

Státní ústav pro kontrolu léčiv

CERTIFICATE NUMBER: **ukls96057/2022**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

^{1,2}

Part 1

Issued following an inspection in accordance with :

Art. 63 of Regulation (EU) 536/2014

The competent authority of Czechia confirms the following:

The manufacturer: **Zentiva k.s.**

Site address: **Dolní Mecholupy U Kabelovny 130, Prague, 102 37, Czechia**

OMS Organisation Id. / OMS Location Id.: **ORG-100004108 / LOC-100002580**

Has been inspected under the national inspection programme in accordance with Art. 61 of Regulation (EU) No 536/2014.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2022-11-15**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569³

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.

¹The certificate referred to in paragraph Art. 15 of Directive 2001/20/EC, shall also be required for imports coming from third countries into a Member State.

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

³These requirements fulfil the GMP recommendations of WHO.

Part 2

1 MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.6 Liquids for internal use
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.6 Liquids for internal use

2022-12-12

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

Confidential
State Institute for Drug Control
Tel: *Confidential*
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