

20-MINUTE COMPLIANCE CHECK

Temperature compliance report

Corrbrack Pharma Distribution Ltd (example)

HPRA GDP

PREPARED FOR

Siobhán Delahunt
Corrbrack Pharma Distribution Ltd (example)

SCOPE

Good Distribution Practice for medicines in Ireland (HPRA WDA holders)

PREPARED BY

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JTF Wireless · 19 October 2026

BASIS

What you told us on the call. We have not inspected your records.

SUMMARY

Your temperature controls need focused work before the HPRA inspection.

42%

overall, across 25 questions
answered

20

gaps to close

2

answers nobody could confirm

Your check scored 42%. You already have a review process and some monitoring in place, but several controls need attention before next year's inspection.

The Responsible Person reviews records quarterly rather than monthly, the alarms have not been tested since installation, and the courier agreement does not require excursion reports.

Your top three risks

1. **RP reviews are too far apart** **Not met**
2. **Alarm response remains untested** **Not met**
3. **Courier excursions may go unreported** **Not met**

YOUR SCORE

By section

SECTION		SCORE	MET	PARTLY	NOT MET	NOT KNOWN
Records and review		40%	1	2	2	0
Alarms and out of hours		25%	0	2	2	0
Calibration and traceability		33%	0	2	0	1
Excursions and CAPA		83%	2	1	0	0
Mapping and qualification		30%	0	3	2	0
Data integrity		50%	1	0	0	1
Training		50%	0	1	0	0
Documentation		50%	1	0	1	0

By regime

Each answer counts for every regime it applies to, so you were asked each question once.

REGIME		SCORE	QUESTIONS
HPRA GDP		42%	25
Good Distribution Practice for medicines in Ireland (HPRA WDA holders)			

Why they matter

RP reviews are too far apart Not met

The HPRA expects a recorded monthly review by the Responsible Person. Your quarterly review shows a process exists, but it does not yet provide the monthly evidence an inspector will ask to see.

HPRA GDP IA-G0011 sections 3.2, 3.3, 3.4 and 4: Records checked daily and independently reviewed (for ambient storage, reviewed and approved) monthly by the Responsible Person, with a record of the review; a longer interval only with documented rationale where alarms notify out of hours.

HPRA GDP IA-G0011 section 8: All records reviewed, and the review recorded.

Alarm response remains untested Not met

The alarms have not been checked since installation, so you cannot yet show that an alert reaches the right person. Frequent alarms during picking are being muted; a safe, recorded end-to-end test should check the set points and response without putting stock out of range.

HPRA GDP IA-G0011 section 10: Alarms regularly checked for functionality at the designated set points, in a way that does not subject products to out-of-specification temperatures; records maintained.

HPRA GDP EU GDP 3.3: Alarms regularly tested for adequate functionality.

Courier excursions may go unreported Not met

The courier agreement does not require excursion reporting, and courier deliveries are not monitored. Without a reporting obligation, you may not learn of a temperature event affecting deliveries to Cork or Galway, leaving you unable to assess it.

HPRA GDP IA-G0046 chapters 1 and 9: Technical agreements describe GDP roles, including transport and the management of deviations; transport arrangements set out in a service level agreement, with subcontracting.

HPRA GDP HPRA Medicinal Products Newsletter 73 (February 2023): Technical agreements were found deficient where they did not require temperature excursions to be reported.

What the rules ask

GAP	ANSWER	REGULATION AND SOURCE
Are temperature records checked daily and independently reviewed and approved by the Responsible Person every month, with each review recorded? You said: The RP reviews the records quarterly	Not met	HPRA GDP IA-G0011 sections 3.2, 3.3, 3.4 and 4: Records checked daily and independently reviewed (for ambient storage, reviewed and approved) monthly by the Responsible Person, with a record of the review; a longer interval only with documented rationale where alarms notify out of hours. Source HPRA GDP IA-G0011 section 8: All records reviewed, and the review recorded. Source
Are alarms regularly checked for functionality at their set points, through to the person alerted, without taking product out of specification, with records kept? You said: Not checked since installation	Not met	HPRA GDP IA-G0011 section 10: Alarms regularly checked for functionality at the designated set points, in a way that does not subject products to out-of-specification temperatures; records maintained. Source HPRA GDP EU GDP 3.3: Alarms regularly tested for adequate functionality. Source
Do your agreements with carriers, storage providers and other contractors set temperature responsibilities and require them to report excursions to you, and are they audited? You said: Courier agreement has no excursion reporting clause	Not met	HPRA GDP IA-G0046 chapters 1 and 9: Technical agreements describe GDP roles, including transport and the management of deviations; transport arrangements set out in a service level agreement, with subcontracting. Source HPRA GDP HPRA Medicinal Products Newsletter 73 (February 2023): Technical agreements were found deficient where they did not require temperature excursions to be reported. Source
Is every alarm delay set and justified from data: long enough that door openings and blips do not trigger it, short enough to catch a real failure? You said: Cold room alarm has no delay and sounds at most picks; staff mute it	Not met	HPRA GDP IA-G0011 section 10: Probes sit in a suitable load simulator so that transient rises, such as doors opened during picking, do not trigger alarms. Source
Is there a written trigger to re-map after changes, and a risk-based interval for re-mapping? You said: No trigger; warehouse heating changed last year without re-mapping	Not met	HPRA GDP IA-G0011 sections 3.2, 3.3 and 4: Re-map after repair or replacement of the refrigeration unit, layout or set-point changes, changes to duty and back-up condensers, premises or heating changes; moving a fridge may need it. Source
Is the monitoring independent of each unit's own controller, with its own sensor rather than the fridge's display or control probe? You said: Cold room recorded from the refrigeration controller's own probe	Not met	HPRA GDP IA-G0011 section 3.1: Recording probes should be independent of controlling probes, and placed where mapping found the greatest temperature variability. Source

