

Landesamt Fuer Soziales Jugend Und Versorgung

CERTIFICATE NUMBER: **DE_RP_01_GMP_2025_0032**

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: **Arkema GmbH**

Site address: **Morschheimer Strasse 19, Kirchheimbolanden, Rhineland-Palatinate, 67292**

OMS Organisation Id. / OMS Location Id.: **ORG-100015463 / LOC-100028706**

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: **Sect. 64 para 1 and 3 German Medicinal Product Act**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2025-06-04**, it is considered that it complies with:

- The principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC and an appropriate level of GMP as referred to in Article 46(f) of Directive 2001/83/EC, transposed in the following national legislation: Sect. 64 para 1 and 3 German Medicinal Product Act.

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> 1.2.1.17 Other: Hydrogen peroxide Solutions(en)
1.6	Quality control testing
	<i>1.6.3 Chemical/Physical</i>

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

Hydrogen Peroxid 3% (Peroxal 3 OG) Starting Material: Hydrogen Peroxid 60%(en)

Hydrogen Peroxid 30% (Peroxal 30 PG) Starting Material: Hydrogen Peroxid 60%(en)

Hydrogen Peroxid 35% (Peroxal 35 PG) Starting Material: Hydrogen Peroxid 60%(en)

Hydrogen Peroxid 50% (Peroxal 50 PG) Starting Material: Hydrogen Peroxid 60%(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance:Hydrogen Peroxid 3% (Peroxal 3 OG) Starting Material: Hydrogen Peroxid 60%	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.4 Other: Manufacturing of Hydrogen Peroxid Solutions
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active Substance:Hydrogen Peroxid 30% (Peroxal 30 PG) Starting Material: Hydrogen Peroxid 60%	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.4 Other: Manufacturing of Hydrogen Peroxid Solutions
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active Substance:Hydrogen Peroxid 35% (Peroxal 35 PG) Starting Material: Hydrogen Peroxid 60%	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.4 Other: Manufacturing of Hydrogen Peroxid Solutions
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active Substance:Hydrogen Peroxid 50% (Peroxal 50 PG) Starting Material: Hydrogen Peroxid 60%	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.4 Other:

	Manufacturing of Hydrogen Peroxid Solutions
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

2025-07-10

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

Confidential
Landesamt Fuer Soziales Jugend Und Versorgung
Tel: *Confidential*
Fax: *Confidential*