

MANUFACTURER'S AUTHORISATION^{1, 2}

1. Authorisation Number DE_HH_01_MIA_2020_0011
2. Name of authorisation holder Bode Chemie GmbH
3. Address(es) of manufacturing site(s) Bode Chemie GmbH, Melanchthonstrasse 27, Hamburg, Hamburg, 22525, Germany
4. Legally registered address of authorisation holder Melanchthonstrasse 27, Hamburg, Hamburg, 22525, 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. 44 of Directive 2001/82/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 2020-08-06
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 : Bode Chemie GmbH, Melanchthonstrasse 27, Hamburg,
Hamburg, 22525, Germany

Human Medicinal Products
Veterinary 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> 1.2.1.4 Impregnated matrices 1.2.1.5 Liquids for external use 1.2.1.17 Other: Gels(en)
	<i>1.2.2 Batch certification</i>
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.5 Liquids for external use
1.6	Quality control testing
	<i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

commissioned enterprise for the storage: Loxxess Hamburg GmbH & Co. KG Siebenstuecken 2
24558 Henstedt-Ulzburg commissioned enterprise for the storage of the batch documentation:
Rhenus Archiv Services GmbH Eversween 41 21107 Hamburg

SCOPE OF AUTHORISATION**ANNEX 2**

Name and address of the site : Bode Chemie GmbH, Melanchthonstrasse 27, Hamburg,
Hamburg, 22525, Germany

Human Investigational Medicinal Products
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Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)
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Part 1 - MANUFACTURING OPERATIONS

1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.5 Liquids for external use 1.2.1.15 Other: Gels(en)
	<i>1.2.2 Batch certification</i>
1.6	Quality control testing
	1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical