



## MANUFACTURER'S AUTHORISATION

(This English translation is for reference only. It is not part of the official certificate.)

1. Authorisation number/file number	DE_SN_01_MIA_2025_0023/26-5117/91
2. Name of authorisation holder	ABX advanced biochemical compounds Biomedizinische Forschungsreagenzien GmbH (LOC-100018392)
3. Address(es) of manufacturing site(s)	ABX advanced biochemical compounds Biomedizinische Forschungsreagenzien GmbH Heinrich-Gläser-Straße 10-14 01454 Radeberg (LOC-100018392)
4. Legally registered address of authorisation holder	Heinrich-Gläser-Straße 10-14 01454 Radeberg
5. Scope of authorisation and dosage forms	ANNEX 1 and ANNEX 2
6. Legal basis of authorisation	Sect 13 para 1 Arzneimittelgesetz (German Drug Law) Art. 61 para 1 to 3 of Regulation (EU) No. 536/2014 in conjunction with Sect 13 para 5 AMG
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Dr. Anne Lewerenz
8. Signature	
9. Date	11/09/2025
10. Annexes attached	Annex 1 and Annex 2 Annex 4 (Addresses of Contract Laboratories) Annex 5 (Name of Qualified Person)

**SCOPE OF AUTHORISATION**

Annex 1

Name and address of the site:

ABX advanced biochemical compounds Biomedizinische Forschungsreagenzien GmbH,  
Heinrich-Gläser-Straße 10-14, 01454 Radeberg

Human Medicinal Products
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**AUTHORISED OPERATIONS**

Manufacturing Operations (according to part 1)

**Part 1 - MANUFACTURING OPERATIONS**

<b>1.1</b>	<b>Sterile Products</b>
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i>
	<p>1.1.1.4 Small volume liquids</p> <p>Special requirements</p> <p>5. Radiopharmaceuticals</p>
	<i>1.1.3 Batch certification</i>
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.2 Secondary packing</i>
<b>1.6</b>	<b>Quality control testing</b>
	<i>1.6.1 Microbiological: sterility</i>
	<i>1.6.3 Chemical/Physical</i>
	<i>1.6.4 Biological</i>

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

This manufacturing authorisation is only valid for premises in accordance with Site Master File in a current version registered and approved by the authority.

This manufacturing authorisation applies the medicinal products in accordance with the product assortment list most recently notified by the authorisation holder and approved by the authority.

The holder of the manufacturing authorisation uses the following contract archive for the storage of pharmaceutical documents: Grove Spedition GmbH, Gewerbegebiet 7, 01689 Niederau OT Ockrilla.

to 1.6.3:

This authorisation only applies to the quality control tests contained in in accordance with Site Master File in a current version registered and approved by the authority.

to 1.6.4:

This authorisation is only valid for testing for bacterial endotoxins (Ph. Eur. 2.6.14).

**SCOPE OF AUTHORISATION**

Annex 2

Name and address of the site:

ABX advanced biochemical compounds Biomedizinische Forschungsreagenzien GmbH,  
Heinrich-Gläser-Straße 10-14, 01454 Radeberg

Investigational Medicinal Products for Human Use
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**AUTHORISED OPERATIONS**

Manufacturing Operations (according to part 1)

**Part 1 - MANUFACTURING OPERATIONS**

<b>1.1</b>	<b>Sterile Products</b>
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i>
	<p>1.1.1.4 Small volume liquids</p> <p>Special requirements</p> <p>5. Radiopharmaceuticals</p>
	<i>1.1.3 Batch certification</i>
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.2 Secondary packing</i>
<b>1.6</b>	<b>Quality control testing</b>
	<i>1.6.1 Microbiological: sterility</i>
	<i>1.6.3 Chemical/Physical</i>
	<i>1.6.4 Biological</i>

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

This manufacturing authorisation is only valid for premises in accordance with Site Master File in a current version registered and approved by the authority.

This manufacturing authorisation applies the medicinal products in accordance with the product assortment list most recently notified by the autorisation holder and approved by the authority.

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to 1.6.3:

This authorisation only applies to the quality control tests contained in in accordance with Site Master File in a current version registered and approved by the authority.

to 1.6.4:

This authorisation is only valid for testing for bacterial endotoxins (Ph. Eur. 2.6.14).

Address(es) of Contract Laboratories

VKTA - Strahlenschutz, Analytik & Entsorgung Rossendorf  
e. V.  
Bautzner Landstraße 400  
01328 Dresden

Analysis performed as part of the release analysis - gamma  
spectroscopy

Name(s) of Qualified Person(s)

Mr. Dr. Marco Müller

Mr. Dr. René Martin

Mr. Dr. Dirk Müller

Mr. Dr. Sebastian Weidlich