

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_HE_01_MIA_2023_0016/V4 18 L 18.01 / 1535-B |
| 2. Name of authorisation holder | RubiePharm Arzneimittel GmbH
(LOC-100008783) |
| 3. Address(es) of manufacturing site(s) | RubiePharm Arzneimittel GmbH
Brüder-Grimm-Straße 62
36396 Steinau an der Straße
(LOC-100003890)
RubiePharm Arzneimittel GmbH
Brüder-Grimm-Straße 121
36396 Steinau an der Straße
(LOC-100008783) |
| 4. Legally registered address of authorisation holder | Brüder-Grimm-Straße 121
36396 Steinau an der Straße |
| 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 | Sonja Uhrmacher |
| 8. Signature | On behalf |
| 9. Date | 31/07/2023 |
| 10. Annexes attached | |

Annex 1
Annex 4 (Addresses of Contract Laboratories)
Annex 8 (Manufactured products authorised)

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

RubiePharm Arzneimittel GmbH, Brüder-Grimm-Straße 62, 36396 Steinau an der Straße

Human Medicinal Products

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)*

1.2.1.11 Semi-solids

1.2.1.12 Suppositories

*1.2.2 Batch certification***1.4 Other products or manufacturing activity***1.4.1 Manufacture of:*

1.4.1.2 Homeopathic products

1.5 Packaging*1.5.1 Primary Packing*

1.5.1.11 Semi-solids

1.5.1.12 Suppositories

*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

List of products and manufacturing steps see current annex 8.

Ref. to 1.4.1.2: only within the allowed manufacturing operations according to 1.2 and 1.5.

Ref. to 1.5.2: tablets also (see current annex 8)

Partial testing in contract laboratories according to sect 14 para 4 German Drug law (see annex 4).

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

RubiePharm Arzneimittel GmbH, Brüder-Grimm-Straße 121, 36396 Steinau an der Straße

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

1.6	Quality control testing
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	<i>1.6.3 Chemical/Physical</i>
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Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

QC-sampling and storage.

Partial testing in contract laboratories according to sect 14 para 4 German Drug Law (see annex 4).

Address(es) of Contract Laboratories

HHAC Labor Dr. Heusler GmbH
Hindenburgstr. 33 und 52
76297 Stutensee
1.6.3: Chemical and physical testing

Labor LS SE & Co. KG
Mangelsfeld 4, 5, 6
97708 Bad Bocklet-Großenbrach
1.6.2: Microbiological testing non-steril products

Artesan Pharma GmbH & Co. KG
Wendlandstraße 1
29439 Lüchow
1.6.3: Chemical and physical testing

Herbrand PharmaChemicals
Brambachstr. 31
77723 Gengenbach
1.6.3: Chemical and physical testing

Tentamus Pharma & Med Deutschland GmbH
Columbistraße 14
97688 Bad Kissingen
1.6.3: Chemical and physical testing

Annex 8

Products authorised to be manufactured (in accordance with Article 41 and 42 of Directive 2001/83/EC and/or Article 89 and 90 of Regulation (EU) 2019/6, as amended).

- siehe aktuelle Anlage 8 -
- see current annex 8 -