MANUFACTURER'S AUTHORISATION [1, 2]

1. Authorisation Number	DE_SH_01_MIA_2021_0009
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 forms [2]	ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation	Art. 40 of Directive 2001/83/EC
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	confidential
8. Signature	
9. Date	2021-03-05
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

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**
	1.4.3 Other: Batch certification within the scope of importation(en)

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.3	**Other importation activities**
	2.3.1 Site of physical importation *2.3.4 Other: Active pharmaceutical ingredients of microbial origin(en)*

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

Production of Veterinary Medicinal Products: The products are in principle also suitable for use in Veterinary Medicinal Products.