

20-MINUTE COMPLIANCE CHECK

Temperature compliance report

Brindlecombe Pharma Distribution (example)

MHRA GDP

PREPARED FOR

Priya Lomax
Brindlecombe Pharma Distribution (example)

SCOPE

Good Distribution Practice for medicines (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 records are relatively strong, but alarm gaps leave overnight temperature failures hard to catch.

48%

overall, across 24 questions
answered

17

gaps to close

2

answers nobody could confirm

Records, calibration and excursion procedures are relatively strong.

Loggers record continuously, but they are downloaded weekly and have no live alarm. An overnight failure could go unnoticed until the next download.

Your top three risks

1. No live temperature alert **Not met**
2. Nobody alerted overnight **Not met**
3. Alarm path not demonstrated **Not met**

YOUR SCORE

By section

SECTION		SCORE	MET	PARTLY	NOT MET	NOT KNOWN
Records and review		75%	2	2	0	0
Alarms and out of hours		10%	0	1	3	1
Calibration and traceability		75%	1	1	0	0
Excursions and CAPA		88%	3	1	0	0
Mapping and qualification		38%	0	3	1	0
Data integrity		0%	0	0	1	1
Training		100%	1	0	0	0
Documentation		25%	0	1	1	0

By regime

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

REGIME		SCORE	QUESTIONS
MHRA GDP		48%	24
Good Distribution Practice for medicines (WDA holders)			

Why they matter

No live temperature alert Not met

Your loggers have no live alarm, so an excursion may only be discovered when the weekly download is reviewed. By then, stock may already have been affected.

MHRA GDP EU GDP 3.3: Alarms alert to excursions from pre-defined storage conditions, with levels set appropriately.

Nobody alerted overnight Not met

Nobody is currently alerted out of hours. That leaves the overnight failure you are worried about without someone prompted to respond.

MHRA GDP EU GDP 3.3: Alarms alert to excursions from storage conditions.

Alarm path not demonstrated Not met

Alarm testing was raised at your last inspection. Testing needs to show that an alert reaches the person on call and is escalated if they do not respond, not just that a sounder works.

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

What the rules ask

GAP	ANSWER	REGULATION AND SOURCE
Does every unit have alarm limits set just inside its range, so a named person is told before the stock goes out? You said: Loggers have no live alarm	Not met	MHRA GDP EU GDP 3.3: Alarms alert to excursions from pre-defined storage conditions, with levels set appropriately. Source
Who is alerted out of hours, how, and what happens if they do not acknowledge in time? You said: Nobody is alerted out of hours	Not met	MHRA GDP EU GDP 3.3: Alarms alert to excursions from storage conditions. Source
Are the alarms tested end to end, from the sensor at its set points to the person on call and the escalation, on a set cycle and after changes, with each test recorded? You said: Raised at the last inspection	Not met	MHRA GDP EU GDP 3.3: Alarms regularly tested for adequate functionality. Source
Has the monitoring system been validated for its use, and is there a written description of it? You said: No validation pack for the logger software	Not met	MHRA GDP EU GDP 3.3.1: Computerised systems validated before use, with a written description. Source
Is there a written trigger to re-map after changes, and a risk-based interval for re-mapping? You said: No written trigger; the racking change was not assessed	Not met	MHRA GDP EU GDP 3.2.1: Repeat mapping per risk assessment or after significant modifications. 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	MHRA GDP EU GDP chapter 7 and 9.2: A written contract sets each party's duties; the contract giver assesses and audits the contractor; transport providers report excursions. 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 in 2021, racking changed since	Partly	MHRA GDP EU GDP 3.2.1: Initial mapping before use under representative conditions; monitoring devices at the extremes of fluctuation. Source MHRA GDP MHRA Inspectorate blog, temperature mapping (2016): Permanent probe positions cover the widest fluctuations or hot and cold spots, justified by the mapping risk assessment. Source
For each alarm, is there a record of who acknowledged it, when, and what they did? You said: Notebook in the warehouse office	Partly	MHRA GDP EU GDP 9.2: Excursions reported and handled by procedure. 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: Duration is hard to establish from weekly downloads

Partly

MHRA GDP EU GDP chapter 2 and 9.2: The Responsible Person's duties include decisions on returned and affected stock. [Source](#)

How are temperatures recorded: continuously, including nights and weekends, or at manual checks only?

You said: Loggers record continuously but are only downloaded on Mondays

Partly

MHRA GDP EU GDP 3.2.1 and 3.3: Storage conditions monitored and recorded, with monitoring equipment placed by the mapping; alarms alert to excursions. [Source](#)

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

You said: Vans have loggers, read only on return

Partly

MHRA GDP EU GDP 9.2: Storage conditions maintained in transport; monitoring equipment calibrated at least yearly; excursions reported and investigated. [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?

Not known

MHRA GDP EU GDP 3.3.1: Only authorised people enter or change data; data protected. [Source](#)
MHRA GDP EU GMP Annex 11, sections 9 and 12: Audit trails and access security for computerised systems. [Source](#)
MHRA GDP MHRA GxP data integrity guidance (2018), 6.13 and 6.16: Data attributable, legible, contemporaneous, original and accurate; no shared logins; audit trails on and reviewed. [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: No live alarms yet, so no delays have been worked out

Not known

MHRA GDP MHRA Inspectorate blog, reply of 3 August 2018: Monitoring systems are typically set with a small alarm delay, based on risk assessment and confirmed by validation. [Source](#)

Are the records reviewed and signed off at a set frequency, showing who reviewed them, when, and whether any issue was found?

You said: Reviewed weekly, sign-off not consistent

Partly

MHRA GDP Chapter 4: Documentation and records kept and reviewable. [Source](#)
MHRA GDP MHRA GxP data integrity guidance, 6.15: Data review documented with a positive statement of whether issues were found, the date and the reviewer's signature. [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: Route risk assessment from 2019; vans not checked in summer

Partly

MHRA GDP EU GDP 9.2: A risk-based approach used when planning transport routes; controls set where the risk assessment shows they are needed. [Source](#)
MHRA GDP MHRA Inspectorate blog, transport risks (2020): Vehicle type, season and route assessed as transport risks, with interim controls while fleets are replaced. [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: Two loggers swapped without updating the register

Partly

MHRA GDP EU GDP 3.3: Records of calibration kept. [Source](#)

Are monitoring, alarm, calibration and excursion procedures written down, version-controlled and current?

You said: SOP names the previous logger model

Partly

MHRA GDP EU GDP chapter 4: Written procedures; documentation controlled. [Source](#)

What to do, in order

Quick wins

1. Set a temporary checking rota for nights and weekends, with a named person to review readings and act on concerns.
2. Write down who responds to a temperature concern, who covers their absence and when it is escalated.
3. Record each check and response, including who reviewed it, when and what they did.
4. Review the cold-room racking change against the existing mapping study and probe positions. Record whether the evidence still supports them before deciding if another study is needed.
5. Update the logger register for the swapped units and check that each certificate matches the sensor in use.

Bigger changes

1. Add live alarms to the existing continuous recording, with appropriate limits and a named out-of-hours escalation path.
2. Set a recorded cycle for testing the full alarm path, including delivery, acknowledgement and escalation, and repeat tests after changes.
3. Assess whether the racking change affects cold-room mapping. Arrange further mapping if the existing evidence no longer supports the probe positions.
4. Validate the logger software for its intended use and keep a written description of the monitoring system.

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 could help you assess the cold-room evidence while you address the monitoring gaps.

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

Next steps with us

If useful, we can talk through the alarm priorities and the racking change on a follow-up call or site visit. You can ask for a quote if you want one.

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SOURCES

MHRA GDP	EU Guidelines on Good Distribution Practice of medicinal products for human use (2013/C 343/01), applied in Great Britain by the MHRA https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013XC1123(01)
MHRA GDP	MHRA: Good manufacturing practice and good distribution practice https://www.gov.uk/guidance/good-manufacturing-practice-and-good-distribution-practice
MHRA GDP	The Human Medicines Regulations 2012, regulation 43 https://www.legislation.gov.uk/uksi/2012/1916/regulation/43

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