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Agency for medicinal products and medical devices of the Republic of Slovenia

Certificate No: 455-101/2020-1

CERTIFICATE OF GDP COMPLIANCE OF A DISTRIBUTOR OF ACTIVE SUBSTANCES FOR USE AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

Issued following an inspection in accordance with Art. 111 of Directive 2001/83/EC

The competent authority of Slovenia confirms the following:

The active substance distributor APIPharm veletrgovina d.o.o.- warehouse at SCHENKER mednarodna špedicija d.d., Ljubljana,

Site address: Brnčičeva ulica 51, Ljubljana - Črnuče, 1231, Slovenia

has been inspected in accordance with Art . 111(1) of Directive 2001/83/ECand in connection with registration no 805-5/2020-19

From the knowledge gained during inspection of this active substance distributor, the latest of which was conducted on 2020-09-21, it is considered that it complies with the principles of Good Distribution Practice for active substances referred to in Article 47 of Directive 2001/83/EC.

This certificate reflects the status of the site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of that inspection. However this period of validity may be reduced using regulatory risk management principles, by an entry in the Restrictions or Clarifying Remarks field.

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

2020-11-09

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



Mr Jaka Zavasnik

Agency for medicinal products and medical devices of the Republic of Slovenia

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EMA/171905/2012

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