

Chief Pharmaceutical Inspectorate

CERTIFICATE NUMBER: *ISF.405.116.2024.IP.1 WTC/0196_02_06/211*

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: ***Tarchomińskie Zakłady Farmaceutyczne "Polfa" S.A.***

Site address: ***Ul. Aleksandra Fleminga 2, Warsaw, 03-176, Poland***

OMS Organisation Id. / OMS Location Id.: ***ORG-100000121 / LOC-100002430***

Has been inspected under the national inspection programme in connection with manufacturing
authorisation no. ***078/0196/15*** 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 ***2024-06-27***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572
and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in
Part 2.³

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.

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

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

³These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms: granules for oral suspension, powder for oral suspension(en) 1.2.1.13 Tablets
	<i>1.2.2 Batch certification</i>
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms: granules for oral suspension, powder for oral suspension(en) 1.5.1.13 Tablets
	<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: 1.2.1.1, 1.2.1.8, 1.2.1.13, 1.5.1.1, 1.5.1.8 and 1.5.1.13 concerns also manufacturing of medicinal products containing active substances from β -Lactam antibiotics group.

2024-09-19

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

Confidential
Chief Pharmaceutical Inspectorate
Tel: **Confidential**
Fax: **Confidential**

EudraGMP