



TEMPERATURE MAPPING PROTOCOL FOR FILL BIN HOLD

TABLE OF CONTENTS

| S.No. | ITEM DESCRIPTION | PAGE No. |
|--------------|--|-----------------|
| 1.0 | PROTOCOL APPROVAL | 2 |
| 2.0 | OVERVIEW | 3 |
| 2.1 | Objective | 3 |
| 2.2 | Purpose | 3 |
| 2.3 | Scope | 3 |
| 2.4 | Responsibility | 3-4 |
| 2.5 | Execution Team | 5 |
| 2.6 | Risk analysis | 6 |
| 3.0 | PREREQUISITES | 6 |
| 4.0 | ACCEPETANCE CRITERIA | 6 |
| 5.0 | REVALIDATION CRITERIA | 6 |
| 6.0 | TEMPERATURE MAPPING PROCEDURE | 7-8 |
| 7.0 | DIAGRAM OF AREA SHOWING LOCATIONS | 8 |
| 8.0 | DATA LOGGER / SENSOR LOCATION NUMBER AND NAME | 8 |
| 9.0 | TEST INSTRUMENT CALIBRATION DETAILS | 9 |
| 10.0 | DISCREPANCIES AND CORRECTIVE ACTION TAKEN | 10 |
| 11.0 | LIST OF ANNEXURES | 11 |
| 12.0 | ABBREVIATION SHEET | 12 |
| 13.0 | SUMMARY AND CONCLUSION | 13 |
| 14.0 | FINAL REPORT | 14 |



TEMPERATURE MAPPING PROTOCOL FOR FILL BIN HOLD

1.0 PROTOCOL APPROVAL:

Signing of this approval page of Protocol indicates agreement with the validation approach described in this document. If modification to the validation approach becomes necessary, an addendum shall be prepared and approved. The protocol cannot be used for execution unless approved by the following authorities.

This protocol of Temperature/Humidity mapping has been reviewed and approved by the following persons:

| FUNCTION | NAME | DESIGNATION | DEPARTMENT | SIGNATURE | DATE |
|-------------|------|-------------|-------------------|-----------|------|
| PREPARED BY | | | QUALITY ASSURANCE | | |
| REVIEWED BY | | | QUALITY ASSURANCE | | |
| | | | ENGINEERING | | |
| | | | PRODUCTION | | |
| APPROVED BY | | | HEAD OPERATION | | |
| | | | QUALITY ASSURANCE | | |



TEMPERATURE MAPPING PROTOCOL FOR FILL BIN HOLD

2.0 OVERVIEW:

2.1 Objective:

The objective of this protocol is to develop a plan for monitoring of temperature and humidity of Fill Bin Hold Area and to identify the minimum and maximum temperature and humidity observed and also to identify the location for monitoring of temperature/humidity on daily basis where the more fluctuation observed and also to demonstrate the reproducibility of the temperature humidity in the area. The mapping shall be performed in line of WHO TRS 961.

2.2 Purpose:

The purpose of this protocol is to establish documentary evidence to ensure that the temperature humidity inside the Fill Bin Hold area maintained & is suitable for storing the granules in bin awaited for next processing step.

2.3 Scope:

The protocol describes the procedure, documentation, acceptance criteria & revalidation criteria to be used. This protocol shall be used for the mapping of Fill Bin Hold area.

2.4 Responsibility:

In accordance with protocol, following functions shall be responsible for the Temperature humidity mapping of the Fill Bin Hold area.

Execution Team (Comprising members from Production, Engineering and Quality Assurance) and their responsibilities are following:

- Prepares the temperature/humidity mapping protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system validation.
- Distributes the finalized protocol for review and approval signatures.
- Execution of protocol.
- Review of protocol, the completed data package and the final report.
- The data logger/sensor shall be placed by the Engineering Persons
- The printout of temperature/humidity mapping data shall be reviewed by production, engineering and QA person.



TEMPERATURE MAPPING PROTOCOL FOR FILL BIN HOLD

- In case of any failure of Temperature/Humidity observed the production person shall inform to engineering and QA and engineering persons shall take corrective action.

Head – production/ Engineering:

- Review of protocol, the completed data package and the final report.
- Assist in the resolution of validation deficiencies.

Head – Operation / Quality Assurance:

- Review and Approval of protocol, the completed qualification data package and the final report.



TEMPERATURE MAPPING PROTOCOL FOR FILL BIN HOLD

2.5 Execution Team:

The satisfactory mapping of the room shall be verified by executing the studies described in this protocol. The successfully executed protocol document indicates that the Temperature/Humidity is maintained in the room throughout the mapping period.

