Agency For Medicinal Products And Medical Devices Of Croatia

CERTIFICATE NUMBER: ***530-10/25-06/02; 381-13-08/256-25-06***

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: ***Stellapharm J.V. Co. Ltd.***
Site address: ***No. 40 Tu Do Avenue, Vietnam Singapore Industrial Park, An Phu Ward, Thuan An, Binh Duong, 820000, Viet Nam***
OMS Organisation Id. / OMS Location Id.: ***ORG-100018994*** / ***LOC-100027760***

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, transposed in the following national legislation:Art. 40 of Medicinal Products Act (official Gazette, No. 76/13, 90/14 and 100/18).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2025-03-28***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572. [3]

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.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis 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	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell Special Requirements 7 Other: Highly potent products(en) 1.2.1.8 Other solid dosage forms: powder for oral solution and suspension, granules for oral solution(en) 1.2.1.13 Tablets Special Requirements 7 Other: Highly potent products(en)
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell Special Requirements 7 Other: Highly potent products(en) 1.5.1.8 Other solid dosage forms: powder for oral solution and suspension, granules for oral solution(en) 1.5.1.13 Tablets Special Requirements 7 Other: Highly potent products(en)
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Digitally signed by Dumbravă Natalia
Date: 2026.05.25 09:18:02 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC testing	Products
Building 1	***Solid Production 1***			***confidential***
Building 2 (Highly potent products)	***Solid Production 2 (Oncology Production)***			***confidential***
Building 2 (Highly potent products)	***Hormone Solid Production***			***confidential***

2025-07-18

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

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Confidential
Agency For Medicinal Products And Medical Devices Of Croatia
Tel:***Confidential***
Fax:***Confidential***