

Federal Agency For Medicines And Health Products

CERTIFICATE NUMBER: **BE/GMP/2023/082**

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 Belgium confirms the following:

The manufacturer: ***Reliance Life Sciences Private Limited***

Site address: ***R 282 Dhirubhai Ambani Life Sciences Centre, Thane Belapur Road, Ghansoli, Navi Mumbai, Maharashtra, 400701, India***

OMS Organisation Id. / OMS Location Id.: ***ORG-100006228 / LOC-100010914***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC, transposed in the following national legislation: Article 114 of the royal decree of 14 December 2006 related to medicinal products for human and veterinary use.

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

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2023-06-22**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572.³
- The principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC and an appropriate level of GMP as referred to in Article 46(f) 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.

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> 1.1.1.2 Lyophilisates
	<i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.3 Small volume liquids
1.3	Biological medicinal products (list of product types)
	<i>1.3.1 Biological medicinal products (list of product types)</i> 1.3.1.5 Biotechnology products 1.3.1.8 Other: Biological drug substance(en)
1.5	Packaging
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i> <i>1.6.4 Biological</i>

Manufacture of active substance. Names of substances subject to inspection:

TENECTEPLASE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance:TENECTEPLASE	
3.3	Manufacturing of Active Substance using Biological Processes
	3.3.2 Cell Culture: Mammalian 3.3.3 Isolation / Purification
3.5	General Finishing Steps
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing 3.6.4 Biological Testing

2023-12-05

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

Confidential
Federal Agency For Medicines And Health Products
Tel: **Confidential**
Fax: **Confidential**