



Health And Youth Care Inspectorate

CERTIFICATE NUMBER: *NL/H 23/2050752*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER^{1,2}

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Netherlands confirms the following:

The manufacturer: **Ofipharma B.V.**

Site address: **Drenthweg 25, Ter Apel, 9561 AZ, Netherlands, GPS: 52.888775, 7.056152**

OMS Organisation Id. / OMS Location Id.: **ORG-100024255 / LOC-100067766**

Has been inspected under the national inspection programme in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:

Art. 100 of the Medicines Act

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation:

Art. 100 of the Medicines Act

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2023-10-10**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.³
- The principles of GMP for active substances³ referred to in Article 47 of Directive 2001/83/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (<http://eudragmdp.ema.europa.eu/>). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

¹ The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC is also applicable to importers.

² Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

³ These requirements fulfil the GMP recommendations of WHO.



Part 2

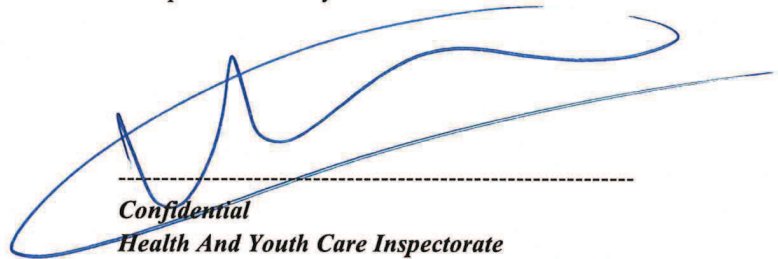
Human Medicinal Products

4. Other Activities - Active Substances:

The certificate holder is authorized to repack APIs, both potent and non-potent, into smaller quantities. A list of APIs to which these actions apply is not required. For detailed information on the types of APIs, please refer to the API registration with registration number 5736 API, issued in accordance with the applicable regulations of the Ministry of Health, Welfare and Sports.

2024-03-04

Name and signature of the authorised person of the
Competent Authority of Netherlands



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