



12-09-2019

PREJETO

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

CERTIFICATE NUMBER: 401-12/2019-4

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 Slovenia confirms the following:
The manufacturer: **ISTRABENZ PLINI, plini in plinske tehnologije, d.o.o.**
Site address: **Sermin 8A, Koper, 6000, Slovenia**

Has been inspected under the national inspection programme in connection with manufacturing
authorisation no. **800-12/2017-3** 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
2019-07-11 , 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 certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, 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 These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	1.2.2 Batch certification
1.5	Packaging
	1.5.1 Primary Packing 1.5.1.7 Medicinal gases
1.6	Quality control testing
	1.6.3 Chemical/Physical

Any restrictions related to the scope of this certificate :

All manufacturing activities are limited to the production of medicinal oxygen (filling of cylinders).

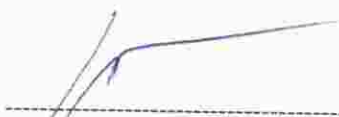
Clarifying remarks (for public users)

All manufacturing activities are limited to the production of medicinal oxygen (filling of cylinders).

2019-09-11

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





Mr. Rok Martincic
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the Republic of Slovenia*
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