5.2.2 | | Risk Analysis | | |
| 5.2.3 | | Risk Reduction or Mitigation | | |
| 6.0 | Acceptance Criteria | 15 | | |
| 7.0 | Risk control strategy | 15 | | |
| 8.0 | Summery & Conclusion | 15 | | |
| 9.0 | Report Preparation and Approval | 15 | | |
| 10.0 | References & Annexures | 16 | | |



REPORT FOR RISK ASSESSMENT FOR THE HANDLING OF RAW MATERIAL STORED AT AMBIENT CONDITION IN WAREHOUSE

1.0 Report Approval

This is a specific Report for Risk assessment and Mitigation for handling of Raw material stored at Ambient Temperature in warehouse.

The Report has been approved by the following:

Prepared By:

| Name | Designation | Department | Signature | Date |
|------|-------------|-------------------|-----------|------|
| | | Quality Assurance | | |

Checked By:

| Name | Designation | Department | Signature | Date |
|------|-------------|-------------------|-----------|------|
| | | Warehouse | | |
| | | Quality Assurance | | |

Approved By:

| Name | Designation | Department | Signature | Date |
|------|-------------|-------------------|-----------|------|
| | | Quality Assurance | | |



REPORT FOR RISK ASSESSMENT FOR THE HANDLING OF RAW MATERIAL STORED AT AMBIENT CONDITION IN WAREHOUSE

2.0 Overview:

Objective:

The Objective of this Report is to adopt a systematic process for the assessment, control, communication and review of risk associated with the handling of Raw Material stored at ambient Temperature in Warehouse.

Purpose and Scope

The purpose of this report is to outline a scientific and practical approach for decision making process by applying a suitable tool of risk assessment covering all aspects of risk associated with the handling of Raw Material stored at ambient Temperature in Warehouse.

Risk Assessment Team

- Quality Assurance Executive/Officer/Manager
- Warehouse Executive/Officer/Manager

Responsibility

| S.No. | Department | Designation | Responsibility |
|-------|-------------------|------------------------------|--|
| 1. | Quality Assurance | Executive /Officer / Manager | Preparation, Review and approval of Protocol & report To review all the Procedural controls To perform impact evaluation for the risk associated with the handling the raw material stored at ambient temperature in ware house. Assist and regulate the implementation of risk mitigation procedures/activity Final approval of Protocol & report By head quality Assurance |
| 2. | Warehouse | Executive /Officer /Manager | Preparation, Review and approval of Protocol & report To provide all relevant information for the identification, analysis and evaluation of risk associated with handling the raw material stored at ambient temperature in ware house. |

3.0 Introduction:

Risk analysis for the handling of Raw material in warehouse at Ambient Condition shall be done by considering the below mentioned factors:

- The Risk Impact on the Process
- The Risk impact on the Product Quality
- The Risk impact on the environment
- The Risk impact on the person
- The Risk impact on the regulatory compliance
- The risk impact on the customer



REPORT FOR RISK ASSESSMENT FOR THE HANDLING OF RAW MATERIAL STORED AT AMBIENT CONDITION IN WAREHOUSE

4.0 Quality Risk Management Process

Risk assessment is a systematic process of organizing information to support a risk decision to be made within a risk management process. It consists of identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards.

Quality risk assessment begins with a well-defined problem description or risk question.

For the risk assessment process, three fundamental questions are considered:

- What might go wrong?
- What is the likelihood (**Occurrence**) it will go wrong?
- What are the consequences (**severity**)?

- **Risk Identification**

Risk Identification is the systematic use of information to identify hazards referring to risk questions or problem descriptions. Information may include historical data, theoretical analysis, informed opinions, and concerns of stakeholders. Risk Identification will be conducted by reviewing the types of events that might occur in both normal and unusual situations. This may be done by challenging the normal presumptions, and considering the possibilities of unanticipated situations. For each risk event, the underlying (root) cause should be determined that will create the potential risk occurrence.

Risk Identification addresses the “what might go wrong” question, including identifying the possible consequences. This provides the basis for the further steps in the quality risk management process.

- **Risk Analysis**

Risk analysis is the estimation of risk associated with the identified hazards.

It is the quantitative or qualitative process of linking the likelihood of occurrence and severity of harm, and sometimes the detectability of harm, is also considered during estimation of risk.

- **Risk Evaluation**

Risk Evaluation compares the identified and analyzed risk against the given risk criteria. Risk evaluation considers the strength of evidence for all three of the fundamental questions.

Risks are ranked by scoring various criteria with appropriate numerical ratings, adding to scores to determine the overall score of each risk, and sorting the risks into descending order based on each score. A risk scoring threshold is established, over which risks must be mitigated using adequate design and/or process controls that will protect the system. Those risks that fall below the threshold are either unmitigated or scheduled for later mitigation. An additional threshold or characteristic of risk can be used to determine the differentiation of non-mitigation versus postponed mitigation.



REPORT FOR RISK ASSESSMENT FOR THE HANDLING OF RAW MATERIAL STORED AT AMBIENT CONDITION IN WAREHOUSE

- **Risk Control**

Risk control includes decision making to reduce or mitigate risk. The purpose of risk control is to reduce the risk to the acceptance level

The risk control is done by considering the following question

- Is the risk above an acceptable level?
- What can be done to reduce or eliminate risk?
- What is appropriate balance among benefits, risks and resources?
- Are new risk is introduced as a result identified risk being controlled?

- **Risk Reduction**

Risk reduction focuses on processes the mitigation or avoidance of quality risk when it exceeds the acceptable level. Risk reduction includes action taken to mitigate the severity, occurrence or probability of harm and the processes that improve the detectability of harm. It is the part of risk control strategy and involves

- Engineering Control
- Procedural Control
- Manual control etc.

5.0 Risk Assessment for the handling the raw material stored at ambient temperature in Warehouse

5.1 Risk Assessment Legend

A. Severity

| Ranking | Effect | Criteria |
|----------------|---------------|--|
| 10 | Hazardous | Hazardous effect without warning. Safety related. Regulatory non-compliant. |
| 9 | Serious | Potential hazardous effect. Able to stop without mishap. Regulatory compliance in jeopardy. |
| 8 | Extreme | Item inoperable but safe. Customer very dissatisfied. |
| 7 | Major | Performance severely affected but functional and safe. Customer dissatisfied. |
| 6 | Significant | Performance degraded but operable and safe. Non-vital part inoperable. Customer experiences discomfort. |
| 5 | Moderate | Performance moderately affected. Fault on non-vital part requires repair. Customer experiences some dissatisfaction. |
| 4 | Minor | Minor effect on performance. Fault does not require repair. Non-vital fault always noticed. Customer experiences minor nuisance. |
| 3 | Slight | Slight effect on performance. Non-vital fault notice most of the time. Customer is slightly annoyed. |
| 2 | Very Slight | Very slight effect on performance. Non-vital fault may be noticed. Customer is not annoyed. |
| 1 | None | No effect. |



REPORT FOR RISK ASSESSMENT FOR THE HANDLING OF RAW MATERIAL STORED AT AMBIENT CONDITION IN WAREHOUSE

B. Probability or Occurrence

| Ranking | Possible Failure | Probability of Failure |
|---------|------------------|------------------------|
| 10 | ≥ 1 in 2 | Almost certain. |
| 9 | 1 in 3 | Very high. |
| 8 | 1 in 8 | High. |
| 7 | 1 in 20 | Moderately high. |
| 6 | 1 in 80 | Medium |
| 5 | 1 in 400 | Low |
| 4 | 1 in 2,000 | Slight |
| 3 | 1 in 15,000 | Very slight. |
| 2 | 1 in 150,000 | Remote. |
| 1 | 1 in 1,500,000 | Almost impossible. |

C. Detection

| Ranking | Detection | Likelihood of Detection by design control |
|---------|----------------------|---|
| 10 | Absolute Uncertainty | No design control or design control will not detect potential cause |
| 9 | Very Remote | Very remote chance design control will detect potential cause. |
| 8 | Remote | Remote chance design control will detect potential cause. |
| 7 | Very Low | Very low chance design control will detect potential cause. |
| 6 | Low | Low chance design control will detect potential cause. |
| 5 | Moderate | Moderate chance design control will detect potential cause. |
| 4 | Moderately High | Moderately high chance design control will detect potential cause. |
| 3 | High | High chance design control will detect potential cause. |
| 2 | Very High | Very high chance design control will detect potential cause. |
| 1 | Almost Certain | Almost certain that the design control will detect potential cause. |



REPORT FOR RISK ASSESSMENT FOR THE HANDLING OF RAW MATERIAL STORED AT AMBIENT CONDITION IN WAREHOUSE

5.2 Risk Assessment Tool – Failure Mode effect Analysis (FMEA)

5.2.1 Risk Identification

Risk assessment team shall identify all possible failure modes associated with the handling the raw material stored at ambient temperature.

1. Identification of Failure Mode

- a. Equipment Malfunctioning.
- b. Failure of instrument.
- c. Calibration of Instrument expired.
- d. Failure of process.
- e. Failure of procedure.

2. Identification of Potential cause

- a. Equipment Malfunctioning.
- b. Instrument malfunctioning.
- c. Operator Error.
- d. Inefficient Provisions for operations etc.

3. The consequences i.e. End results of failure mode

Higher the temperature it will have following impact

- a. Poor process Performance.
- b. Poor Product Quality.
- c. Deterioration of Environmental condition for manufacturing.
- d. Regulatory non compliance.
- e. Unsafe operating conditions.
- f. Unsafe environmental conditions etc.
- g. Customer dis-satisfied.



REPORT FOR RISK ASSESSMENT FOR THE HANDLING OF RAW MATERIAL STORED AT AMBIENT CONDITION IN WAREHOUSE

4. Justification:

The identification done for the risk shall have scientific rational and must be justified for its validity. The below mentioned table shall be used for Risk Identification process.

| S.No. | Failure Mode {What can go wrong) | Potential cause of Failure | What are the Consequences | Justification |
|----------------------------|--|---|--|--|
| Risk Identification | | | | |
| 1. | Case-I Equipment/ Instruments | 1) The sensors of Ambient warehouse A,B,C are not in state of calibration i.e. the due date of calibration would have been expired of sensor No. Sensor No....., Sensor No....., Sensor No..... 2) Electrical fluctuation 3) Equipment Breakdown 4) Preventive Maintenance of Temperature Monitoring system | The quality attributes of Raw material stored used for various products hold get adversely effected if the temperature is not prevailed. | It might be possible that after the due date the sensors may not give the actual value for theses parameters. So the actual temperature may be at higher side or lower side |



REPORT FOR RISK ASSESSMENT FOR THE HANDLING OF RAW MATERIAL STORED AT AMBIENT CONDITION IN WAREHOUSE

| S.No. | Failure Mode {What can go wrong} | Potential cause of Failure | What are the Consequences | Justification |
|----------------------------|--|---|--|---|
| Risk Identification | | | | |
| 2. | Case-II Manpower effect | 5) Non availability of supervisory control. 6) People are not trained for the Handling of procedures. 7) Non existence of verification procedures or supervisory control. | Product quality will not stable as desired. | Untrained Persons can make mistakes & errors because of unawareness about the end results |
| 3. | Case-III/ Temperature Controlling effect | 8) Inappropriate door Opening and Closing 9) Air curtains are not properly installed | Product quality will not stable as desired. | Inappropriate door opening & Closing give a chance of Temperature fluctuation |
| 4. | Case-IV Environment effect | 10) Temperature may be Higher side during Summer Seasonal. 11) Temperature may be Lower side during Winter Seasonal. | Consistent Product quality and yield will not be achieved. output quality. Product quality & yield consistency may vary batch to batch. Which is results in Regulatory non compliance Customer dis satisfactions | Actual temperature may be at higher side or lower side |



