

Agency for Medicinal Products and Medical Devices of Croatia

CERTIFICATE NUMBER: **UP/T-530-10/20-03/17; 381-13-08/322-20-03**

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 Croatia confirms the following:

The manufacturer: ***Swiss Parenterals Ltd.***

Site address: ***808, 809 & 810, Kerala Industrial Estate, GIDC, Nr. Bavla, Ahmedabad, Gujarat, 382220, India***

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 **2020-02-28**, 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. 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.

¹ The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC is also applicable to importers.

² Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

³ These 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 1.1.1.4 Small volume liquids 1.1.1.6 Other: Powder for solution for injection or infusion(en)
	<i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.3 Small volume liquids
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>

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC testing	Products
Block B		Line 1 (Dry powder line)		confidential
Block B		Line 2 (Ampoule line)		confidential
Block B		Line 3 (Vial line)		confidential

Clarifying remarks (for public users)

1.1.1.6. Refers to filling process of sterile dry power for solution for injection or infusion, 1.1.2.3. Refers to ampoules, 1.1.1.2. i 1.1.2.3. Refers to vials

2020-07-31

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

Confidential
Agency for Medicinal Products and Medical Devices of
Croatia
Tel: **Confidential**
Fax: **Confidential**