


**Landesamt für Gesundheit und Soziales  
Mecklenburg-Vorpommern  
- Arzneimittelüberwachungs- und -prüfstelle –**

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**MANUFACTURER'S AUTHORISATION**

(This English translation is for reference only. It is not part of the official certificate.)

1. Authorisation number/file number	DE_MV_01_MIA_2019_0003/310.101.01.10
2. Name of authorisation holder	bmp, bulk medicines & pharmaceuticals production gmbh
3. Address(es) of manufacturing site(s)	bmp, bulk medicines & pharmaceuticals production gmbh Neuhofer Weiche 48 D-19370 Parchim
4. Legally registered address of authorisation holder	Neuhofer Weiche 48 D-19370 Parchim
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. Andreas Schieweck
8. Signature	On behalf 
9. Date	25/02/2019
10. Annexes attached	Annex 1 Annex 4 (Addresses of Contract Laboratories)



**SCOPE OF AUTHORISATION**

Annex 1

Name and address of the site:

bmp, bulk medicines &amp; pharmaceuticals production gmbh, Neuhofer Weiche 48, D-19370 Parchim

Human Medicinal Products Veterinary Medicinal Products
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**AUTHORISED OPERATIONS**

Manufacturing Operations (according to part 1)

**Part 1 - MANUFACTURING OPERATIONS****1.2 Non-sterile products***1.2.1 Non-sterile products (processing operations for the following dosage forms)*

1.2.1.1 Capsules, hard shell

1.2.1.8 Other solid dosage forms

1.2.1.13 Tablets

**1.4 Other products or manufacturing activity***1.4.3 Other  
Micronisation,  
Manufacturing of composites of active substances and excipients***1.5 Packaging***1.5.1 Primary Packing*

1.5.1.2 Capsules, soft shell

1.5.1.3 Chewing gums

*1.5.2 Secondary packing***1.6 Quality control testing***1.6.3 Chemical/Physical*Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

1.2.1.8 Other solid dosage forms: Powders, sugar-coated tablets (sugar-coated tablets: only packaging) 1.2.1.13 Tablets: without Granulation
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Address(es) of Contract Laboratories

PhytoLab GmbH & Co. KG  
Dutendorfer Straße 5-7  
91487 Vestenbergsgreuth

Methods of analysis:

- wet-chemical analysis of herbal medicines and active pharmaceutical ingredients
- assays for herbal drugs,
- Analysis of pesticide residues

BAV Institut für Hygiene und Qualitätssicherung GmbH  
Hanns-Martin-Schleyer-Str. 25  
77656 Offenburg

Methods of analysis:

- microbiological tests (compendial methods)
- determination of heavy metals

Techpharm GmbH  
Draisstr. 14

76646 Bruchsal

Methods of analysis:

- wet chemical analysis according to pharmacopoeia
- physical analysis according to pharmacopoeia
- pharmaceutical technological analysis according to pharmacopoeia
- pharmaceutical chemical analysis according to pharmacopoeia

Euofins BioPharma Product Testing Hamburg GmbH  
Großmoorbogen 25  
21079 Hamburg

Methods of analysis:

- wet chemical analysis according to pharmacopoeia
- analysis of pesticide residues
- determination of heavy metals
- Analysis of organic substances

Labor LS SE & Co. KG  
Mangelsfeld 4, 5, 6  
97708 Bad Bocklet-Großenbrach

Methods of analysis:

- pharmaceutical chemical analysis
- pharmaceutical technological analysis (compendial methods)
- chromatographic assays
- microbiological tests (compendial methods)
- biological assays
- determination of heavy metals