REPORT FOR RISK ASSESSMENT FOR THE HANDLING OF RAW MATERIAL STORED AT AMBIENT CONDITION IN WAREHOUSE

5.2.2 Risk Analysis

| S. No. | Failure Mode {What can go wrong} | Potential cause of Failure | Existing Design Control | What are the Consequences | Severity | Probability | Detection | Risk Priority Number |
|----------------------|-------------------------------------|--|---|---|-----------------------|-------------|-----------|----------------------|
| | | | | | (S) | (P) | (D) | RPN=S x P x D |
| Risk Analysis | | | | | Risk valuation | | | |
| 1. | Equipment/ Instruments | Temperature Working of Sensors No., (Sensor No. 02) (Sensor No. 03) (Sensor No. 04) Working of Temperature sensors | The sensors of Ambient ware house A,B,C in state of calibration i.e. the due date of calibration would have been expired Electrical fluctuation | <p>The sensor was calibrated done in due time by qualified external agency "STAR CALIBRATION."</p> <p>The sensors of Ambient Ware house A,B,C worked efficiently in the whole year and there is no any abrupt changes observed in the quality profile of the product stored in the RM warehouse store.</p> <p>Daily monitoring of temperature by Temperature Monitoring system No.....</p> <p>Alarms are configured to monitor the temperature and shootouts.</p> | 1 | 5 | 10 | =1×5×10=50 |



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REPORT FOR RISK ASSESSMENT FOR THE HANDLING OF RAW MATERIAL STORED AT AMBIENT CONDITION IN WAREHOUSE

| S.No. | Failure Mode {What can go wrong} | Potential cause of Failure | Existing Design Control | What are the Consequences | Severity | Probability | Detection | Risk Priority Number |
|---------------|-------------------------------------|---|--|--|----------|-------------|-----------|---------------------------|
| | | | | | (S) | (P) | (D) | $RPN=S \times P \times D$ |
| Risk Analysis | | | | | | | | Risk valuation |
| 1. | Temperature Controlling effect | | Air curtains are installed on the Entry & Exit door of the warehouse | Work order system to rectify the failure of door functioning | | | | |
| 2. | Documentation | Persons are not trained for the lay down procedures | 1) SOP on Storage of Material in Warehouse Areas and Monitoring of Temperature in these Areas Refer. SOP No..... 2) Procedure for Entry in Restricted areas of Warehouse Refer SOP No..... 3) Material compatibility chart is fixed in the plant to avoid any incidental or accidental reactions among the material. | Trained Persons to handle the material in warehouse | 1 | 5 | 10 | 50 |



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5.2.3 Risk Reduction or Mitigation

| S.No. | Failure Mode {What can go wrong} | Existing Design Control | Severity | Probability | Detection | Risk Priority Number | Additional Design Control | Severity | Probability | Detection | Risk Priority Number |
|-------|-------------------------------------|---|-----------------|-------------|-----------|----------------------|--|----------|-------------|-----------|----------------------|
| | | | (S) | (P) | (D) | (RPN) | | (S) | (P) | (D) | (RPN) |
| | | | Risk Mitigation | | | | | | | | |
| 1. | Working of Temperature sensors | <p>The sensor was calibrated done in due time by qualified external agency “.....”</p> <p>The sensors of Ambient ware house A,B,C worked efficiently in the whole year and there is no any abrupt changes observed in the quality profile of the product stored in the RM warehouse store.</p> <p>Daily monitoring of temperature Alarms are configured to monitor the temperature and shootouts</p> <p>Maximum time for extension time for calibration/mapping should not exceed 15 days.</p> <p>The data of Mapping shall be thoroughly evaluated for the efficient working of monitoring sensor.</p> | 1 | 5 | 10 | =50 | <p>Since the existing design control, efficiently control the risk associated with the handling of RM stored at ambient Temperature in ware house So there is no any additional design control is required</p> | 1 | 5 | 10 | =50 |