Has each transport route been risk-assessed, and each van or shipper validated for it, covering summer and winter, the longest route and door openings? You said: No route risk assessment; the shipper was qualified in a chamber only	Not met	HPRA GDP IA-G0011 section 3.5: Insulated containers qualified under actual transport conditions to the furthest delivery point, for seasonal extremes, full and empty and door openings; chamber studies alone are not considered reflective; refrigerated vehicles validated and mapped. Source
Does the monitoring alarm immediately to the right people, with alert limits set so action can be taken before an excursion and action limits for the excursion itself? You said: One alarm at 8 °C; no early alert	Partly	HPRA GDP IA-G0011 section 10: Monitoring systems alarm to notify relevant personnel immediately; set points may contain alert and action limits, with alert limits set so preventive action can be completed before an excursion. Source HPRA GDP EU GDP 3.3: Alarms alert to excursions from pre-defined storage conditions, with levels set appropriately. Source
Is every recording probe accurate to ± 0.5 °C or better and calibrated at least annually, at three or more points across its range, on the entire monitoring system, with auxiliary probes covering the store meanwhile? You said: Annual, but one point at 5 °C and the receiver not included	Partly	HPRA GDP IA-G0011 section 7: Probes calibrated at least annually against a traceable reference, at three or more points across their range, on the entire monitoring system (probes, receiver box, display), with the method stated and auxiliary probes in place during calibration. Source HPRA GDP IA-G0011 section 3.3: Temperature recording probes accurate to at least ± 0.5 °C. Source
For each excursion, is the impact assessed from the start, peak and duration, and the decision on the stock recorded by the right person with the evidence they used? You said: Rises under 10 minutes are not raised as excursions	Partly	HPRA GDP IA-G0011 section 6: An excursion is any deviation from labelled conditions for any duration; the manufacturer or MA holder is consulted on quality impact and the outcome documented. Source
Is there out-of-hours provision for alarms, with named alarm nominees trained in what to do and the actions described in a procedure? You said: Calls the warehouse manager only; no second nominee or training record	Partly	HPRA GDP IA-G0011 section 10: Provision made for an out-of-hours response; alarm nominees trained in the actions they may take, with the actions, alarms and set points described in a procedure. Source
Has each storage area been mapped under representative conditions, and is each monitoring probe's position justified from that mapping? You said: Cold room mapped on installation; its probe sits by the door	Partly	HPRA GDP IA-G0046 chapter 5 and IA-G0011 section 3.1: Mapping performed and documented for areas over a few square metres; recording probes placed at the greatest variability the mapping found, in every storage area. Source
How are temperatures recorded: continuously, including nights and weekends, or at manual checks only? You said: Cold room continuous; ambient loggers downloaded weekly	Partly	HPRA GDP IA-G0011 sections 3.4 and 4: A continuous temperature monitoring system is required for the storage of medicinal products, at the locations found by mapping. Source

Are storage conditions held and recorded on every delivery, with calibrated loggers, and are transport excursions reported and investigated?

You said: Own vans logged; courier deliveries not monitored

Partly

HPRA GDP IA-G0011 sections 3.5.2 and 4: Loads at risk of freezing monitored with calibrated data loggers; a procedure for corrective action when goods were transported outside their conditions. [Source](#)

Does each person have their own login, can only authorised people change data or settings, and does the system keep an audit trail that is reviewed?

