

**Agency for medicinal products and medical devices of the Republic of
Slovenia**CERTIFICATE NUMBER: **450-30/2013-2****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: **Jadran Galenski Laboratorij d.d. - Pulac**

Site address: **Pulac 4a, Rijeka, 51000, Croatia**

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 .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on
2013-06-18 , 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 authorisation referred to in paragraph 40(1) of Directive 2001/83/EC and 44(1) of Directive 2001/82/EC, as amended, 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 The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive
2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).

Part 2

Human Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.1	Sterile products
	1.1.3 Batch certification
1.2	Non-sterile products
	1.2.2 Batch certification
1.6	Quality control testing
	1.6.1 Microbiological: sterility
	1.6.2 Microbiological: non-sterility

Any restrictions related to the scope of this certificate :

Manufacturing activities include storage and distribution of medicinal products.

Clarifying remarks (for public users)

Manufacturing activities include storage and distribution of medicinal products.

2013-12-23



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

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

Tel:
Fax: