




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_0011/24.05.03-081 |
| 2. Name of authorisation holder | HAPA pharm GmbH |
| 3. Address(es) of manufacturing site(s) | HAPA pharm GmbH
Phoenixseestraße 4
44263 Dortmund |
| 4. Legally registered address of authorisation holder | Phoenixseestraße 4
44263 Dortmund |
| 5. Scope of authorisation and dosage forms | ANNEX 1 |
| 6. Legal basis of authorisation | Sect 13 para 1 and sect 72 para 1
Arzneimittelgesetz (German Drug Law) |
| 7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation | Dr. Nina Makowski |
| 8. Signature | On behalf
 |
| 9. Date | 22/12/2021 |
| 10. Annexes attached | Annex 1
Annex 4 (Addresses of Contract Laboratories)
Annex 5 (Name of Qualified Person) |



SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

HAPA pharm GmbH, Phoenixseestraße 4, 44263 Dortmund

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Importation of Medicinal Products (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

1.2 Non-sterile products

1.2.2 Batch certification

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

Item 1.2.2 only applies to the batch certification of Cannabis Flowers and Cannabis extracts for individual pharmacy-manufacturing



Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.2	Batch certification of imported medicinal products
	<i>2.2.2 Non-sterile products</i>

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

The import is limited to Cannabis Flowers and specified Cannabis extracts, which are listed in the corresponding certificates according to sect 72a AMG (German Drug Law).



Address(es) of Contract Laboratories

WESSLING GmbH
Johann-Krane-Weg 42
48149 Münster
Complete analytical testing of Cannabis products placed on
the market as recipe drugs by HAPA pharm GmbH



Name(s) of Qualified Person(s)

Mrs. Silke Heinemann

Mr. Dr. Maik Siebelmann

