


**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\_2020\_0019/LAGuS  
300-310.148.01.10
2. Name of authorisation holder Pharmadrug Production GmbH
3. Address(es) of manufacturing site(s) Pharmadrug Production GmbH  
Friedrich-Barnewitz-Straße 7  
18119 Rostock
4. Legally registered address of authorisation holder Friedrich-Barnewitz-Straße 7  
18119 Rostock
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 13/11/2020
10. Annexes attached Annex 1  
Annex 4 (Addresses of Contract Laboratories)



**SCOPE OF AUTHORISATION**

Annex 1

Name and address of the site:

Pharmadrug Production GmbH, Friedrich-Barnewitz-Straße 7, 18119 Rostock

Human Medicinal Products
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**AUTHORISED OPERATIONS**

Manufacturing Operations (according to part 1)

**Part 1 - MANUFACTURING OPERATIONS****1.1 Sterile Products***1.1.3 Batch certification***1.2 Non-sterile products***1.2.2 Batch certification*

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Address(es) of Contract Laboratories	<p>BioChem Labor für biologische und chemische Analytik GmbH  Daimlerstr. 5b  76185 Karlsruhe  test methods:  HPLC-Analytics, GC-Analytics, TLC-Analytics,  Determination of loss on drying  Microbiological examination of non-sterile products: Total microbial count and detection of specific micro-organisms</p> <p>Zentrallaboratorium Deutscher Apotheker GmbH  Carl-Mannich-Straße 20  65760 Eschborn  test methods:  HPLC-Analytics, GC-Analytics, TLC-Analytics, ICP-MS analytics, testing for foreign matter, Determination of heavy metals in herbal drugs and herbal drug preparations, Determination of aflatoxin in herbal drugs, Determination of pesticides residues, Determination of loss on drying, Microbiological examination of non-sterile products: Total microbial count and detection of specific micro-organisms.</p> <p>Labor L+S AG  Mangelsfeld 4, 5, 6  97708 Bad Bocklet-Großenbrach  test methods:  HPLC-Analytics, GC-Analytics, TLC-Analytics, ICP-MS analytics, Testing for foreign matter, Determination of heavy metals in herbal drugs and herbal drug preparations, Determination of aflatoxin in herbal drugs, Determination of pesticides residues, Determination of loss on drying, Microbiological examination of non-sterile products: Total microbial count and detection of specific micro-organisms.</p> <p>Quality Services International GmbH  Flughafendamm 9a  28199 Bremen  test methods:  HPLC-Analytics, GC-Analytics, TLC-Analytics, ICP-MS analytics, Testing for foreign matter, Determination of heavy metals in herbal drugs and herbal drug preparations, Determination of aflatoxin in herbal drugs, Determination of pesticides residues, Determination of loss on drying, Microbiological examination of non-sterile products: Total</p>
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microbial count and detection of specific micro-organisms.



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