



ISF.405.29.2026.IP.1
WTC/0079_01_02/50

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

Chief Pharmaceutical Inspector

/the Competent Authority of Poland/

confirms the following:

the manufacturer:

**Sieć Badawcza Łukasiewicz - Instytut Chemii Przemysłowej
imienia Profesora Ignacego Mościckiego
ul. Rydygiera 8, 01-793 Warszawa, POLAND**

site address:

**Sieć Badawcza Łukasiewicz - Instytut Chemii Przemysłowej
imienia Profesora Ignacego Mościckiego
ul. Rydygiera 8, 01-793 Warszawa, POLAND**

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2025, item 750 as amended) in connection with the entry in the Register no **1/WTC0079/API/15**.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **03/02/2026 – 05/02/2026**, it is considered that it complies with the principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC.

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.

27-03-2026



Chief Pharmaceutical Inspector

Łukasz Pietrzak

Part 2

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

- Alfacalcidol
- Calcitriol
- Calcifediol monohydrate

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Purification steps (crystallisation)
3.5	General Finishing Steps
	3.5.1 Physical processing steps (drying) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.4 Other (storage, distribution)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

27 -03- 2026



Chief Pharmaceutical Inspector

Łukasz Pietrzak

Part 2

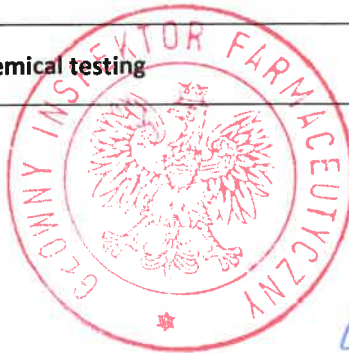
3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

- Tacalcitol monohydrate

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Purification steps (preparative HPLC, crystallisation)
3.5	General Finishing Steps
	3.5.1 Physical processing steps (drying) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.4 Other (storage, distribution)
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Part 2

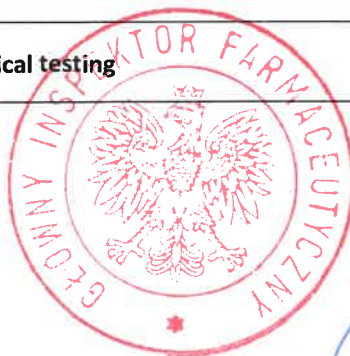
3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

- Anastrozole

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Purification steps (chromatographic column, crystallisation)
3.5	General Finishing Steps
	3.5.1 Physical processing steps (drying, milling) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.4 Other (storage, distribution)
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Chief Pharmaceutical Inspector

Łukasz Pietrak

Part 2

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

- Imatinib Mesylate

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Purification steps (crystallisation)
3.5	General Finishing Steps
	3.5.1 Physical processing steps (drying, milling, mixing) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.4 Other (storage, distribution)
3.6	Quality Control Testing
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Chief Pharmaceutical Inspector

Łukasz Piętrzak

Part 2

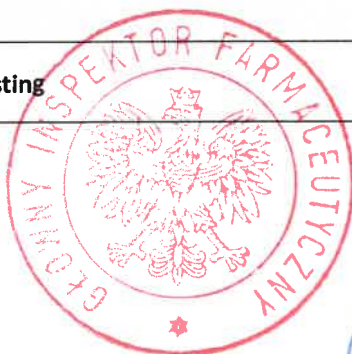
3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

- Carvedilol

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Purification steps (crystallisation)
3.5	General Finishing Steps
	3.5.1 Physical processing steps (drying, grinding/micronisation, mixing) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.4 Other (storage, distribution)
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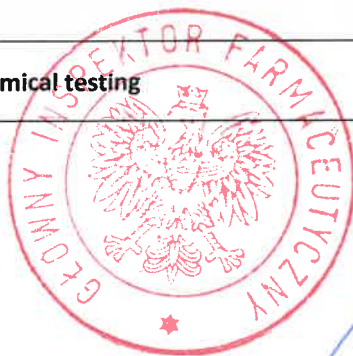
3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

- Cladribine

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Purification steps (preparative HPLC, crystallisation)
3.5	General Finishing Steps
	3.5.1 Physical processing steps (drying) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.4 Other (storage, distribution)
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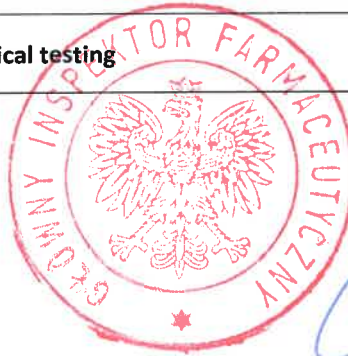
3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

- Sunitinib malate

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Purification steps (crystallisation)
3.5	General Finishing Steps
	3.5.1 Physical processing steps (drying, grinding) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.4 Other (storage, distribution)
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Chief Pharmaceutical Inspector

Łukasz Piętrzak