Execution team is responsible for the execution of temperature mapping of room. All executors involved with this protocol shall sign within the prescribed format given below:

| NAME | DEPARTMENT | DESIGNATION | SIGNATURE | DATE |
|------|------------|-------------|-----------|------|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

2.6 Risk analysis:

The Fill Bin Hold Area was created for storing of the granules in bin awaited for next processing step. The product is not exposed in this area and only storing for Compression purpose. As such the risk to product is low and if unfortunately temperature/humidity is out of limit for longer time during storage may lead to product abnormality. The risk analysis shall be carried out in line with HACCP tool as per the manual.

The risk hazard analysis and control point identified as per **Annexure I**.

The risk evaluation has been done as per **Annexure II**.

Conclusion of risk analysis:

All the risk related to Fill Bin Hold Area temperature and humidity mapping and excursion evaluated by HACCP tool (Hazard analysis and critical control point) and has been concluded that the risk which is identified during analysis are found high but adequate control point in place.



TEMPERATURE MAPPING PROTOCOL FOR FILL BIN HOLD

3.0 PREREQUISITES:

- Calibrated data logger and sensors or wireless data logger.
- All Standard Operating Procedure shall be verified if any.
- All the measuring parameters shall be verified.

4.0 ACCEPTANCE CRITERIA:

The temperature and humidity in the room should be maintained throughout activity and should be in between temperature $22 \pm 3^{\circ}\text{C}$ and humidity $50 \pm 5\%$.

5.0 REVALIDATION CRITERIA:

- Change/Modification in Fill Bin Hold area
- Change in storage condition.
- Change/Modification in HVAC system.

6.0 TEMPERATURE MAPPING PROCEDURE:

- AHU shall be in running condition upto the end of study and operate the HVAC system to get the Temperature $22 \pm 3^{\circ}\text{C}$ and humidity $50 \pm 5\%$ in the area.
- Calibrated wireless data logger/sensor shall be used for temperature/humidity mapping process.
- The total area of Fill Bin Hold Area is 102.536 m^2 . Fill Bin Hold Area shall be divided in equal squares of 5 meter. At least one probe shall be kept in each square identifying the critical spot. Reason for identifying the location shall be recorded. Place 8 numbers of temperature/humidity data logger/sensor in room as per attached drawing of annexure III and Table no. 08. As per 5 meter criteria only 5 data logger is required hence 8 data logger is considered for temperature mapping.
- Data logger/sensor shall be placed within 5 meter of the area in the respective room.
- Risk analysis shall be performed for the number of sensor selected and placement of the sensor.
- The temperature/humidity of data logger/sensor shall be placed at different working heights and at different locations so as to get the data of actual temperature / humidity maintained throughout the room. The data logger shall be placed in such a way that, the highest, lowest,



TEMPERATURE MAPPING PROTOCOL FOR FILL BIN HOLD

middle stacking height shall be covered.

- Switch on the data logger and check the working of Data logger.
- Set the print interval time of mapping data i.e. 05 minutes.
- Start the mapping and check the data logger/sensor reading on daily basis twice in a day frequency and same shall be recorded for continues Seven days and record the observation in **Annexure III**.
- If the temperature is beyond the acceptance limit, immediately rectify the situation and record in discrepancy section and take corrective action.
- At the end of the study remove the data logger and note down the data logger ID from where data logger removed in section No. 09.
- Stop the mapping on data logger and capture the data from data logger and identify the following details.
- Note down the minimum, maximum and mean temperature/humidity.
- Decision to put the digital hygrometer for routine monitoring shall be taken on the location where maximum fluctuation observed in room & hot Zone.
- Finally observed location shall be taken for the routine monitoring on the basis of temperature mapping study and marking is to be done for identified location observed in room.

7.0 DIAGRAM OF AREA SHOWING THE LOCATIONS:

The diagram of the location of temperature/humidity mapping in the area.

