

MANUFACTURER'S AUTHORISATION^{1, 2}

1. Authorisation Number DE_RP_01_MIA_2019_0039
2. Name of authorisation holder mikle-pharm GmbH
3. Address(es) of manufacturing site(s) mikle-pharm GmbH, Sandgasse 17, Landau, Rheinland-Pfalz, 76829, Germany
4. Legally registered address of authorisation holder Sandgasse 17, Landau, Rheinland-Pfalz, 76829, Germany
5. Scope of authorisation and dosage forms² ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation Art. 40 of Directive 2001/83/EC
Art. 13 of Directive 2001/20/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation confidential
8. Signature
9. Date 2020-01-29
10. Annexes attached Annex 1 and/or Annex 2
Optional Annexes as required:
Annex 3 (Addresses of Contract Manufacturing Site(s))
Annex 4 (Addresses of Contract laboratories)
Annex 5 (Name of Qualified Person)
Annex 6 (Name of responsible persons)
Annex 7 (Date of inspection on which authorisation granted, scope of last inspection)
Annex 8 (Manufactured/ imported products authorised)³

¹ The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC and 44(1) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.

² Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

³ The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).

SCOPE OF AUTHORISATION

ANNEX 1

Name and address of the site : mikle-pharm GmbH, Sandgasse 17, Landau, Rheinland-Pfalz,
76829, Germany

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
	<i>1.2.2 Batch certification</i>
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.2	Batch certification of imported medicinal products
	<i>2.2.2 Non-sterile products</i>

SCOPE OF AUTHORISATION

ANNEX 2

Name and address of the site : mikle-pharm GmbH, Sandgasse 17, Landau, Rheinland-Pfalz,
76829, Germany

Human Investigational Medicinal Products
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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
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	<i>1.2.2 Batch certification</i>
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Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

2.2	Batch certification of imported medicinal products
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	<i>2.2.2 Non-sterile products</i>
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