

MANUFACTURER'S AUTHORISATION^{1, 2}

1. Authorisation Number DE_SH_01_MIA_2017_1012
2. Name of authorisation holder B.M.P. Bulk Medicines & Pharmaceuticals GmbH
3. Address(es) of manufacturing site(s) B.M.P. Bulk Medicines & Pharmaceuticals GmbH, Bornbarch 16, Norderstedt, Schleswig-Holstein, 22848, Germany
4. Legally registered address of authorisation holder Bornbarch 16, Norderstedt, Schleswig-Holstein, 22848, 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
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation confidential
8. Signature
9. Date 2017-11-22
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 : B.M.P. Bulk Medicines & Pharmaceuticals GmbH, Bornbarch
16, Norderstedt, Schleswig-Holstein, 22848, Germany

Human Medicinal Products
Veterinary Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS**1.4 Other products or manufacturing activity***1.4.1 Manufacture of*

1.4.1.4 Other: Batch certification only within the scope of importation(en)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**2.3 Other importation activities***2.3.4 Other: Import of active pharmaceutical ingredients of microbial origin(en)*