



MANUFACTURER'S AUTHORISATION

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

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| 1. Authorisation number/file number | DE_BB_01_MIA_2026_0009//6301/chiracon/01 |
| 2. Name of authorisation holder | Chiracon GmbH
(LOC-100079717) |
| 3. Address(es) of manufacturing site(s) | Chiracon GmbH
Im Biotechnologiepark 9
14943 Luckenwalde
(LOC-100079717)
Chiracon GmbH
Lise-Meitner-Strasse 2
14943 Luckenwalde
(LOC-100099419)
CHIRACON GmbH
Biotechnologiepark 3
14943 Luckenwalde
(LOC-100099452) |
| 4. Legally registered address of authorisation holder | Im Biotechnologiepark 9
14943 Luckenwalde |
| 5. Scope of authorisation and dosage forms | ANNEX 1 |
| 6. Legal basis of authorisation | Sect 13 para 1 Arzneimittelgesetz (German Drug Law) |
| 7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation | Dr. Steffen Rodewald |
| 8. Signature | On behalf |

9. Date

17/04/2026

10. Annexes attached

Annex 1

Annex 4 (Addresses of Contract Laboratories)

Annex 7 (Date of inspection on which authorisation granted, scope of last inspection)

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

Chiracon GmbH, Im Biotechnologiepark 9, 14943 Luckenwalde

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 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 spray-dried preparations
	<i>1.2.2 Batch certification</i>
1.6	Quality control testing
	<i>1.6.3 Chemical/Physical</i>

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

Chiracon GmbH, Lise-Meitner-Strasse 2, 14943 Luckenwalde

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AUTHORISED OPERATIONS

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SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

CHIRACON GmbH, Biotechnologiepark 3, 14943 Luckenwalde

Human Medicinal Products

AUTHORISED OPERATIONS Manufacturing Operations (according to part 1)
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Part 1 - MANUFACTURING OPERATIONS	
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	<i>1.2.2 Batch certification</i>
1.6	Quality control testing
	<i>1.6.3 Chemical/Physical</i>

Annex 4

Address(es) of Contract Laboratories

CUP Laboratoien Dr. Freitag GmbH
Carl-Eschebach-Str. 7
01454 Radeberg
water content (Karl-Fischer)
microbiological testing

Date of Inspection on which
authorisation was granted

17/10/2025

Scope of last Inspection

acceptance inspection

