

Comprehensive Temperature Mapping and Stratification Study of an Ambient Pharmaceutical Warehouse Influenced by Local CTU Heat Sources

Pujari Prasantha

Antibody-Drug Conjugates Division, Manufacturing Site,
United States

Article Info

Article history:

Received Mar 20, 2026

Revised Sep 19, 2026

Accepted Oct 10, 2026

Keywords:

Temperature mapping
Pharmaceutical warehouse
Controlled room temperature
Ambient warehouse
CTU farm

ABSTRACT

This paper reports a temperature mapping study of a GMP-regulated ambient pharmaceutical warehouse of about 10,000 square feet (930 m²) whose storage space borders an interface zone with 44 controlled temperature units (CTUs). The study followed a risk-based IQ/OQ/PQ sequence with 63 calibrated wireless loggers sampling at 5-minute intervals in three 72-hour sessions: the empty warehouse (OQ, October 2023), the warehouse loaded to about 80 % (PQ, October 2023) and a winter session (February 2024). In the empty warehouse the mean over all channels was 21.87 °C; the global minimum (18.65 °C) was recorded on a wire-rack shelf and the global maximum (27.58 °C) at a logger mounted on top of a refrigeration unit, at 04:20, outside working hours. In the loaded session the sharp equipment-cycle peaks of the empty session were absent and a slow diurnal wave dominated, with isolated peaks of about 30 °C on working days. In winter, regular peaks of 30–35 °C coincided with heating cycles, and one channel started above 40 °C and ran at 28–32 °C for the rest of the session. The paper states the mean kinetic temperature (MKT) equation and its activation-energy convention and explains why MKT cannot replace a duration-based evaluation of excursions. The underlying time series and per-channel statistics could not be released, so the results are presented as a documented case with explicit limitations. The practical outcomes are recommendations on destratification, a buffer zone around heat-rejecting units and the placement of permanent monitoring points.

Copyright © 2026 Institute of Advanced Engineering and Science.
All rights reserved.

Corresponding Author:

Pujari Prasantha,
Antibody-Drug Conjugates Division, Manufacturing Site,
United States.
Email: prasantha.pujari@gmail.com

1. INTRODUCTION

Regulatory attention in the pharmaceutical industry has extended from manufacturing (GMP) to the whole supply chain, where Good Distribution Practice (GDP) now sets the expectations for storage and transport [1], [2], [3]. Controlled room temperature (CRT) storage, defined by USP <659> as 20–25 °C with permitted excursions between 15 and 30 °C, is a central element of that chain [4]. Departures from this regime can alter the physicochemical properties of a product, reduce its potency and, in some cases, generate degradation products [5].

Large ambient warehouses present a particular problem because a uniform temperature field is required over hundreds or thousands of square metres. Unlike small climatic chambers (up to about 20 m³) built around forced-air circulation, a warehouse is exposed to diurnal and seasonal changes of the outdoor temperature, air infiltration through loading docks, heat release from lighting, handling equipment and process units, and the aerodynamic resistance of rack structures [6].

Current guidance describes how such facilities should be mapped. USP <1079> and <1079.4> set out a risk-based approach to the qualification of storage areas, including probe placement maps and the requirement that a study be long enough to capture workflow and system variations and that seasonal extremes be considered [7], [8]. The WHO model guidance and its technical supplement on temperature mapping recommend a logger grid at 5–10 m spacing with loggers at high, medium and low level, a study duration of at least seven consecutive days (five working days and two weekend days) for warehouses and other ambient storage areas, and separate studies in the warmest and coldest seasons where seasonal variation affects the area [9], [10]. The EU GDP guidelines require an initial mapping exercise before use, repeated after significant modification, and the ISPE Good Practice Guide on cold chain management gives a comparable risk-based framework [3], [11]. Applying these requirements to a specific building still requires adaptation to its architecture and operating profile. One configuration that the guidance does not address in detail is a warehouse in which refrigeration equipment, up to a cluster of controlled temperature units (a CTU farm), shares the building volume with ambient storage and rejects condenser heat into it.

The facility studied here is such a case: an ambient warehouse of about 10,000 square feet (930 m²) with no HVAC zoning between storage cells, bordered by an interface zone with 44 autonomous CTUs, and with further refrigeration units standing in the storage area itself. The question addressed is whether a passive ambient-control arrangement of this kind holds CRT conditions under variable external and internal loads, and where its permanent monitoring points should be placed.

Several specific risks follow from this configuration. Thermal inhomogeneity may produce vertical stratification, in particular in winter and summer, with excursions at the upper rack levels [6]. Loading changes both the thermal inertia of the system and its airflow paths, so the same stored mass can act as a damping factor and as an obstacle to circulation; the coupled airflow and heat-transfer behaviour of packed storage has been modelled for other warehouse types [12]. Local anomalies may arise around heat-rejecting equipment. Finally, short excursions have to be interpreted: mean kinetic temperature (MKT) is widely used for this purpose, and its limits need to be stated [13], [14].

The aim of this work is to document the temperature mapping of this warehouse in the empty and loaded states and during a winter period, to interpret the results against current guidance, and to derive recommendations for the placement of permanent monitoring sensors. The objectives were:

- to develop a risk-based mapping protocol that accounts for room geometry, equipment layout and material flows;
- to collect temperature data in the empty (OQ) and loaded (PQ) warehouse and under winter conditions;
- to compare the sessions using absolute temperature metrics and MKT, and to state the limits of the MKT approach;
- to identify locations of elevated risk and to formulate recommendations for the permanent monitoring system.

The contribution of the paper is a documented case rather than a new method. It describes how heat-rejecting refrigeration units inside an ambient storage zone appear in the mapping record, compares empty and loaded profiles recorded with the same 63-channel grid, and shows how winter heating cycles affect the choice of control points for the environmental monitoring system. The underlying time series and per-channel statistics belong to the site's validation record and could not be released for publication. The paper therefore relies on the summary outputs reproduced in the figures and tables, and the limitations that follow from this are stated in Section 3.6.

2. RESEARCH METHOD

The study was conducted at a GMP-compliant warehouse used for pharmaceutical substances, components and consumables. The total storage area is about 10,000 square feet (930 m²). The warehouse is classified as an ambient temperature-controlled area with a target range of 20–25 °C and permitted operational excursions of 15–30 °C. Temperature is monitored continuously, with alarms, by the site's process automation system (PAS), which serves as the permanent monitoring system; temperature is not controlled at individual storage locations.

Three parts of the facility define the thermal model: the main storage area, the receiving and shipping area and the CTU farm interface. The main storage area is built with multi-level pallet racks arranged in parallel rows, which set the characteristic directions of air movement. The receiving and shipping area, about 2,000 square feet (190 m²), has roll-up dock doors fitted with air curtains to limit heat exchange with the outside; frequent door openings expose it to the outdoor temperature. The CTU farm interface covers about 1,500 square feet (140 m²) and houses 44 autonomous refrigerated units. Each unit controls its own interior independently of the ambient environment, but its condenser rejects heat into the warehouse, so the interface is treated as a

potential source of localized temperature elevation and airflow disturbance. A floor plan of the facility is not reproduced in this paper; the logger layout in Figure 1 serves as the spatial reference.

The qualification followed the V-model lifecycle and the risk-based approach of USP 〈1079.4〉 [8]: installation qualification (IQ), operational qualification (OQ) in the empty warehouse, performance qualification (PQ) in the loaded warehouse, and seasonal mapping.

During IQ the racks, the HVAC elements and the PAS sensors were verified against the design documentation, and all data loggers were calibrated before OQ. OQ mapped the empty warehouse to establish the baseline behaviour of the climate system without the damping effect of stored product. PQ mapped the warehouse loaded to about 80 % of rack capacity with a combination of actual materials and simulated loads, to confirm stability under the thermal inertia and airflow obstruction of real operation.

The acceptance criteria of the qualification protocol were: all logger readings within 15–30 °C; the warehouse operating predominantly within 20–25 °C; MKT below 25 °C at every location; PAS probe readings consistent with the co-located loggers; and no alarm or excursion left without a documented investigation. Transient spikes up to 40 °C were acceptable only if they lasted no longer than 24 hours and MKT stayed below 25 °C, in line with USP 〈659〉 [4]. Wire-rack channels were recorded for information and were not part of the acceptance criteria.

Seasonal mapping was planned for the coldest and warmest periods. The winter session (February 2024) is analysed in this paper. A summer session was also performed at the site; its dates and results were not retrieved for this analysis and are not used here.

The logger placement plan was derived from a risk assessment of the warehouse volume that considered the geometry, rack layout and height, airflow obstructions, heat-generating equipment, the positions of the fixed PAS probes and the door locations. Figure 1 shows the resulting layout in the main storage area.

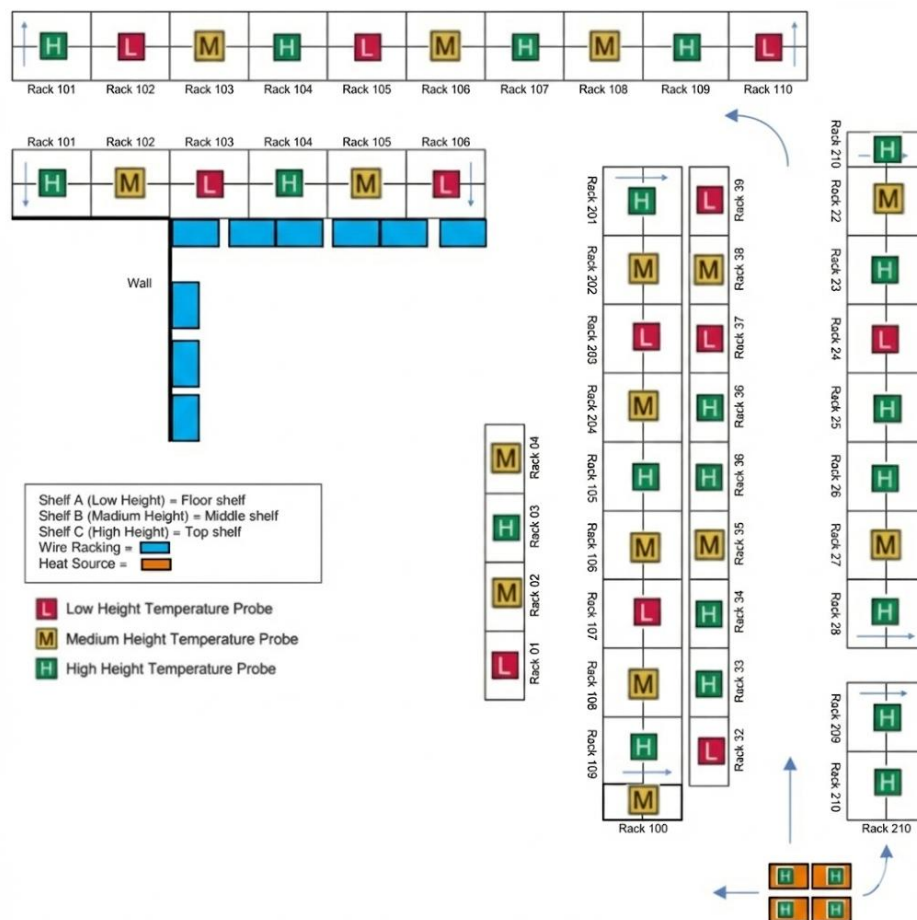


Figure 1. Layout of temperature data loggers in the main warehouse. L, M and H mark loggers at low, medium and high level, which correspond to the bottom, middle and top shelf positions in Table 1; blue: wire racking; orange: heat sources

In total 63 channels were used. Forty-nine loggers were mounted on pallet racks at three levels (bottom, middle and top shelf) with a horizontal spacing of no more than 18 ft (about 5.5 m); this spacing is consistent with the 5–10 m grid recommended by WHO [10]. Their positions, as recorded in the session channel list, are given in Table 1; the same channel assignment was used in the empty and loaded sessions. Six loggers were placed on wire racks used for auxiliary materials. Four loggers were co-located with the fixed PAS probes to compare the permanent system with the mapping loggers. Four loggers were placed at identified heat sources: on top of two refrigeration units in the storage area (designated MM refrigerators in the channel list) and on top of two QC refrigerators. These units are refrigeration equipment standing within or beside the ambient storage space; whether they form part of the 44-unit CTU farm interface is not recorded in the channel descriptions. Table 2 lists the fourteen supplementary channels.

Table 1. Pallet-rack channels LC 1–LC 49 as recorded in the session channel list (rack index and shelf position; sampling interval 5 min for all channels)

Channel	Position	Channel	Position	Channel	Position
LC 1	Rack 1A Bottom	LC 18	Rack 18B Middle	LC 35	Rack 35B Middle
LC 2	Rack 2B Middle	LC 19	Rack 19C Top	LC 36	Rack 36A Bottom
LC 3	Rack 3C Top	LC 20	Rack 20B Middle	LC 37	Rack 37C Top
LC 4	Rack 4B Middle	LC 21	Rack 21C Top	LC 38	Rack 38B Middle
LC 5	Rack 5B Middle	LC 22	Rack 22B Middle	LC 39	Rack 39C Bottom
LC 6	Rack 6A Bottom	LC 23	Rack 23A Bottom	LC 40	Rack 40A Top
LC 7	Rack 7B Middle	LC 24	Rack 24B Middle	LC 41	Rack 41B Middle
LC 8	Rack 8C Top	LC 25	Rack 25C Top	LC 42	Rack 42C Bottom
LC 9	Rack 9B Middle	LC 26	Rack 26B Middle	LC 43	Rack 43B Middle
LC 10	Rack 10A Bottom	LC 27	Rack 27A Bottom	LC 44	Rack 44A Top
LC 11	Rack 11C Top	LC 28	Rack 28B Middle	LC 45	Rack 45B Middle
LC 12	Rack 12B Middle	LC 29	Rack 29C Top	LC 46	Rack 46C Bottom
LC 13	Rack 13A Bottom	LC 30	Rack 30B Middle	LC 47	Rack 47B Middle
LC 14	Rack 14B Middle	LC 31	Rack 31A Bottom	LC 48	Rack 48A Top
LC 15	Rack 15C Top	LC 32	Rack 32A Bottom	LC 49	Rack 49B Middle
LC 16	Rack 16B Middle	LC 33	Rack 33B Middle		
LC 17	Rack 17A Bottom	LC 34	Rack 34C Top		

Table 2. Supplementary channels LC 50–LC 63: wire racks, heat sources and PAS co-location points

Channel	Group	Position as recorded in the channel list
LC 50	Wire rack	Wire rack adjacent to Rack 8, bottom shelf
LC 51	Wire rack	Wire rack adjacent to Rack 8 and Rack 7, middle shelf
LC 52	Wire rack	Wire rack adjacent to Rack 7 and Rack 6, top shelf
LC 53	Wire rack	Wire rack adjacent to Rack 6 and Rack 5, middle shelf
LC 54	Wire rack	Wire rack adjacent to Rack 5, bottom shelf
LC 55	Wire rack	Wire rack adjacent to the wall, middle shelf
LC 56	Heat source	Top of far-left MM refrigerator
LC 57	Heat source	Top of far-right MM refrigerator
LC 58	Heat source	Top of QC refrigerator 49380
LC 59	Heat source	Top of QC refrigerator 49381
LC 60	PAS co-location	PAS TT_EAST_50006
LC 61	PAS co-location	PAS TT_SOUTH_50008
LC 62	PAS co-location	PAS TT_NE_50009
LC 63	PAS co-location	PAS TT_NW_50011

Data were collected using a validated wireless temperature monitoring system equipped with calibrated temperature sensors and validated data-acquisition software operated under the site's applicable electronic-record controls in accordance with 21 CFR Part 11 requirements. The sampling interval was 5 minutes, which resolves the daily cycle and short events such as door openings while keeping the data volume manageable. All sensors were calibrated at three points with NIST traceability before and after the study; the acceptance criterion for drift was ± 0.5 °C.

Each session ran for 72 hours: OQ from 3 to 6 October 2023 (Tuesday to Friday), PQ from 7 to 10 October 2023 (Saturday to Tuesday) and the winter session from 23 to 26 February 2024 (Friday to Monday).

The PQ and winter windows therefore include a weekend; the OQ window does not. A 72-hour window captures three diurnal cycles but is shorter than the seven consecutive days recommended by WHO for ambient warehouses [10]; USP <1079.4> requires a duration sufficient to capture workflow and system variations and consideration of seasonal extremes [8]. This point is taken up in Section 3.6.