8.0 DATA LOGGER / SENSOR LOCATION NUMBER AND NAME

| Area name | Location No. | Location name | Location height from the floor (in mm) |
|--------------------|--------------|---|--|
| Fill Bin Hold area | T1 | Left side of entry door(rear side), Top of wall | 2200 |
| | T2 | Left side of entry door, Middle of wall | 1200 |
| | T3 | Front wall of entry door,(left corner) Bottom of wall | 400 |
| | T4 | Front wall of entry door,(Right corner) Top of wall | 2500 |
| | T5 | Right side of entry door, bottom of wall | 300 |
| | T6 | Right side of entry door(corner) middle of wall | 1400 |
| | T7 | Above the entry door | 1500 |
| | T8 | Hanging in the middle | 600 |



TEMPERATURE MAPPING PROTOCOL FOR FILL BIN HOLD

9.0 Test Instrument Calibration Details:

| Location No. / Name | Channel number | Instrument ID No. (Before mapping) | Calibration Detail | | | Instrument ID (After Mapping) |
|---------------------|----------------|------------------------------------|---------------------|--------------------|------------------------|-------------------------------|
| | | | Calibration Done on | Calibration due on | Checked By sign / Date | |
| T1 | | | | | | |
| T2 | | | | | | |
| T3 | | | | | | |
| T4 | | | | | | |
| T5 | | | | | | |
| T6 | | | | | | |
| T7 | | | | | | |
| T8 | | | | | | |
| Data logger | NA | | | | | |

Remarks: (If Any)

Reviewed By Sign/Date:



TEMPERATURE MAPPING PROTOCOL FOR FILL BIN HOLD

10.0 DISCREPANCIES AND CORRECTIVE ACTION TAKEN:

Discrepancies:

Corrective Action Taken:

Deviation Accepted By:
(Sign/Date)

Deviation Approved By:
(Sign/Date)



TEMPERATURE MAPPING PROTOCOL FOR FILL BIN HOLD

11.0 LIST OF ANNEXURES:

| Annexure No. | Document Title |
|--------------|----------------|
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |

Remarks (if any):

Done By & Date:

Verified By & Date:



TEMPERATURE MAPPING PROTOCOL FOR FILL BIN HOLD

12.0 ABBREVIATIONS SHEET:

Following Abbreviations are used in the Temperature mapping protocol of Fill Bin Hold Area

| S. No. | ABBREVIATION | DESCRIPTION |
|--------|--------------|--|
| 1. | Sr. | Serial |
| 2. | QAD | Quality Assurance Department |
| 3. | MIS | Miscellaneous |
| 4. | No. | Number |
| 5. | °C | Degree Centigrade |
| 6. | % RH | Relative humidity |
| 7. | HVAC | Heating ventilation and Air Conditioning |
| 8. | i.e. | That Is |
| 9. | T | Temperature |
| 10. | I.D. | Identity |
| 11. | QA | Quality Assurance |
| 12. | RM | Raw material |



TEMPERATURE MAPPING PROTOCOL FOR FILL BIN HOLD

13.0 SUMMARY & CONCLUSION:

SUMMARY:

CONCLUSION:

Prepared By (Sign/Date):

Checked By (Sign/Date):



TEMPERATURE MAPPING PROTOCOL FOR FILL BIN HOLD

14.0 FINAL REPORT APPROVAL:

It has been verified that mapping required for Fill Bin Hold area has been completed as per the predefined protocol. The data required for this protocol completion has been attached to this protocol or included in the qualification summary report. Verified that all amendments and discrepancies are documented, approved and attached to this protocol.

Signature in the block below indicates that all items in this mapping report of Fill Bin Hold area has been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

| FUNCTION | NAME | DESIGNATION | DEPARTMENT | SIGNATURE | DATE |
|----------------|------|-------------|----------------------|-----------|------|
| REVIEWED BY | | | QUALITY ASSURANCE | | |
| | | | ENGINEERING | | |
| | | | PRODUCTION | | |
| APPROVED BY | | | HEAD OPERATION | | |
| | | | QUALITY ASSURANCE | | |



