


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

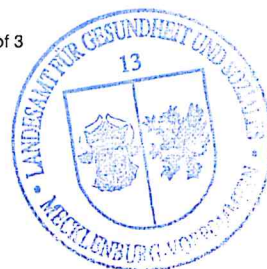
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MANUFACTURER'S AUTHORISATION

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

1. Authorisation number/file number	DE_MV_01_MIA_2022_0002/310.101.01.10
2. Name of authorisation holder	bmp, bulk medicines & pharmaceuticals production gmbh (LOC-100029813)
3. Address(es) of manufacturing site(s)	bmp, bulk medicines & pharmaceuticals production gmbh (LOC-100029813) 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 (AMG, German Drug Law)
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Thea Pallas
8. Signature	On behalf 
9. Date	11/03/2022
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 & pharmaceuticals production gmbh, Neuhofer Weiche 48, D-19370 Parchim

Human Medicinal Products

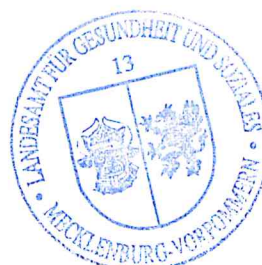
AUTHORISED OPERATIONS

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>
	1.2.1.8 Other solid dosage forms
1.4	Other products or manufacturing activity
	<i>1.4.3 Other</i> Micronisation, Manufacturing of composites of active substances and excipients
1.5	Packaging
	<i>1.5.1 Primary Packing</i>
	1.5.1.2 Capsules, soft shell
	<i>1.5.2 Secondary packing</i>
1.6	Quality control testing
	<i>1.6.3 Chemical/Physical</i>

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)

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

Eurofins 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