Processing comprised descriptive statistics (minimum, maximum and mean per channel and for the whole warehouse), visual time-series analysis to identify trends, HVAC cycles and outliers, and MKT calculation. MKT expresses a fluctuating temperature history as the single temperature that would produce the same cumulative thermal stress, assuming Arrhenius kinetics [15], [16]:

$$\text{MKT} = (\Delta H/R) / \{ -\ln[(e^{(-\Delta H/RT_1)} + e^{(-\Delta H/RT_2)} + \dots + e^{(-\Delta H/RT_n)}) / n] \} \quad (1)$$

where ΔH is the activation energy, $R = 8.314 \text{ J}\cdot\text{mol}^{-1}\cdot\text{K}^{-1}$, $T_1 \dots T_n$ are the sampled absolute temperatures and n is their number. USP <1150> adopts $\Delta H = 83.144 \text{ kJ}\cdot\text{mol}^{-1}$ as the convention for pharmaceutical storage [15]. The validation software was run at its default activation-energy setting, which was not changed for this study; the version-specific documentation of that default was not retrieved for this revision, so the USP value is quoted here as the reference convention.

Where the text below quotes values that are not in the statistical reports (peak heights, peak spacing, approximate event durations), they are readings taken from the charts reproduced in the figures, with a precision of about $\pm 1^\circ\text{C}$ and ± 10 minutes. No per-channel statistics were computed from the images.

3. RESULTS AND DISCUSSION

3.1. Temperature profile of the empty warehouse (OQ stage)

OQ in the empty warehouse shows the behaviour of the HVAC system without the damping effect of stored product. Free air movement makes the volume responsive to external influences and to the on/off cycles of the climate equipment. Figure 2 shows the 72-hour profile.

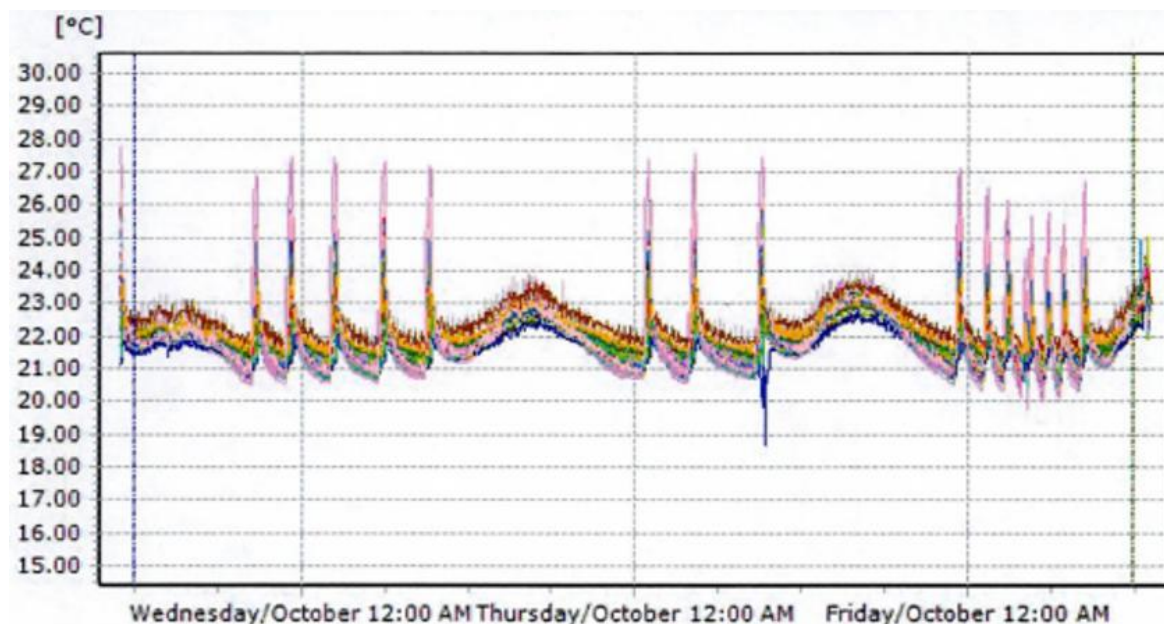


Figure 2. Temperature profile of the empty warehouse, 3–6 October 2023 (63 channels)

The channels track each other closely, which indicates good mixing in the empty volume. Regular narrow peaks above 25°C , reaching about $27\text{--}27.5^\circ\text{C}$, appear in groups on the first and third days. Their regular spacing resembles the signature of control cycles of the climate equipment, but the cause was not established within this study. The mean over all channels and the full window was 21.87°C , within the target range. Figure 3 reproduces the statistical report.