REPORT FOR RISK ASSESSMENT FOR THE HANDLING OF RAW MATERIAL STORED AT AMBIENT CONDITION IN WAREHOUSE

| S. No. | Failure Mode {What can go wrong} | Existing Design Control | Severity | Probability | Detection | Risk Priority Number | Additional Design Control | Severity | Probability | Detection | Risk Priority Number |
|--------|----------------------------------|---|-----------------|-------------|-----------|----------------------|--|----------|-------------|-----------|----------------------|
| | | | (S) | (P) | (D) | (RPN) | | (S) | (P) | (D) | (RPN) |
| | | | Risk Mitigation | | | | | | | | |
| 1. | Documentation | 1) SOP on Storage of Material in Warehouse Areas and Monitoring of Temperature in these Areas Refer. SOP . 2) Procedure for Entry in Restricted areas of Warehouse Refer SOP . 3) List of Raw material list is made available with warehouse along with respected MSDS 4) Material compatibility chart is fixed in the Warehouse to avoid any incidental or accidental reactions among the material | 1 | 5 | 10 | =50 | Since the existing design control, efficiently control the risk associated with the handling of RM stored at ambient Temperature in ware house So there is no any additional design control is required | 1 | 5 | 10 | =50 |



REPORT FOR RISK ASSESSMENT FOR THE HANDLING OF RAW MATERIAL STORED AT AMBIENT CONDITION IN WAREHOUSE

6.0 Acceptance Criteria:

The Risk Priority Number shall be within the range $0 < RPN < 125$

7.0 Risk Control Strategy

| S.No. | Risk Priority Number | Risk Decision | Risk control strategy |
|-------|----------------------|-----------------|------------------------------------|
| 1. | $0 < RPN < 125$ | Risk Acceptable | No control is required |
| 2. | $125 < RPN < 500$ | Risk Reduction | Additional Procedural Control |
| | | | Manual Control |
| | | | Documentary Evidence |
| 3. | $500 < RPN < 1000$ | Risk Reduction | Rugged Procedural control |
| | | | Additional Manual Control |
| | | | Auditing |
| | | | Engineering controls (if Possible) |

8.0 Summary & Conclusion:

On the basis of Risk assessment process using FMEA tool it is concluded that RM stored at ambient temperature in warehouse is associated with an acceptable level of risk and there is no any adverse impact of on carrying out the handling the raw material at ambient temperature in warehouse under the given set up.

Hence it is concluded that the batches manufactured during the Year -2024 (Winter i.e Jan. 2024 and summer i.e June-2024 were satisfactory with respect to desired Yield attributes.

Yield & Quality attributes of each batch was checked is made in APQR & found well with in the acceptance criteria.

9.0 Report Preparation and Approval:

The report shall be prepared by evaluating all possible risks and finally shall be approved by Quality Assurance head.

10.0 References & Annexures:

1. Risk Management Master Plan
2. ICH Q9



**REPORT FOR RISK ASSESSMENT FOR THE HANDLING OF RAW MATERIAL STORED AT
AMBIENT CONDITION IN WAREHOUSE**

Annexures

| Annexure No. | Annexure Title |
|---------------------|--|
| 1. | Temperature details in summer month |
| 2. | Temperature details in Winter month |
| 3. | List of RM stored in Ambient warehouse |
| 4. | Products Yield details |
| 5. | SOP's |
| 6. | Backup data |
| 7. | List of material and respective storage condition |
| 8. | Calibration record of RTD sensor Instrument Tag No..... |



REPORT FOR RISK ASSESSMENT FOR THE HANDLING OF RAW MATERIAL STORED AT AMBIENT CONDITION IN WAREHOUSE

Annexure-01 (Summer Seasonal)