TEMPERATURE MAPPING PROTOCOL FOR FILL BIN HOLD

Annexure I

HAZARD ANALYSIS AND CRITICAL CONTROL PARAMETERS

| Sr. No | PROCESS STEP | HAZARD | RISK | CRITICAL LIMIT/FREQUENCY | JUSTIFICATION | CORRECTIVE AND PREVENTIVE ACTION | ESTABLISHMENT OF VERIFICATION |
|--------|---------------------------|--|------|---|--|---|---|
| 1 | Filled bin hold area | If temperature does not maintained in the area there is a possibilities of degradation of product and hazard to the patient. | Low | Specified limit is $22 \pm 3^{\circ} \text{c} / 50 \pm 5\%$. The frequency of monitoring during mapping is 5 minutes for continuous Seven days. Routine monitoring shall be performed at twice in a day frequency at the position where fluctuation is more. | The temperature mapping is carried out to check the temperature accuracy/ distribution avoid the degradation of the product. | Personal entering into Filled bin hold area are well trained in GMP practices. | SOP of temperature monitoring is in place. Protocol based study for temperature mapping is done. |
| 2 | Man and material movement | Possibilities of excursion in temperature may be observed which may lead to the abnormality of product stored. | High | Specified limit is $22 \pm 3^{\circ} \text{c} / 50 \pm 5\%$. The temperature mapping is performed for seven consecutive days with temperature logging at 5 minutes frequency. | Effect of routine operations done in the area with normal man and material movement shall be evaluated by using online data logging system during mapping and same shall be verified during routine monitoring. Door closure is available. | Personal entering into Filled bin hold area, are well trained in GMP practices. Training to be given for entry exit to new employee. | SOP is in place for entry and exit to Filled bin hold area, Door closure is available. |
| 3 | Door opening and closing | Possibilities of excursion in temperature may be observed which may lead to the abnormality of product stored. | High | Specified limit is $22 \pm 3^{\circ} \text{c} / 50 \pm 5\%$. The temperature mapping is performed for Seven consecutive days with temperature logging at 5 minutes frequency. | Effect of routine operations done in the area with normal man and material movement shall be evaluated by using online data logging system during mapping and same shall be verified during routine monitoring. Door closure is available. | Personal entering into dispensed material hold area, are well trained in GMP practices. Training to be given for entry exit to new employee. | SOP is in place for entry and exit to filled bin hold area. Door closure is available. |
| 4 | Breakdown of HVAC | Breakdown of HVAC may have direct impact on the temperature and may not be maintained in the area which may lead to product abnormality. | High | Specified limit is $22 \pm 3^{\circ} \text{c} / 50 \pm 5\%$ The temperature monitoring is performed at twice in a day frequency. The temperature mapping is performed for Seven consecutive days with temperature logging at 5 minutes frequency. | In case of failure of HVAC due to continues running temperature may increase. | The preventive maintenance for HVAC system shall be done for proper functioning to be maintained. The Diesel generator is provided if power failure occurred. | Routine monitoring shall be carried out twice in day. SOP for preventive maintenance is in place. |



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

TEMPERATURE MAPPING PROTOCOL FOR FILL BIN HOLD

Annexure I

HAZARD ANALYSIS AND CRITICAL CONTROL PARAMETERS

| Sr. No | PROCESS STEP | HAZARD | RISK | CRITICAL LIMIT/FREQUENCY | JUSTIFICATION | CORRECTIVE AND PREVENTIVE ACTION | ESTABLISHMENT OF VERIFICATION |
|--------|---|---|------|---|---|--|---|
| 5 | Sensor location selection during mapping | Wrong selection of sensor location would lead to faulty temperature mapping result which would not be the representative of the area. | High | Specified limit is $22 \pm 3^{\circ} \text{c} / 50 \pm 5\%$. The frequency of monitoring during mapping is 5 minutes for consecutive Seven days and routine monitoring shall be performed with twice in day. | The room shall be equally divided within 5 m area and 8 number sensors shall be placed in the area at different height (minimum and maximum covering door opening, middle of the room and corners. | Correct placement of temperature sensors would give the temperature mapping data which would be the representative of the room | Approved protocol of temperature mapping and drawing shall be prepared prior to putting the sensor on location and put the sensor as per the drawing. |
| 6 | Faulty sensor/ Wrong sensor/ Faulty data logger | Faulty sensor may gives the faulty result | High | Specified limit is $22 \pm 3^{\circ} \text{c} / 50 \pm 5\%$. The calibration of the data logger shall be verified before start of the activity. | Before start of the activity the calibration of data logger shall be verified. | The calibration of sensor and data logger shall be carried out as per predefined frequency | The calibration of SOP is in place for sensors and data logger. |
| 7 | Sensor hanging in middle | If wrong selection of sensor location then the result will not be representative the actual status Filled bin hold area. | Low | Specified limit is $22 \pm 3^{\circ} \text{c} / 50 \pm 5\%$. The frequency of monitoring during mapping is 5 minutes for continues Seven days. | The data logger shall be hanged in middle which select because the material is kept in middle and which represent result of all area. | Correct placement of temperature sensors in the middle of the room would give the temperature mapping data which would be the representative of the room. | Sensor location diagram temperature mapping is in place and location is marked on the drawing. |
| 8 | Near door | If wrong selection of data logger location then the result will not be representative the actual status of filled bin holds area. | High | Specified limit is $22 \pm 3^{\circ} \text{c} / 50 \pm 5\%$. The frequency of monitoring during mapping is 5 minutes for consecutive Seven days. | The data logger shall be hanged near door which has been selected because door opening and closing possibilities temperature increases into room and maximum temperature is observed at door location | Correct placement of temperature sensors near the door would give the temperature mapping data which would be the representative of the area. | Sensor location diagram temperature mapping is in place and location is marked on the drawing. |
| 9 | All wall / racks of Filled bin hold area | If wrong selection of data logger location then the result will not be representative the actual status of filled bin holds area. | Low | Specified limit is $22 \pm 3^{\circ} \text{c} / 50 \pm 5\%$. The frequency of monitoring during mapping is 5 minutes for consecutive Seven days. | This location is selected at specified height and on the wall / inside the racks so the sensor shall represent the condition of the room at different location with different height. | Correct placement of temperature sensors at right and left side wall / racks of entry would give the temperature mapping data which would be the representative of the area. | Sensor location diagram temperature mapping is in place and location is marked on the drawing. |