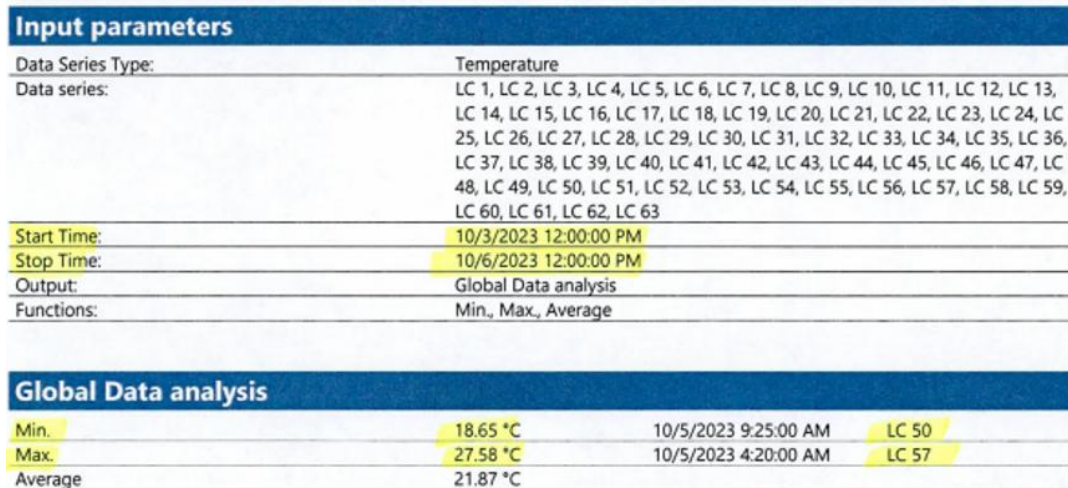


Figure 3. Statistical report of the empty-warehouse session (global minimum, maximum and mean over 63 channels)

The global minimum of 18.65 °C occurred at LC 50, a wire-rack bottom shelf adjacent to rack 8, at 09:25 on 5 October, and the global maximum of 27.58 °C at LC 57 at 04:20 on the same day. LC 57 is one of the four heat-source channels, mounted on top of a refrigeration unit (Table 2). Both extremes therefore come from channels outside the 49 pallet-rack positions; the range of the pallet-rack channels alone is narrower but is not available in the released outputs. The maximum occurred at a heat-source position outside working hours, when no handling or door activity would be expected. This timing is consistent with local heat rejection from the unit; it would also be consistent with a night-time control mode of the HVAC system, and the available summary data do not allow the two contributions to be separated.

Both extremes lie within the permitted 15–30 °C band. No top-versus-bottom comparison across the rack levels is available for this session, so the vertical gradient in the October sessions is not quantified here.

3.2. Impact of loading on thermal stability (PQ stage)

PQ was performed with racks loaded to about 80 %. Loading obstructs airflow and may create dead zones, while the stored mass adds heat capacity and thermal inertia. Figure 4 shows the loaded-warehouse profile.

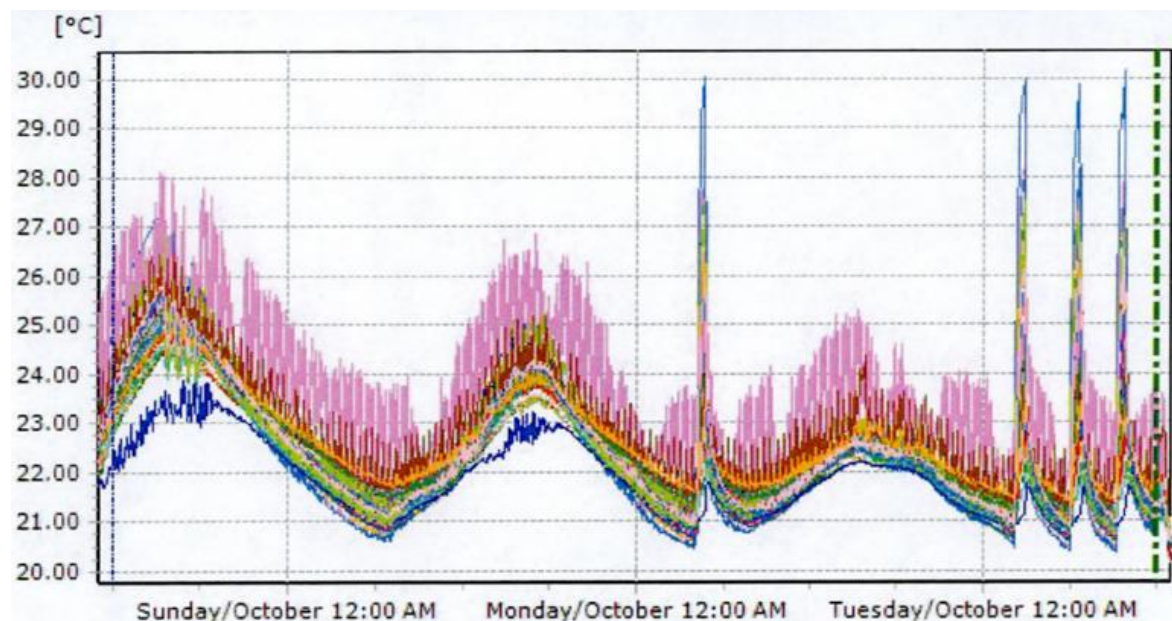


Figure 4. Temperature profile of the loaded warehouse, 7–10 October 2023 (63 channels)

Compared with Figure 2, the loaded profile is dominated by a slow diurnal wave of roughly 21–26 °C, and the sharp control-cycle peaks of the empty session are absent. The channels form a dense bundle, indicating homogeneous conditions across the racks. One channel shows a persistent high-frequency oscillation of about 1–2 °C superimposed on the diurnal wave, which resembles the on/off cycling of a refrigeration compressor; a second channel runs about 1 °C below the bundle. The channel-level statistics needed to attribute these two traces with certainty are not available in the released outputs.

The comparison supports, qualitatively, the expected stabilizing effect of loading: the response to equipment cycles is attenuated and temperature fronts are more gradual. The two sessions were, however, recorded in different weeks under different outdoor conditions, and the diurnal amplitude in the loaded session is larger than the baseline drift of the empty session. The comparison should therefore be read as a difference in the character of the fluctuations, not as a measured damping ratio.

Four isolated peaks reaching about 30 °C occur in the loaded session, all on Monday 9 and Tuesday 10 October and none during the weekend; on the chart each lasts on the order of tens of minutes. Their timing points to operational events on working days, but the specific cause and the affected locations were not established in the records available for this paper. No statistical report was released for the loaded session, so its per-channel extremes are not stated; the chart places the highest readings at about 30 °C, at the upper limit of the permitted band.

