



**GDP INSPECTION REPORT**

**WDA(H) 5827/34897770**

**NORDIC PHARMA LIMITED**

**ISSUED BY:**

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

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File Ref: Insp GDP 5827/34897770-0002  
Inspection Date: 07/10/2025  
Company: NORDIC PHARMA LIMITED

### GDP Inspection Report

<b>1. Report Reference no.:</b>	Insp GDP 5827/34897770-0002
<b>2. Inspected site(s) and contact details:</b>	NORDIC PHARMA LIMITED BUILDING 1410 ARLINGTON BUSINESS PARK THEALE READING RG7 4SA UNITED KINGDOM
<b>3. Authorised operations:</b>	<input checked="" type="checkbox"/> Procurement <input type="checkbox"/> Holding <input checked="" type="checkbox"/> Supply <input checked="" type="checkbox"/> Export <input checked="" type="checkbox"/> Products imported from countries on a list <input checked="" type="checkbox"/> Products certified under Article 51 of Directive 2001/83/EC <input type="checkbox"/> Products not certified under Article 51 of Directive 2001/83/EC <input type="checkbox"/> Other activities: (please specify)
<b>4. Inspection date(s):</b>	07/10/2025
<b>5. Inspector(s):</b>	Name(s) of the Inspector(s).  ██████████  MHRA
<b>6. References:</b>	Wholesale Distribution Authorisation Number or Registration Number of Broker: WDA(H) 5827



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## 7. Introduction:

### **Business Background**

Nordic Pharma Limited (NPL) was the UK affiliate of Nordic Group B.V.. It acted as a marketing authorisation holder, and distributed medicines on behalf of Nordic Group B.V. and other partners within the company group. The group comprised of Sever, Esperante and Draupner that specialised in repurposed products that were provided to Nordic Pharma for commercialisation. [REDACTED]

### **Review of WDA(H)**

#### **MEDICINAL PRODUCTS**

##### **P, POM**

- With "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)
- Without "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in GB or EEA and intended for the UK market
- Without "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in the UK and not intended for the UK market
- With a Marketing Authorisation in EEA member state(s) and intended for the GB parallel import market

##### **Medicinal products with additional requirements**

- Narcotic or psychotropic products
- Medicinal products derived from blood
- Immunological medicinal products
- Radiopharmaceuticals (including radionuclide kits)
- Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)
- Medicinal gases
- Cold chain products (requiring low temperature handling)
- Other products

##### **Date of previous inspection:**

Name(s) of Inspector(s) involved in previous inspection: [REDACTED]

Date of last inspection: 07/03/2023

##### **Overview of inspection findings from last inspection and the corrective action taken:**

Satisfactory



File Ref: Insp GDP 5827/34897770-0002  
 Inspection Date: 07/10/2025  
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<b>8. Scope of Inspection:</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 and review of variation to add [REDACTED] as additional Responsible Person
<b>9. Inspected activities:</b>
GDP Inspection of GDP activities, operations, records and documentation under the licence pertaining to this site: procurement, supply and export.
<b>10. Activities not inspected:</b>
<b>11. Personnel met during the inspection:</b>
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
<b>12. Inspectors findings and observations relevant to the inspection and deficiencies:</b>

- Quality Management**

Nordic Pharma Limited operated a GDP quality system that was managed alongside the national and company-wide quality system but with clear autonomy. The UK quality system had been reviewed and integrated into a single UK quality system. Processes for quality management and operations were clearly reflected within operating procedures.

The General Manager fulfilled the role of Licence Holder, and had direct line management authority over finance, commercial, marketing, regulatory and quality functions, and oversight and indirect management of supply chain and the Responsible Persons. She reported to the corporate directorate and also had communication links to the EU/UK QPPv.

Quality risk management was described within operating procedure for Change Control, [REDACTED] version [REDACTED]. This did not include specific or general definitions of occurrence, severity or risk with the consequence that these terms could be interpreted incorrectly when compared to different application of the same terms. Risks were tracked in a risk log and were generally raised in association with a quality event such as a deviation. An over-arching risk assessment was in place that described risks associated with exportation. Assessments reviewed contained appropriate level of detail.

The change control process was not adequately applied to the change in business model to distribute unlicensed medicines with the consequence that separate associated change controls (e.g. [REDACTED] and [REDACTED]) were not cross-referenced or coordinated and the underlying core change identified.