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

TEMPERATURE MAPPING PROTOCOL FOR FILL BIN HOLD

Annexure II

Risk Evaluation for Hazard Identification

| Process Step | Occurrence (O) | Justification | Severity (S) | Justification | Risk matrix (O X S) | Risk | Action plan |
|--|----------------|---|--------------|--|---------------------|------|---|
| Filled bin hold area | 2 | SOP of temperature monitoring is in place. Protocol of temperature mapping is in place. | 2 | The temperature mapping is carried out to check the temperature accuracy/distribution avoid the degradation of the product. | 4 | Low | Adequate measures are available to identify the critical control parameters in the system. |
| Man and material movement | 5 | Man and material movement is occurred for transfer of the material for several time during the day activity hence the occurrence almost certain | 1 | The temperature mapping is carried out to check the temperature accuracy/distribution with various in operation condition avoid the degradation of the product. Door closure is available. | 5 | Low | Adequate measures are available to identify the critical control parameters in the system. Door closure is available. |
| Door opening and closing | 5 | Door opening occurs several times for transfer of the material. | 1 | Effect of routine operations done in the area with normal man and material movement shall be evaluated by using online data logging system during mapping and same shall be verified during routine monitoring. Door closure is available. | 5 | Low | Automatic door closing system is in place. Control measures are adequate for monitoring of temperature at daily basis twice in day which easily identify the excursion of temperature. Door closure is available. |
| Breakdown of HVAC | 1 | HVAC system has been installed to control the temperature and relative humidity and also preventive maintenance is in place.. | 4 | All ready HVAC connection has been provided in area to maintain the desired temperature condition; | 4 | Low | In dispensed material hold area HVAC system has been provided and additional preventive maintenance shall be in a place. |
| Selection of Sensor location during mapping | 1 | The area is divided into equally and sensor shall be placed at different location with at different height | 4 | Wrong selection of location may not provide actual status of all area. | 4 | Low | Proper distribution of sensor for temperature mapping shall be verified as per the diagram. |
| If Faulty sensor/ Wrong sensor/ Faulty data logger | 1 | The activity shall be carried out by approved external vendor with calibrated data logger. | 4 | Faulty data and wrong representation of area shall be given by data logger. | 4 | Low | Prior to start the activity calibration and working of data logger shall be verified. |



TEMPERATURE MAPPING PROTOCOL FOR FILL BIN HOLD

Annexure III

1. CHECK LIST BEFORE STARTING OF TEMPERATURE MAPPING

| S.No. | Check point | Verification status | Verified by |
|-------|--|---------------------|-------------|
| 1. | Data logger/sensor calibration status | | |
| 2. | Data logger/sensor working | | |
| 3. | Data logger/sensor placed at defined location as per drawing | | |

2. PHYSICAL VERIFICATION OF DATA LOGGER DURING TEMPERATURE MAPPING

| S.No. | Date | Morning | | | | | | | | Verified by | Evening | | | | | | | | Verified by | |
|-------|----------------------------------|---------|----|----|----|----|----|----|----|-------------|---------|----|----|----|----|----|----|----|-------------|----|
| | | T1 | T2 | T3 | T4 | T5 | T6 | T7 | T8 | | NA | T1 | T2 | T3 | T4 | T5 | T6 | T7 | | T8 |
| | Location No. | | | | | | | | | | | | | | | | | | | |
| | Data logger Code No./Channel No. | | | | | | | | | | | | | | | | | | | |
| | 1. | | | | | | | | | | | | | | | | | | | |
| | 2. | | | | | | | | | | | | | | | | | | | |
| | 3. | | | | | | | | | | | | | | | | | | | |
| | 4. | | | | | | | | | | | | | | | | | | | |
| | 5. | | | | | | | | | | | | | | | | | | | |
| | 6. | | | | | | | | | | | | | | | | | | | |
| | 7. | | | | | | | | | | | | | | | | | | | |
| | 8. | | | | | | | | | | | | | | | | | | | |
| | 9. | | | | | | | | | | | | | | | | | | | |
| | 10. | | | | | | | | | | | | | | | | | | | |

