

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_NW_05_MIA_2016_0028/24.05.03-006 |
| 2. Name of authorisation holder | Möller Pharma GmbH & Co. Herstellungs- und Vertriebs KG |
| 3. Address(es) of manufacturing site(s) | Möller Pharma GmbH & Co. Herstellungs- und Vertriebs KG
Lise-Meitner-Straße 2
45659 Recklinghausen |
| 4. Legally registered address of authorisation holder | Forststraße 7
45659 Recklinghausen |
| 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. Petra Rempe |
| 8. Signature | On behalf |
| 9. Date | 09/13/2016 |
| 10. Annexes attached | Annex 1 |



SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

Möller Pharma GmbH & Co. Herstellungs- und Vertriebs KG, Lise-Meitner-Straße 2,
45659 Recklinghausen

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;

- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;

- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form (applicable to all sections of Part 1 apart from sections 1.5.2 and 1.6)

1.2 Non-sterile products

1.2.1 Non-sterile products

1.2.1.5 Liquids for external use

1.2.1.6 Liquids for internal use

1.2.1.8 Other solid dosage forms

1.6 Quality control testing

1.6.3 Chemical/Physical

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

Regarding point 1.2.1.5 and 1.2.1.6:
tinctures, extracts (liquid extracts, solid extracts), distillates (also "Melissenmischdestillat" and "Kräuterbronchialtropfen"), alcoholic mixtures (also spirits and Franzbranntweine)

Regarding point 1.2.1.8:
dry extracts