Temperature Record for the Month of June-2024

| Dated —————> | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
|--|------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|
| Ambient Warehouse A | Min | 33.0 | 33.0 | 33.0 | 33.0 | 33.3 | 33.3 | 33.3 | 32.5 | 32.1 | 32.1 | 33.3 | 33.3 | 32.2 | 30.9 | 28.5 |
| | Max | 44.2 | 44.2 | 43.9 | 43.9 | 44.2 | 44.1 | 43.2 | 37.0 | 40.2 | 42.1 | 42.1 | 42.1 | 42.1 | 42.1 | 40.0 |
| | Average | 36.8 | 36.8 | 37.1 | 38.4 | 37.6 | 37.4 | 36.3 | 34.3 | 34.7 | 36.5 | 36.5 | 36.9 | 36.5 | 35.7 | 33.6 |
| Ambient Warehouse B | Min | 32.7 | 32.7 | 32.7 | 32.7 | 34.3 | 34.3 | 34.3 | 34.0 | 33.2 | 33.2 | 34.5 | 34.5 | 33.3 | 31.9 | 29.0 |
| | Max | 42.7 | 42.7 | 42.9 | 42.9 | 43.8 | 43.6 | 43.2 | 37.5 | 40.0 | 41.3 | 41.3 | 41.3 | 41.3 | 41.3 | 39.7 |
| | Average | 36.7 | 36.7 | 36.9 | 37.7 | 38.2 | 38.1 | 37.3 | 35.4 | 35.7 | 36.9 | 36.9 | 37.2 | 36.9 | 36.2 | 34.4 |
| Ambient Warehouse C | Min | 31.3 | 31.3 | 31.3 | 31.3 | 32.4 | 32.4 | 32.4 | 31.4 | 30.9 | 30.9 | 31.9 | 31.9 | 30.8 | 29.8 | 26.6 |
| | Max | 42.7 | 43.6 | 43.6 | 42.7 | 43.4 | 43.3 | 42.3 | 35.9 | 39.4 | 41.1 | 41.1 | 41.1 | 41.1 | 41.1 | 38.7 |
| | Average | 35.1 | 35.4 | 35.4 | 36.5 | 36.6 | 36.4 | 35.3 | 33.2 | 33.6 | 35.3 | 35.2 | 35.6 | 35.3 | 34.5 | 32.3 |
| | | | | | | | | | | | | | | | | |
| Dated —————> | | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 |
| Ambient Warehouse A | Min | 28.5 | 28.0 | 30.9 | 28.0 | 30.9 | 30.9 | 30.9 | 30.9 | 30.9 | 30.9 | 30.9 | 30.8 | 30.9 | 30.9 | 30.9 |
| | Max | 40.0 | 40.0 | 38.0 | 37.5 | 39.9 | 42.8 | 39.9 | 40.5 | 40.9 | 40.9 | 40.9 | 36.9 | 37.7 | 37.7 | 37.7 |
| | Average | 33.6 | 34.3 | 34.6 | 34.4 | 35.4 | 36.9 | 36.1 | 35.9 | 36.5 | 35.4 | 35.6 | 34.4 | 34.5 | 34.0 | 34.1 |
| Ambient Warehouse B | Min | 29.0 | 29.5 | 31.9 | 29.5 | 31.9 | 31.9 | 31.9 | 31.9 | 31.9 | 31.9 | 31.9 | 31.9 | 31.9 | 31.9 | 31.9 |
| | Max | 39.7 | 39.7 | 37.8 | 37.5 | 39.3 | 40.1 | 40.0 | 40.0 | 40.8 | 40.8 | 40.8 | 37.5 | 38.0 | 38.0 | 38.0 |
| | Average | 34.4 | 34.9 | 35.1 | 35.1 | 35.9 | 36.8 | 36.6 | 36.3 | 36.9 | 26.1 | 36.1 | 35.3 | 35.3 | 34.9 | 35.0 |
| Ambient Warehouse C | Min | 26.6 | 27.3 | 39.8 | 27.3 | 29.8 | 29.8 | 29.8 | 29.8 | 29.8 | 29.8 | 29.8 | 29.8 | 29.8 | 29.8 | 29.8 |
| | Max | 38.7 | 38.7 | 37.2 | 36.8 | 39.5 | 42.2 | 39.4 | 39.5 | 40.3 | 40.3 | 40.3 | 36.1 | 37.2 | 37.2 | 37.2 |
| | Average | 32.3 | 33.2 | 33.5 | 33.4 | 34.4 | 35.9 | 35.0 | 34.8 | 35.4 | 34.3 | 34.5 | 33.3 | 33.5 | 33.0 | 33.1 |



REPORT FOR RISK ASSESSMENT FOR THE HANDLING OF RAW MATERIAL STORED AT AMBIENT CONDITION IN WAREHOUSE

Annexure-02 (Winter Seasonal)