You said: Not sure whether the audit trail can be switched off

Not known

HPRA GDP EU GDP 3.3.1 and IA-G0046 chapter 4: Only authorised people enter or change data; the HPRA points to EU GMP Annex 11 for computerised systems. [Source](#)

Have warehouses been mapped empty and full, in summer and in winter, and cold rooms and large fridges mapped on installation empty and full with an ambient probe outside?

You said: Warehouse mapped in winter only

Partly

HPRA GDP IA-G0011 section 4: Warehouses mapped in the empty and full states, in both summer and winter, to assess worst-case conditions; areas such as skylights and controlled drug storage included. [Source](#)

HPRA GDP IA-G0011 section 3.3: Large refrigerators and walk-in cold rooms mapped on installation, empty and full, with an ambient probe outside the unit. [Source](#)

Is each calibration certificate matched to its sensor's serial number, reviewed against your own acceptance criteria and signed off by you, with due dates tracked?

You said: Certificates filed but not reviewed or signed

Partly

HPRA GDP IA-G0011 section 7 and IA-G0046 chapter 5: All calibration certificates reviewed and approved by the wholesaler to confirm the results are acceptable, with the review documented. [Source](#)

How long are temperature records kept, is that the longest period any rule or customer agreement asks for, and how quickly can you pull up a given week?

You said: Kept 5 years; two customer quality agreements ask for 15

Partly

HPRA GDP S.I. No. 538/2007, Schedule 2, paras 8(1) and 13: Records kept available for inspection for not less than five years, and the EU GDP guidelines (at least five years) followed. [Source](#)

Are the people who record readings and respond to alarms trained for it, with the training recorded?

You said: Drivers not trained on the temperature procedures

Partly

HPRA GDP IA-G0011 section 9: Training for all staff in storage and distribution, delivery drivers included, covering this guide, with records for each employee. [Source](#)

When a calibration result is outside your acceptance criterion, is the effect on readings since the last good calibration assessed and recorded?

Not known

HPRA GDP IA-G0011 section 7: If a probe fails calibration, the possible impact on previous readings is reviewed. [Source](#)

What to do, in order

Quick wins

1. Set a monthly RP review date and record each review and approval. Keep the existing record checks visible alongside it.
2. Write a safe alarm-test procedure covering the set points, the person alerted and the response. Record the test without taking stock out of specification.
3. Log alarms during picking and when they are muted. Use the data to justify an alarm delay that filters door openings but still catches a real failure.
4. Ask the courier to agree in writing how and when it will report temperature excursions. Set an interim contact and escalation procedure while the agreement is updated.
5. Stop routine deletion of temperature records while you check retention periods. Two customer quality agreements require 15 years, while records are currently kept for 5 years.

Bigger changes

1. Review continuous monitoring and alarm arrangements, including an independent cold-room sensor, early alerts and out-of-hours response.
2. Plan representative summer and winter mapping, including empty and full conditions. Set written triggers to re-map after changes such as the warehouse heating change.
3. Bring calibration across the recording system into line with the stated requirements, with certificates checked against sensor IDs and signed off.
4. Risk-assess delivery routes and validate the vans or shippers for the conditions they face, rather than relying only on chamber qualification.

1 question was not covered this time; we will pick it up with you.

If you want a hand closing the gaps

JTF provides temperature mapping alongside monitoring and calibration. That combination is relevant to your seasonal mapping, probe-position and monitoring gaps.

JTF offers accredited calibration for every sensor it supplies: temperature in its UKAS lab (10723), CO₂, humidity and others through accredited partners.

Next steps with us

If useful, we can arrange a follow-up call to work through the alarm-test plan and seasonal mapping scope. We can discuss a site visit or a quote if you want one.

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SOURCES

HPRA GDP	HPRA IA-G0011-3: Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medicinal Products and Active Substances https://assets.hpra.ie/data/docs/default-source/external-guidance-document/ia-g0011-guide-to-control-and-monitoring-of-storage-and-transportation-conditions-v3.pdf?sfvrsn=25081551_6
HPRA GDP	HPRA IA-G0046-8: Guide to Good Distribution Practice of Medicinal Products for Human Use https://assets.hpra.ie/data/docs/default-source/external-guidance-document/ia-g0046-guide-to-good-distribution-practice-of-medicinal-products-for-human-use-v8.pdf?sfvrsn=f185f63b_18
HPRA GDP	EU Guidelines on Good Distribution Practice of medicinal products for human use (2013/C 343/01) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013XC1123(01)
HPRA GDP	S.I. No. 538 of 2007, Medicinal Products (Control of Wholesale Distribution) Regulations 2007, as amended https://www.irishstatutebook.ie/eli/2007/si/538/made/en/print

This report summarises what you told us against the published requirements above. It is not an audit or legal advice, and the source documents are what your inspector or auditor works from. Example report: the organisation, people and findings are illustrative.