

Italian Medicines Agency

CERTIFICATE NUMBER: **IT/GMP/E/03/2023**

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 Italy confirms the following:

The manufacturer: **Gensenta Ilac Sanayi Ve Ticaret A.S.**

Site address: **Yenibosna Merkez Mahallesi, Sanayi Caddesi No 13, Bahcelievler, 34197, Turkey**

OMS Organisation Id. / OMS Location Id.: **ORG-100023923 / LOC-100033090**

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 8(2) of Regulation (EC) 726/2004.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2022-10-21**, 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

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.

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

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

³These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.1	Sterile products
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> <i>1.1.1.2 Lyophilisates</i>
1.3	Biological medicinal products (list of product types)
	<i>1.3.1 Biological medicinal products (list of product types)</i> <i>1.3.1.5 Biotechnology products</i>
1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.3 Chemical/Physical</i> <i>1.6.4 Biological</i>

Clarifying remarks (for public users)

Herzuma (Trastuzumab), Remsima (Inflizimab), Inflectra (Infliximab) manufactured in OPP Line 1 and Line 3.

2023-01-31

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

Confidential
Italian Medicines Agency
Tel:***Confidential***
Fax:***Confidential***