Temperature Monitoring record for the Month of January-2024

| Dated \longrightarrow | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | | |
|-------------------------|---------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|--|
| Ambient A | Min | 10.9 | 10.4 | 10.4 | 10.0 | 8.1 | 8.1 | 8.3 | 7.3 | 6.7 | 8.8 | 9.2 | 11.1 | 13.1 | 12.1 | 10.1 | | |
| | Max | 15.2 | 14.8 | 13.9 | 13.4 | 13.0 | 12.6 | 12.6 | 10.7 | 10.7 | 16.0 | 17.1 | 17.4 | 19.3 | 19.1 | 18.9 | | |
| | Average | 12.7 | 11.9 | 12.1 | 11.1 | 10.1 | 10.0 | 9.9 | 9.0 | 8.6 | 12.0 | 12.9 | 13.7 | 15.3 | 15.8 | 13.8 | | |
| Ambient B | Min | 13.1 | 12.3 | 12.4 | 11.6 | 10.2 | 10.2 | 10.2 | 9.5 | 8.6 | 9.9 | 10.9 | 12.3 | 15.0 | 13.7 | 11.8 | | |
| | Max | 16.7 | 16.3 | 15.5 | 15.0 | 14.7 | 14.0 | 12.8 | 12.3 | 12.3 | 17.0 | 17.7 | 17.8 | 19.5 | 19.6 | 19.4 | | |
| | Average | 14.6 | 13.7 | 13.8 | 13.2 | 12.1 | 12.0 | 11.3 | 11.0 | 10.1 | 13.3 | 14.3 | 14.9 | 16.6 | 16.7 | 15.1 | | |
| Ambient C | Min | 10.3 | 10.1 | 10.1 | 9.1 | 7.8 | 7.8 | 7.8 | 7.0 | 6.2 | 8.4 | 8.5 | 11.0 | 12.3 | 11.4 | 10.2 | | |
| | Max | 14.4 | 14.2 | 13.6 | 12.6 | 12.3 | 11.9 | 11.4 | 9.9 | 9.9 | 15.0 | 16.3 | 16.6 | 18.8 | 18.6 | 18.2 | | |
| | Average | 12.3 | 11.3 | 11.7 | 10.5 | 9.8 | 9.7 | 9.8 | 8.7 | 7.9 | 11.3 | 12.2 | 13.1 | 14.6 | 15.1 | 13.3 | | |
| Dated \longrightarrow | | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | |
| Ambient A | Min | 12.3 | 12.5 | 12.8 | 11.1 | 11.1 | 13.1 | 10.6 | 13.5 | 13.7 | 9.9 | 13.2 | 9.5 | 10.6 | 11.2 | 11.7 | 12.3 | |
| | Max | 15.8 | 15.5 | 15.3 | 18.0 | 17.7 | 19.1 | 18.8 | 19.8 | 19.8 | 18.8 | 16.9 | 16.9 | 19.8 | 19.3 | 19.3 | 19.8 | |
| | Average | 13.8 | 14.3 | 14.2 | 13.6 | 13.9 | 16.1 | 14.2 | 16.0 | 16.3 | 13.5 | 15.0 | 13.0 | 14.5 | 14.7 | 14.9 | 15.2 | |
| Ambient B | Min | 13.7 | 15.3 | 15.3 | 12.2 | 12.3 | 13.4 | 12.8 | 13.4 | 13.4 | 11.2 | 14.2 | 11.3 | 13.1 | 12.8 | 13.4 | 13.6 | |
| | Max | 17.4 | 16.9 | 16.6 | 18.7 | 18.5 | 19.3 | 19.3 | 20.1 | 20.1 | 18.8 | 17.8 | 17.5 | 20.1 | 20.1 | 20.1 | 20.2 | |
| | Average | 15.7 | 16.0 | 15.8 | 15.0 | 15.1 | 15.8 | 15.5 | 16.0 | 16.0 | 14.7 | 15.7 | 14.5 | 15.8 | 16.1 | 16.3 | 16.5 | |
| Ambient C | Min | 11.5 | 12.2 | 12.4 | 10.1 | 10.2 | 12.4 | 10.2 | 13.1 | 13.3 | 8.3 | 12.3 | 8.8 | 10.6 | 10.6 | 11.0 | 11.5 | |
| | Max | 16.3 | 14.5 | 14.3 | 17.2 | 16.9 | 18.6 | 18.2 | 19.2 | 19.2 | 18.2 | 16.7 | 16.4 | 19.2 | 18.8 | 18.6 | 19.0 | |
| | Average | 13.9 | 13.4 | 13.3 | 12.9 | 13.1 | 15.9 | 13.7 | 15.9 | 16.0 | 12.8 | 14.4 | 12.4 | 13.8 | 14.0 | 14.2 | 14.4 | |



