




Bezirksregierung Arnberg

MANUFACTURER'S AUTHORISATION

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

- | | |
|--|---|
| 1. Authorisation number/file number | DE_NW_01_MIA_2021_0012/24.2.11-1001-004 |
| 2. Name of authorisation holder | A.R.C.O-Chemie GmbH |
| 3. Address(es) of manufacturing site(s) | A.R.C.O-Chemie GmbH
Wetterstr. 33 - 37
58313 Herdecke |
| 4. Legally registered address of authorisation holder | Wetterstr. 33 - 37
58313 Herdecke |
| 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 | Rolf Hobbie |
| 8. Signature | On behalf
 |
| 9. Date | 19/05/2021 |
| 10. Annexes attached | Annex 1
Annex 5 (Name of Qualified Person) |



SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

A.R.C.O-Chemie GmbH, Wetterstr. 33 - 37, 58313 Herdecke

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>
	1.2.1.2 Capsules, soft shell
1.6	Quality control testing
	<i>1.6.2 Microbiological: non-sterility</i>
	<i>1.6.3 Chemical/Physical</i>



Annex 5

Name(s) of Qualified Person(s)

Mr. W. Langenberg



