




Bezirksregierung Detmold

Leopoldstr. 15
32756 Detmold

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_02_MIA_2023_0004/24.05.01-50 |
| 2. Name of authorisation holder | C. Hedenkamp GmbH & Co.KG
(LOC-100025386) |
| 3. Address(es) of manufacturing site(s) | C.Hedenkamp GmbH & Co.KG
Schierbusch 1
33161 Hövelhof
(LOC-100025386) |
| 4. Legally registered address of authorisation holder | Schierbusch 1
33161 Hövelhof |
| 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. Stephanie Kottmann |
| 8. Signature | On behalf

 |
| 9. Date | 21/02/2023 |
| 10. Annexes attached | Annex 1 and Annex 2
Annex 4 (Addresses of Contract Laboratories) |



SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

C.Hedenkamp GmbH & Co.KG, Schierbusch 1, 33161 Hövelhof

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>
	1.2.1.1 Capsules, hard shell
	1.2.1.8 Other solid dosage forms
	1.2.1.13 Tablets
1.4	Other products or manufacturing activity
	<i>1.4.3 Other batch release for non-sterile products</i>
1.5	Packaging
	<i>1.5.1 Primary Packing</i>
	1.5.1.1 Capsules, hard shell
	1.5.1.2 Capsules, soft shell
	1.5.1.8 Other solid dosage forms
	1.5.1.13 Tablets
	<i>1.5.2 Secondary packing</i>
1.6	Quality control testing
	<i>1.6.3 Chemical/Physical</i>

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

to 1.2.1.13 and 1.5.1.13

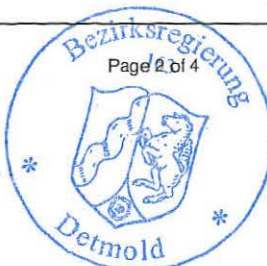
Tablets include effervescent tablets

to 1.2.1.8 and 1.5.1.8

Production and Filling of powder in sticks

to 1.6.3

only tests by HPLC, wet chemistry, physical tests (only determination loss of drying, ash und sulphated ash)



SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

C.Hedenkamp GmbH & Co.KG, Schierbusch 1, 33161 Hövelhof

Investigational Medicinal Products for Human Use

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>
	1.2.1.1 Capsules, hard shell
	1.2.1.8 Other solid dosage forms
	1.2.1.13 Tablets
1.4	Other products or manufacturing activity
	<i>1.4.3 Other</i> batch release for non-sterile products
1.5	Packaging
	<i>1.5.1 Primary Packing</i>
	1.5.1.1 Capsules, hard shell
	1.5.1.2 Capsules, soft shell
	1.5.1.8 Other solid dosage forms
	1.5.1.13 Tablets
	<i>1.5.2 Secondary packing</i>
1.6	Quality control testing
	<i>1.6.3 Chemical/Physical</i>

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

to 1.2.1.8 and 1.5.1.8

Production and Filling of powder in sticks

to 1.2.1.13 and 1.5.1.13 Tablets include effervescent tablets

to 1.6.3

only tests by HPLC, wet chemistry, physical tests (only determination loss of drying, ash und sulphated ash)



SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

C.Hedenkamp GmbH & Co.KG, Schierbusch 1, 33161 Hövelhof

Investigational Medicinal Products for Human Use

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS**1.2 Non-sterile products***1.2.1 Non-sterile products (processing operations for the following dosage forms)*

1.2.1.1 Capsules, hard shell

1.2.1.8 Other solid dosage forms

1.2.1.13 Tablets

1.4 Other products or manufacturing activity*1.4.3 Other
batch release for non-sterile products***1.5 Packaging***1.5.1 Primary Packing*

1.5.1.1 Capsules, hard shell

1.5.1.2 Capsules, soft shell

1.5.1.8 Other solid dosage forms

1.5.1.13 Tablets

*1.5.2 Secondary packing***1.6 Quality control testing***1.6.3 Chemical/Physical*

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

to 1.2.1.8 and 1.5.1.8

Production and Filling of powder in sticks

to 1.2.1.13 and 1.5.1.13 Tablets include effervescent tablets

to 1.6.3

only tests by HPLC, wet chemistry, physical tests (only determination loss of drying, ash und sulphated ash)



Address(es) of Contract Laboratories

BAV Institut für Hygiene und Qualitätssicherung GmbH
Hanns-Martin-Schleyer-Str. 25
77656 Offenburg
microbiological testing according Ph.Eur.

Dr. Graner & Partner GmbH
Lochhausener Straße 205
81249 München
Quality control testing of excipients/active
ingredients/medicinal products
- pharmaceutical-chemical analysis
- pharmaceutical-chemical analysis (compendial methods)
- chromatographic assays
- microbiological assays of non-sterile products

