

Chief Pharmaceutical Inspectorate

CERTIFICATE NUMBER : *IWSF.405.22.2021.IP.7.1 WTC/0037_03_01/89*

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 Poland confirms the following:

The manufacturer : ***Zakłady Farmaceutyczne POLPHARMA S.A. Oddział Medana w Sieradzu***
Site address : ***ul. Polskiej Organizacji Wojskowej 57, Sieradz, 98-200, Poland***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***189/0037/15*** in accordance with Art. 40 of Directive 2001/83/EC .

Other

Distant Assessment

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-04-09*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC 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. 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

1 MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> <ul style="list-style-type: none">1.2.1.2 Capsules, soft shell1.2.1.5 Liquids for external use1.2.1.6 Liquids for internal use1.2.1.11 Semi-solids1.2.1.17 Other: Other non-sterile medicinal product: Rectal solution(en)
1.4	Other products or manufacturing activity
	<i>1.4.1 Manufacture of</i> <ul style="list-style-type: none">1.4.1.1 Herbal products
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> <ul style="list-style-type: none">1.5.1.1 Capsules, hard shell1.5.1.2 Capsules, soft shell1.5.1.5 Liquids for external use1.5.1.6 Liquids for internal use1.5.1.11 Semi-solids1.5.1.13 Tablets1.5.1.17 Other non-sterile medicinal products: Other non-sterile medicinal product: Rectal solution(en)
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	<i>1.6.2 Microbiological: non-sterility</i>
	<i>1.6.3 Chemical/Physical</i>

Clarifying remarks (for public users)

Points 1.2.1.6 and 1.2.1.11 include also manufacturing of medicinal products containing highly toxic substances. Points: 1.2.1.6 and 1.2.1.17 include also manufacturing of medicinal products containing psychotropic substances. Point 1.2.1.6 includes also manufacturing of medicinal products containing sensitizers. The certificate was issued on the basis of remote inspection.

2021-04-28

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

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