3.3. Analysis of critical zones and local heat sources

Channels LC 50–LC 63 (Table 2) covered the zones considered high-risk a priori: six wire-rack positions adjacent to racks 5–8 and to the wall, four heat-source positions on top of refrigeration units, and four positions next to the fixed PAS probes (TT_EAST, TT_SOUTH, TT_NE and TT_NW).

Of the heat-source channels, only the extreme value of LC 57 is documented in the available summary outputs (27.58 °C, Section 3.1); per-channel statistics for LC 56–LC 59 are not reproduced here. The heat-source positions are not product storage locations, but the warm plume above a condenser can reach adjacent pallet positions. The buffer zone recommended in Section 4 is a risk-based design measure that follows from this mechanism, not a quantified finding of this study.

Table 3 gives the 72-hour means of the four PAS co-location channels in the empty-warehouse session. The instrument comparison between each PAS probe and its co-located logger was part of the qualification record and is not reproduced here; the table characterizes the positions of the fixed probes rather than the agreement of the instruments.

Table 3. Mean temperature of the PAS co-location channels LC 60–LC 63, empty-warehouse session (3–6 October 2023)

Data series	Start time	Stop time	Function	Average, °C
LC 60	10/3/2023 12:00 PM	10/6/2023 12:00 PM	Average	22.11
LC 61	10/3/2023 12:00 PM	10/6/2023 12:00 PM	Average	22.17
LC 62	10/3/2023 12:00 PM	10/6/2023 12:00 PM	Average	22.03
LC 63	10/3/2023 12:00 PM	10/6/2023 12:00 PM	Average	22.08

The four means lie within 0.14 °C of each other and 0.16–0.30 °C above the mean over all channels (21.87 °C). The fixed-probe positions therefore represented the warehouse mean closely during OQ, with a slight warm bias. Whether they also capture the worst-case locations is a separate question, taken up in Section 3.4.

3.4. Winter mapping: stratification and heating-related risks

The winter session showed a risk profile different from the October sessions: the dominant feature was overheating at individual positions coinciding with heating cycles. Figure 5 shows the 72-hour profile.

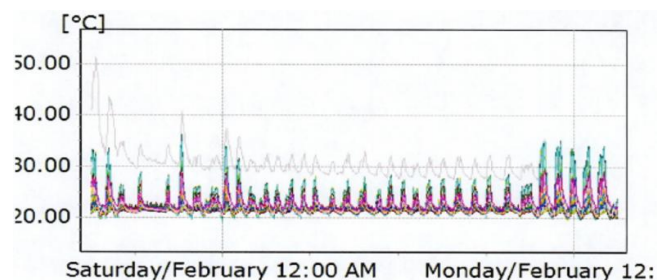


Figure 5. Temperature profile of the winter session, 23–26 February 2024 (63 channels)

Most channels occupy a 20–25 °C corridor with regular narrow peaks spaced about two hours apart; the peaks reach 30–35 °C on several channels, and the largest group occurs on the night of Sunday 25 to Monday 26 February, in the last hours of the session. One channel (light grey trace) behaves differently: it starts near 50 °C at the beginning of the session, falls to about 30 °C within a few hours and then runs at 28–32 °C with peaks up to about 38 °C. This channel was positioned in a hot zone next to a heat source. Its channel number, exact position, status as a storage or non-storage location, and the duration of its exposure above 30 °C could not be established from the records available for this paper. Two explanations are possible on the evidence of the chart alone: a position in the discharge of a heater, or a logger that was warm when deployed and equilibrated during the first hours. The initial monotonic decay from about 50 °C to 30 °C is compatible with either. The trace is therefore reported as an unexplained observation and is included in the limitations (Section 3.6). Figure 6 shows a four-channel detail of the same period in degrees Fahrenheit.

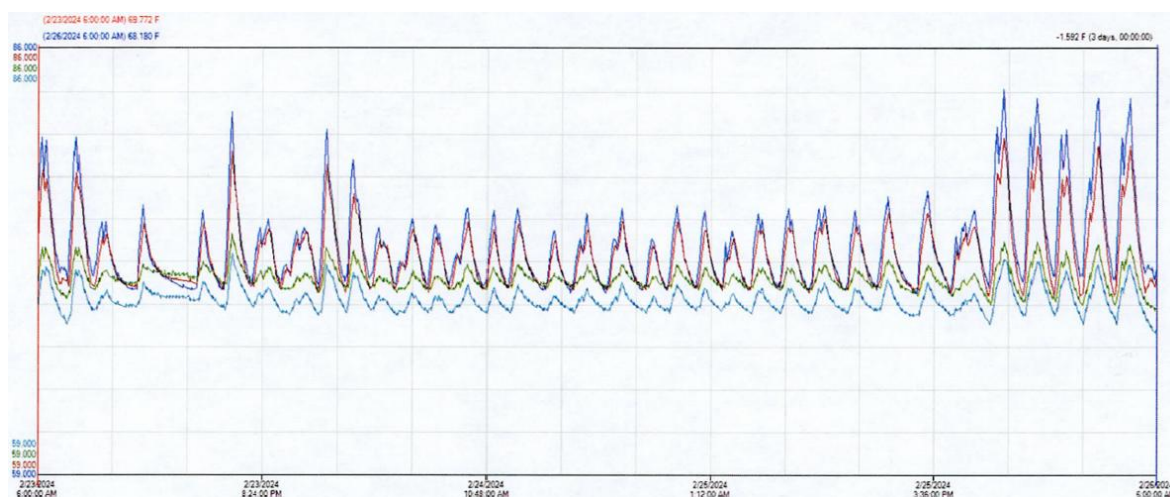


Figure 6. Four-channel detail of the winter session, 23–26 February 2024 (°F scale, 59–86 °F)

The detail plot shows the same rhythmic pattern. Two channels (blue and red) reach about 85 °F (29.4 °C) at each peak, whereas the other two (green and light blue) remain several degrees lower. The identity of the four channels is not stated in the source output and is not inferred here.

The pattern is consistent with convective heating: warm air from the heaters rises and creates a vertical gradient, so positions in the discharge path or under the roof are expected to see the largest peaks. Which rack levels recorded the winter peaks cannot be stated, because the channel-to-location link for the winter session is not available (Section 3.6). Under USP <659>, transient spikes up to 40 °C are permitted for CRT storage provided that they do not exceed 24 hours and that MKT does not exceed 25 °C; spikes above 40 °C are permitted only if the manufacturer so instructs [4]. The peaks of 30–35 °C in Figure 5 fall within this allowance. The grey-trace channel does not: its start above 40 °C and its sustained level of 28–32 °C place it outside the CRT definition unless it is confirmed to be a non-storage position. Independently of that question, regular exposure to peaks of 30–35 °C is undesirable, and corrective action such as destratification fans that return warm air to floor level is recommended; it would also reduce heat loss through the roof.

3.5. Compliance assessment via MKT and excursion analysis

MKT, Equation (1), was used to interpret readings outside the 20–25 °C target range. According to the site's validation record, the MKT computed by the software did not exceed 25 °C at the locations included in the acceptance assessment. The per-location values are not reproduced in this paper, so this statement is a reported outcome of the qualification and not a result that the reader can verify from the figures. It also cannot apply to the grey-trace channel of Section 3.4 if that channel was part of the assessment: a channel that runs at 28–32 °C for most of a 72-hour window has an MKT of about 30 °C by construction. Whether that channel was excluded from the assessment as a non-storage position is not documented in the records available, and the winter MKT statement is therefore limited to the storage-location channels.

Regulatory guidance is explicit that MKT cannot be used to compensate for excursions that breach a product's stability budget and must not mask systematic control problems [4], [7], [13], [14]. In this study MKT and the duration-based criterion of USP <659> (transient spikes of at most 40 °C for at most 24 hours) address different risks: MKT integrates the cumulative thermal history, while the duration criterion limits single events. The regular peaks above 30 °C in winter carry little weight in a 72-hour MKT, yet they indicate a

heating-control problem that MKT does not resolve; and the grey-trace channel cannot be evaluated at all without its time series.

Winter stratification also has an energy dimension: heat accumulated under the ceiling is ineffective for products on the lower levels and increases losses through the roof. Destratification and correct operation of the air curtains in the shipping zone would reduce the HVAC load and stabilize the temperature profile.

3.6. Limitations

The findings are subject to the following limitations. First, a single facility was studied, so the quantitative results are specific to its geometry, HVAC configuration and refrigeration equipment. Second, three 72-hour sessions were analysed, which is shorter than the seven-day minimum recommended by WHO for ambient warehouses [10]; the summer session performed at the site is not included. Third, the underlying time series, the per-channel statistics (including MKT and time above 25 °C and 30 °C) and high-resolution chart exports could not be released for publication; the analysis therefore relies on the summary outputs reproduced in Figures 2–6 and Table 3, and the only values read from the charts are the approximate peak heights, spacings and durations identified as such in the text. Fourth, the channel-to-location link for the winter session, the identity and storage status of the grey-trace channel, and the identity of the four channels in Figure 6 are not available in the published record. Fifth, the relation of the four heat-source refrigeration units to the 44-unit CTU farm interface is not documented, and no channel is recorded as positioned at the interface itself. Sixth, the facility floor plan is not reproduced. Conclusions about the influence of refrigeration equipment on the ambient zone and about the effect of loading are correspondingly qualitative.

4. CONCLUSION

This paper documents the temperature mapping of a 10,000-square-foot (930 m²) ambient pharmaceutical warehouse that contains refrigeration equipment and borders a 44-unit CTU farm, using 63 calibrated channels in three 72-hour sessions. In the empty session the mean over all channels was 21.87 °C and the reported extremes (18.65 °C on a wire-rack shelf, 27.58 °C on top of a refrigeration unit at 04:20) lay within the permitted 15–30 °C band. In the loaded session the sharp equipment-cycle peaks gave way to a slow diurnal wave with a few isolated peaks of about 30 °C on working days; per-channel extremes for this session were not released.

The winter session identified the main vulnerability of the present configuration: peaks of 30–35 °C at several positions coinciding with heating cycles, and one channel next to a heat source that started above 40 °C and ran at 28–32 °C thereafter. The cause, storage status and time series of that channel could not be established from the records available, so the compliance of the winter session is reported here only as the outcome recorded in the site qualification, limited to the storage-location channels.

The practical recommendations are to install destratification devices that remove the winter vertical gradient; to keep a buffer zone around heat-rejecting refrigeration units and the CTU farm interface in which thermolabile products are not stored, as a risk-based design measure; to place permanent monitoring points at the positions where the extremes were recorded and, on the basis of the stratification mechanism, at the upper rack levels; and to accompany every peak above 30 °C with a root-cause review instead of relying on MKT alone.

For other facilities that combine ambient storage with refrigeration equipment, the study offers a mapping configuration (a three-level grid at about 5.5 m spacing, co-location with the fixed probes and dedicated heat-source channels) that is consistent with the WHO spatial-grid recommendation, while its 72-hour duration is shorter than the recommended study duration. Longer sessions, mapping of both seasonal extremes, and publication of per-channel statistics would be needed to turn these observations into quantified benchmarks.

REFERENCES

- [1] D. Bhikadiya, “Pharmaceutical Quality Management Systems: A Comprehensive Review,” *African Journal of Biomedical Research*, vol. 27, no. 5S, pp. 644–653, Dec. 2024, doi: <https://doi.org/10.53555/ajbr.v27i5s.6519>.
- [2] J. Weitzel et al., “Understanding Quality Paradigm Shifts in the Evolving Pharmaceutical Landscape: Perspectives from the USP Quality Advisory Group,” *The AAPS Journal*, vol. 23, no. 6, Oct. 2021, doi: <https://doi.org/10.1208/s12248-021-00634-5>.
- [3] European Commission, “Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01),” *Official Journal of the European Union*, vol. 56, C 343, pp. 1–14, Nov. 2013.
- [4] United States Pharmacopeia, “〈659〉 Packaging and Storage Requirements,” in *USP–NF 2024*. Rockville, MD, USA: United States Pharmacopeial Convention, 2024.

- [5] S. Raj, G. Respicio, D. Zhang, D. Garcia, S. Malta, and H. Long, "Temperature Excursion Management: A Tier-Based Approach for Commercial Oral Solid Dosage Forms," *The AAPS Journal*, vol. 26, p. 108, Oct. 2024, doi: <https://doi.org/10.1208/s12248-024-00976-w>.
- [6] M. G. Şen and T. Başaran, "Experimental and numerical investigation of vertical temperature gradients in warehouses: Retrofit interventions to manage temperature-sensitive products," *Energy and Buildings*, vol. 332, p. 115456, Feb. 2025, doi: <https://doi.org/10.1016/j.enbuild.2025.115456>.
- [7] United States Pharmacopeia, "〈1079〉 Risks and Mitigation Strategies for the Storage and Transportation of Finished Drug Products," in *USP–NF 2024*. Rockville, MD, USA: United States Pharmacopeial Convention, 2024.
- [8] United States Pharmacopeia, "〈1079.4〉 Temperature Mapping for the Qualification of Storage Areas," in *USP–NF 2024*. Rockville, MD, USA: United States Pharmacopeial Convention, official May 2024, doi: https://doi.org/10.31003/USPNF_M16681_02_01.
- [9] World Health Organization, "Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products," in *WHO Expert Committee on Specifications for Pharmaceutical Preparations: Forty-fifth Report*, WHO Technical Report Series, no. 961, Annex 9. Geneva, Switzerland: WHO, 2011.
- [10] World Health Organization, "Temperature mapping of storage areas: Technical supplement to WHO Technical Report Series, No. 961, 2011, Annex 9," Geneva, Switzerland: WHO, May 2015.
- [11] International Society for Pharmaceutical Engineering, *ISPE Good Practice Guide: Cold Chain Management*. Tampa, FL, USA: ISPE, 2011.
- [12] Q. Chen, J. Qian, H. Yang, J. Li, X. Lin, and B. Wang, "Multiscale coupling analysis and modeling of airflow and heat transfer for warehouse-packaging-kiwifruit under forced-air cooling," *Biosystems Engineering*, vol. 244, pp. 166–176, Aug. 2024, doi: <https://doi.org/10.1016/j.biosystemseng.2024.06.007>.
- [13] D. Jenkins, A. Cancel, and T. Layloff, "Mean kinetic temperature evaluations through simulated temperature excursions and risk assessment with oral dosage usage for health programs," *BMC Public Health*, vol. 22, p. 300, Feb. 2022, doi: <https://doi.org/10.1186/s12889-022-12660-9>.
- [14] E. Miura, "Use of Mean Kinetic Temperature for Pharmaceuticals in Japan and Stability Monitoring in the 21st Century," *Therapeutic Innovation & Regulatory Science*, vol. 58, pp. 184–191, Oct. 2023, doi: <https://doi.org/10.1007/s43441-023-00584-4>.
- [15] United States Pharmacopeia, "〈1150〉 Pharmaceutical Stability," in *USP–NF 2024*. Rockville, MD, USA: United States Pharmacopeial Convention, 2024.
- [16] International Council for Harmonisation, "Stability Testing of New Drug Substances and Products Q1A(R2)," *ICH Harmonised Tripartite Guideline*, Feb. 2003.

BIOGRAPHY OF AUTHORS



Prasantha Pujari is a dedicated pharmaceutical validation engineer with extensive hands-on experience in GMP-compliant manufacturing environments, where he specializes in performing Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) for critical equipment, utilities, and controlled storage systems. His expertise centers on implementing risk-based validation strategies that ensure full alignment with FDA, EMA, and international regulatory expectations, while consistently supporting the preparation of audit-ready documentation and inspection readiness. Throughout his career, Prasantha has maintained a strong focus on data integrity and the lifecycle management of validated systems, developing robust approaches that proactively mitigate risks to product quality and patient safety. His technical interests include advancing validation science through applied research, particularly in the thermal qualification of controlled environments. Prasantha has authored original studies exploring temperature mapping and thermal stratification challenges in ambient pharmaceutical warehouses influenced by localized heat sources from controlled temperature units (CTUs). By addressing these real-world issues, his work contributes practical engineering solutions that enhance compliance, reduce temperature excursions, and improve overall stability in regulated pharmaceutical storage settings. He remains actively engaged in technical writing and knowledge dissemination to bridge regulatory requirements with innovative validation practices in the biopharmaceutical industry.