Deviations were reviewed. There was no deviation or CAPA raised to provide an appropriate record and assessment of mitigation for cancellation of [REDACTED]

- Personnel**

Organisational structure / number of staff / reporting / arrangements for deputising



**File Ref:** Insp GDP 5827/34897770-0002  
**Inspection Date:** 07/10/2025  
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Approximately twenty staff were in place with roles described within job descriptions and reflected in an organisational chart. In addition, [REDACTED] vacancies were in place of which [REDACTED] were within the Ophthalmology Business stream.

A matrix described the delegated duties associated with the Responsible Person. Opportunities existed for providing clearer description of the responsibilities and duties of the Licence Holder.

All staff interviewed demonstrated competence and knowledge in their roles and in Good Distribution Practice.

- **Premises and Equipment**

The company operated as a virtual wholesaler. Premises were a shared office building that afforded access restricted to authorised persons only.

- **Documentation**

Documents were readily available in electronic format. Spreadsheets were used to record and track quality events such as risk assessments. Quality system records and other documents were maintained in [REDACTED] that enabled restricted access. Quality complaints were either managed on [REDACTED] or within spreadsheets in [REDACTED] depending on the MAH.

A portal to the pre-wholesaler [REDACTED] provided access to stock records and APIs.

- **Operations**

Nordic Pharma Limited operated as a virtual wholesaler with storage and supply outsourced to [REDACTED]. Stock was sourced from the parent company and imported using the RPI process. [REDACTED] KPI were reported on the portal.

Stock was procured using [REDACTED] accounting software, and stock levels maintained against projected demands.

A variety of export transactions were reviewed. There was lack of evidence to demonstrate that checks of UK sanctions against countries, companies or individuals had taken place. Country profile documents described the best and worst months to ship. A consignment of [REDACTED] supplied as humanitarian aid to [REDACTED] was reviewed. This was sourced from [REDACTED] and facilitated by [REDACTED] in [REDACTED]. Documents of import into [REDACTED] were presented in Hebrew and had not been translated. Documentation was not complete including C88s, and bona fide check of the [REDACTED] customer.

Sales were monitored with EU affiliates reporting monthly sales and shortages. Stock counts carried out for each sku routinely and could be reviewed as live records via the NPL portal of [REDACTED] stock inventory. There had been no known stock adjustments of inventory. Unusual sales patterns were monitored. There were no medicines deemed to be of high diversion risk.

At the time of inspection, no medicines were in short supply. [REDACTED] had recently been in short supply and was reported to the Department of Health. This led to section 1.2 being added to the WDA(H) on 29/08/2024 together with a request to the MHRA to import as an unlicensed medicine. The import was to be from [REDACTED] and the shortage due to an interruption in manufacturing that led to lack of expected availability of several months.

- **Complaints, Returns, Suspected Falsified Medicinal Products and Recalls**

Product quality complaints were referred to the EU/UK QPPv. Two processes were in place, one related to where Nordic Pharma was the MAH, and a separate process where the MAH was not Nordic Pharma. The former were managed locally within a spreadsheet and forms, whereas where Nordic Pharma was not the MAH, complaints were logged in [REDACTED] cloud-based database.

Management of product quality complaint [REDACTED] that related to assessment of internal packaging by [REDACTED] and reported to the company from [REDACTED] failed to take account of the regulatory breach and the way the complaint had been reported to Nordic Pharma Limited. There was no acknowledgement from Nordic Pharma Limited that examination of internal packaging by [REDACTED] constituted activity carried out by them outside of the scope of their



**File Ref:** Insp GDP 5827/34897770-0002  
**Inspection Date:** 07/10/2025  
**Company:** NORDIC PHARMA LIMITED

wholesale dealer authorisation with implication of the integrity of the complaint. Management of [redacted] by Nordic Pharma Limited failed to ensure that the quality team or complaint handling team at [redacted] were made aware of the product quality complaint. The complaint investigation report failed to describe the source of information on which to ascertain that there had been no reported functional or contamination-related product failure with this batch or this product.

There had been no product recalls within the UK. A test of the recall process had been carried out in May / June 2025 and was described in recall report [redacted]. The exercises demonstrated the company and [redacted] could trace stock and confirm customer contacts and was deemed a success.

- **Outsourced Activities**

The Responsible Person / Responsible Person for import was a contracted employee. A technical agreement was in place to define responsibilities.

[redacted] acted as a 4PL service provider. Quarterly review of performance were carried out and more frequent meetings held by the NPL Sales Team. A technical agreement was in place that defied delegated tasks, and routine audits were carried out.

[redacted] was used as an unapproved transport provider, and also made Customs declarations on behalf of NPL.

- **Self-Inspection**

Not inspected in detail.

- **Transportation**

Transportation was outsourced to [redacted] with transport providers being approved by NPL. [redacted] was used to transport medicines but was not listed as an approved subcontractor.

