



Medicines & Healthcare products  
Regulatory Agency

**GDP INSPECTION REPORT**

**WDA(H) 58094/33378105**

**PHARMAETHICAL LTD**

**ISSUED BY:**

**[REDACTED]**  
**GDP Inspector**

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File Ref: Insp GDP 58094/33378105-0003  
Inspection Date: 22/05/2025  
Company: PHARMAETHICAL LTD

GDP Inspection Report

<b>1. Report Reference no.:</b>	Insp GDP 58094/33378105-0003
<b>2. Inspected site(s) and contact details:</b>	PHARMAETHICAL LTD WORKSHOP 4 MAIDSTONE INNOVATION CENTRE GIDDS POND WAY WEAVERING MAIDSTONE ME14 5FY UNITED KINGDOM
<b>3. Inspector(s):</b>	<b>Name(s) of the Inspector(s).</b> [REDACTED]  MHRA
<b>4. Business Model:</b>	Wholesaling activities had not commenced at the time of inspection. The intended business model remained unchanged since initial inspection with proposed to hospitals, pharmacies, and care facilities.  The proposed suppliers included mainline wholesalers. Transport arrangements had been outsourced to [REDACTED]
<b>5. Scope of Inspection:</b>	<b>Major changes since the previous inspection not submitted through licence variation:</b> Variation to replace [REDACTED] with [REDACTED] as Responsible Person. [REDACTED] the previous RP left [REDACTED] in February 2025. [REDACTED] nominated shortly after.
<b>6. Activities not inspected:</b>	Routine inspection assessing compliance with the Guidelines of 5 November 2013 on Good Distribution Practice of Medicinal Products for Human Use and the Human Medicines Regulations 2012.  Due to the inactive trading status of the company the following activities have not been reviewed as part of this inspection: <ul style="list-style-type: none"><li>• Operations: transaction audit; customer and supplier qualification records;</li><li>• Transport KPIs</li><li>• Chapter 6 activities</li></ul>
<b>7. Personnel met during the inspection:</b>	



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■ [REDACTED]
■ [REDACTED]
■ [REDACTED]

**8. Inspectors findings and observations relevant to the inspection and deficiencies:**

A suitably detailed quality management system (QMS) was maintained by the nominated RP. There was evidence of ongoing activities to review and update the QMS as needed.

- a. Deviations raised: none since last inspection.
- b. CAPA records raised
- c. Change records raised and reviewed as follows:
  - i. [REDACTED] raised 12.03..2025 for the change of RP- the relevant change control form was available for review. The form referred to a handover from the previous RP as completed on 30/03/2025, however a handover had never been completed. RP demonstrated good knowledge of ALCOA principles so importance of data integrity was highlighted. Supporting documentation was available. A QTA with the RP had been prepared, even though the RP was a company employee. The QTA in place for the employee RP was not considered to be appropriate and it included references that were not relevant to the scope of the licence.
  - ii. [REDACTED] raised 07.05.2025 for the implementation of an eQMS, [REDACTED] with a target implementation date in October 2025. The change record documented took into consideration all relevant aspects of the change. The record did not explicitly state an action to conduct independent validation, however there was an action pertaining to "IQ, OQ, and PQ validation" (implementation qualification, operational qualification, and performance qualification).
- d. Self-inspection: last conducted in February 2025 by [REDACTED]. A self-inspection schedule was in place and considered reflective of the business model. There was evidence of change records raised to manage follow-up actions from the self-inspection.

The QMS broadly covered all relevant areas of GDP.

The company had 4 employees in total. The RP was working on part-time basis with 1 day/week committed to the licence and at least 1 visit to site per month.

The premises comprised of a rented unit which housed both the wholesale side of the business and an online pharmacy. There was a clear distinction between both parts of the business with clear labelling. Temperature monitoring and control arrangements were considered suitable. Security arrangements in place were acceptable.

There were no changes to the proposed transport arrangements. A review of key performance indicators for the outsourced transport activities was not conducted due to the inactive trading status of the company. Transport should be reviewed upon further inspections.



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**9. Recommendations:**

*\*Your application for variation to a wholesale dealer's authorisation granted pursuant to Regulation 18 of the Human Medicines Regulations 2012 (a "wholesale dealer's licence") will be recommended to the licensing authority.*

*\*Continued support of your wholesale dealer's authorisation) pursuant to Regulation 18 of the Human Medicines Regulations 2012 (a "wholesale dealer's licence") will be recommended to the licensing authority.*

*Site and authorisation pursuant to Regulation 18 of the Human Medicines Regulations 2012 (a "wholesale dealer's licence") will next be inspected as part of the MHRA's risk-based inspection programme, the frequency of inspection being determined by the nature of the activities the licence holder undertakes and previous compliance history. The risk profile of a company may change over time and consequently provisional re-inspection dates given in this report may change".*

The provisional date for the next inspection of this site is 22/05/2028

**10. Summary and conclusions:**

Within the scope of the inspection, the company operates in accordance with the principles of good distribution practice referred to in regulation C17 of the Human Medicines Regulations 2012.

The GDP certificate reflects the status of the inspected site at the time of the inspection noted above. Inspections of other sites that are named on the licence may cause this certificate to be withdrawn if Regulatory action against the licence is taken by the Licensing Authority.

**11. The inspection report should be signed and dated by the Lead Inspector:**

**Name of lead inspector:**

**Organisation:**

MHRA

**Date:** 21/07/2025

Distribution of Report: