

**Regierungspraesidium Tuebingen Leitstelle Arzneimittelueberwachung
Baden-Wuerttemberg**

CERTIFICATE NUMBER: **DE_BW_01_GMP_2024_0156**

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 Germany confirms the following:

The manufacturer: **Gemini Pharmchem Mannheim GmbH**

Site address: **Sandhofer Strasse 96, Waldhof, Mannheim, Baden-Wuerttemberg, 68305**

OMS Organisation Id. / OMS Location Id.: **ORG-100033421 / LOC-100052271**

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive
2001/83/EC.

Other

Distant Assessment

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted
on **2024-09-12**, 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
- The principles of GMP for active substances³ 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.

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

Manufacture of active substance. Names of substances subject to inspection:

Pirarubicin(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance: Pirarubicin

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 Salt formation / Purification steps: Chromatographic purification Crystallization
3.5	General Finishing Steps
	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)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

2024-09-13

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

Confidential
Regierungspraesidium Tuebingen Leitstelle
Arzneimittelueberwachung Baden-Wuerttemberg
Tel: **Confidential**
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