*Physical verification means position of data logger at right position, data logger location & display screen working. Put “√” if found satisfactory & “X” if not satisfactory

Remark:

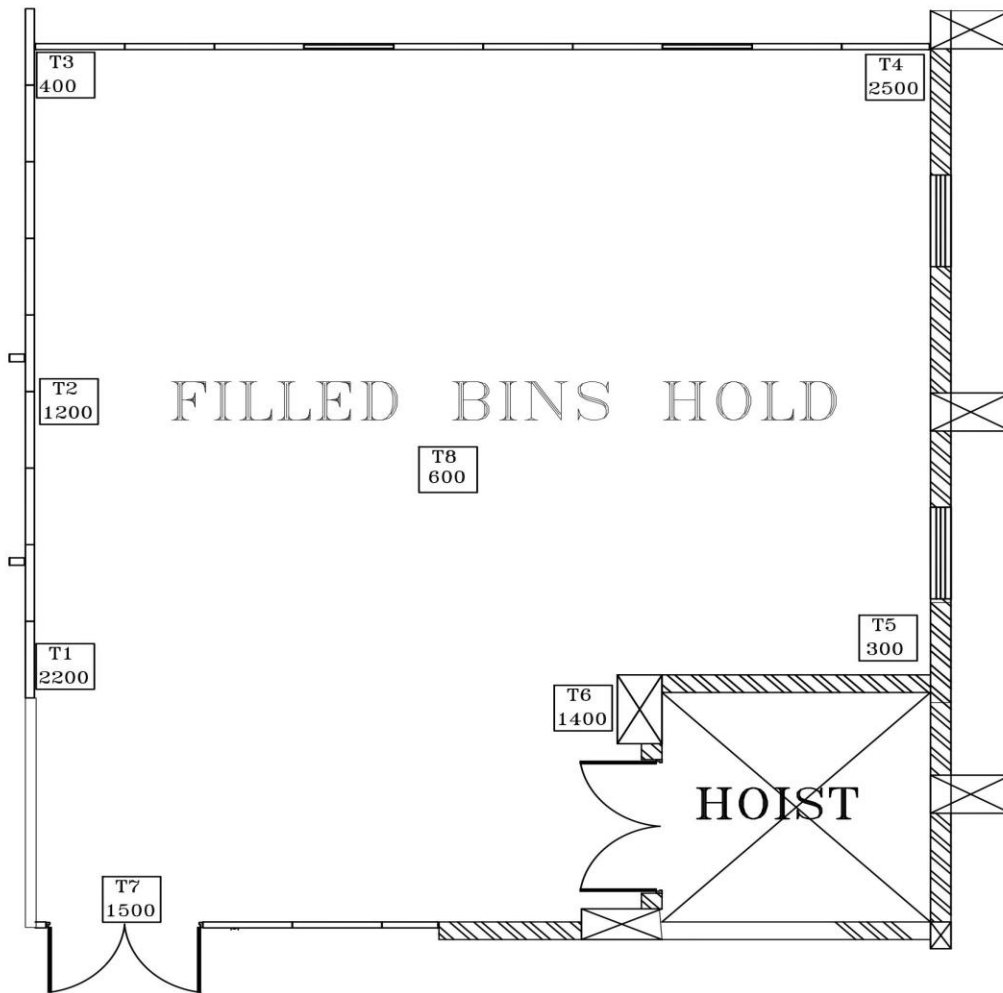
Verified By Sign/Date:



TEMPERATURE MAPPING PROTOCOL FOR FILL BIN HOLD

Annexure IV

LAYOUT



LEGEND:

T: TEMPERATURE MAPPING LOCATION

ALL VALUES ARE IN MM

**TEMPERATURE MAPPING LAYOUT
OF FILLED BIN HOLD
GENERAL BLOCK
SECOND FLOOR**

CHECKED BY

APPROVED BY