- **Specific Provisions for Brokers**

N/A

<b>13. Other specific issues identified:</b>
N/A
<b>14. Miscellaneous:</b>
N/A
<b>15. Annexes attached:</b>
N/A
<b>16. List of Deficiencies classified into critical, major and others:</b>

**1 CRITICAL**

None

**2 MAJOR**

2.1

Management of product quality complaint [redacted] that related to assessment of internal packaging by [redacted] and reported to the company from [redacted]



File Ref: Insp GDP 5827/34897770-0002  
Inspection Date: 07/10/2025  
Company: NORDIC PHARMA LIMITED

- ██████████ failed to take account of the regulatory breach and the manner in which the complaint had been reported to Nordic Pharma Limited.
- 2.1.1 There was no acknowledgement from Nordic Pharma Limited that examination of internal packaging by ██████████ constituted activity carried out by them outside of the scope of their wholesale dealer authorisation with implication of the integrity of the complaint.
- 2.1.2 Management of ██████████ by Nordic Pharma Limited failed to ensure that the quality team or complaint handling team at ██████████ ██████████ were made aware of the product quality complaint.
- 2.1.3 The complaint investigation report failed to describe the source of information on which to ascertain that there had been no reported functional or contamination-related product failure with this batch or this product.
- EU GDP 1.2(i), 1.3(iii), 2.2(ii), 2.2(v), 6.2
- 2.2 The exportation process was not controlled to an appropriate standard as demonstrated by the supply of ██████████ to ██████████
- 2.2.1 Operating procedure ██████████ ██████████ failed to provide appropriate detail in regard to export activity in that there was no procedural requirement to confirm if UK trade sanctions and embargoes were in place with medicines, territories, companies or individuals specific for the individual consignment.
- 2.2.2 There was no CAPA or equivalent to ensure that prior to initiating a second exportation, that procedural gaps identified in ██████████ ██████████ would be considered and revision of the procedure undertaken if required.
- 2.2.3 The charitable donation intended for ██████████ was not controlled by Nordic Pharma Limited beyond supply to the first-tier customer in ██████████
- 2.2.3.1 Nordic Pharma Limited failed to ensure that documentary evidence would be obtained to verify that the supply into ██████████ would be in accordance with medicine regulatory authority agreement of the territories concerned, and Good Distribution Practice standards in line with the donation intended destination.
- 2.2.3.2 The document trail for importation into ██████████ failed to ensure that documents would be assessed and reviewed by an appropriate person within Nordic Pharma Limited.
- 2.2.3.2 The C88 associated with export from the UK was not appropriately reviewed.
- 2.2.3.2.1 The document provided to the inspector was incomplete.
- 2.2.3.2.2 The document provided to the inspector referred to ██████████ ██████████ which was not listed as an approved service provider on the ██████████ quality technical agreement.
- 2.2.3.3 There was no notarised translation of the ██████████ importation documentation that was written in Hebrew.
- EU GDP 1.2(i), 2.2(ii), 2.2(xii), 2.4, 4.1, 4.2, 5.8, 5.9



**File Ref:** Insp GDP 5827/34897770-0002  
**Inspection Date:** 07/10/2025  
**Company:** NORDIC PHARMA LIMITED

**3 OTHER**

- 3.1 There was no deviation or CAPA raised to provide an appropriate record and assessment of mitigation for cancellation of [REDACTED]  
 EU GDP 1.2(v), 1.2(vi)
  
- 3.2 Operating procedure [REDACTED] version [REDACTED] did not include specific or general definitions of occurrence, severity or risk with the consequence that these terms could be interpreted incorrectly when compared to different application of the same terms in the Quality Risk Management procedure.  
 EU GDP 4.2
  
- 3.3 The change control process was not adequately applied to the change in business model to distribute unlicensed medicines with the consequence that separate associated change controls (e.g. [REDACTED] [REDACTED]) were not cross-referenced or coordinated and the underlying core change identified.  
 EU GDP 1.2

**4 COMMENT**

None

<b>17. Inspectors' Comments:</b>
N/A
<b>18. Recommendations:</b>
Continued support of your wholesale dealer's authorisation (WDA(H) 5827) 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 [REDACTED]



**File Ref:** Insp GDP 5827/34897770-0002  
**Inspection Date:** 07/10/2025  
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**19. Summary and conclusions:**

Within the scope of the inspection, the company operated operate 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.

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

**Name:**

[Redacted]

**Signature:**

[Redacted]

**Organisation:**

MHRA

**Date:** 11/10/2025