

Medical Products Agency

CERTIFICATE NUMBER: 6.2.1-2013-098804

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 Sweden confirms the following:

The manufacturer: **Orexo AB**

Site address: **Virdings allé 32 A, Uppsala, 75105, Sweden**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **6.2.1-2013-098804** in accordance with Art. 40 of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2013-11-28** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC³

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. 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 authorisation referred to in paragraph 40(1) of Directive 2001/83/EC and 44(1) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.

² Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database

³ The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).

Part 2

Human Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.13 Tablets
1.6	Quality control testing
	1.6.3 Chemical/Physical

Clarifying remarks (for public users)

1.2.1.13 Manufacturing of tablets in bulk. (1.2.1.13 Tillverkning av tabletter i bulk.)

2014-06-12

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



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