**REPORT FOR RISK ASSESSMENT FOR THE HANDLING OF RAW MATERIAL STORED AT
AMBIENT CONDITION IN WAREHOUSE**

Annexure-03

List of Raw Materials Used with respect to different Products

Area: Ware house

Location: Ambient Room

| S.No | Material Name | List of Products |
|------|--------------------------|---|
| 1 | Sodium Chloride | Cefixime, Cefuroxime Axetil Crystalline, Cefpodoxime Proxetil, |
| 2 | Sodium Thiosulphate | Cefpodoxime Proxetil, |
| 3 | Sodium Sulfide | Cefixime, |
| 4 | Sodium sulfate anhydrous | Cefpodoxime Proxetil, |
| 5 | Sodium bicarbonate | Cefixime, Cefuroxime Axetil Crystalline, Cefpodoxime Proxetil, |
| 6 | Sodium Hydro sulphite | Cefuroxime Axetil Crystalline, Cefpodoxime Proxetil, |
| 7 | Sodium carbonate | Cefixime, Cefuroxime Axetil Crystalline, |
| 8 | Sodium iodide | Cefixime, Cefpodoxime Proxetil, |
| 9 | EDTA Disodium salt | Cefixime, Cefuroxime Axetil Crystalline, Cefpodoxime Proxetil, |
| 10 | Triphenyl phosphate | Cefixime, |
| 12 | Caustic soda flakes | Cefixime, |
| 13 | Sodium bromide | Cefixime, |
| 14 | Sodium Hydroxide pallets | Cefpodoxime Proxetil, |
| 15 | Hyflo Supercel | Cefuroxime Axetil Crystalline, |

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REPORT FOR RISK ASSESSMENT FOR THE HANDLING OF RAW MATERIAL STORED AT AMBIENT CONDITION IN WAREHOUSE

Annexure-04

| Month | Cefpodoxime Proxetil | | Cefuroxime Axetil Amorphous | | Cefuroxime Axetil Crystalline | Cefixime Trihydrate | |
|----------------|----------------------|------------|-----------------------------|------------|-------------------------------|---------------------|------------|
| | In-house | Regulatory | In-house | Regulatory | Regulatory | In-house | Regulatory |
| January | 4 | 0 | 0 | 20 | 14 | 17 | 1 |
| February | 26 | 0 | 22 | 0 | 0 | 17 | 2 |
| March | 28 | 0 | 17 | 0 | 0 | 31 | 0 |
| April | 0 | 0 | 9 | 5 | 14 | 29 | 0 |
| May | 17 | 4 | 12 | 14 | 12 | 14 | 5 |
| June | 14 | 0 | 9 | 12 | 14 | 11 | 10 |
| July | 5 | 0 | 42 | 2 | 0 | 12 | 0 |
| August | 19 | 0 | 0 | 0 | 0 | 30 | 0 |
| September | 13 | 3 | 0 | 5 | 21 | 26 | 0 |
| October | 11 | 0 | 7 | 16 | 0 | 28 | 0 |
| November | 10 | 0 | 12 | 11 | 17 | 32 | 0 |
| December | 10 | 3 | 0 | 25 | 29 | 19 | 0 |
| | 157 | 10 | 130 | 110 | 121 | 266 | 18 |

