

MANUFACTURER / IMPORTER AUTHORISATION

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

1. Authorisation number/file number	DE_NW_05_MIA_2024_0001/24.05.03-051
2. Name of authorisation holder	Wiewelhove GmbH (LOC-100020185)
3. Address(es) of manufacturing site(s)	Wiewelhove GmbH Dörnebrink 19 49479 Ibbenbüren (LOC-100020185) Wiewelhove GmbH Gildestraße 39 49477 Ibbenbüren (LOC-100039656) Wiewelhove GmbH Wilhelmstraße 248 49479 Ibbenbüren (LOC-100042144) Lager Kamp Gildestraße 28 49477 Ibbenbüren (LOC-100072699) Wiewelhove GmbH Gildestraße 4 49477 Ibbenbüren (LOC-100052222)
4. Legally registered address of authorisation holder	Dörnebrink 19 49479 Ibbenbüren
5. Scope of authorisation and dosage forms	ANNEX 1 and ANNEX 2
6. Legal basis of authorisation	Sect 13 para 1 Arzneimittelgesetz (German Drug Law)

Sect 72 para 1 Arzneimittelgesetz (German Drug Law)
Art. 61 para 1 to 3 of Regulation (EU) No. 536/2014 in conjunction with Sect 13 para 5 AMG

7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

Dr. Petra Rempe

8. Signature

On behalf

9. Date

11/01/2024

10. Annexes attached

Annex 1 and Annex 2
Annex 4 (Addresses of Contract Laboratories)

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

Wiewelhove GmbH, Dörnebrink 19, 49479 Ibbenbüren

Human Medicinal Products

AUTHORISED OPERATIONS
 Manufacturing Operations (according to part 1)
 Importation of Medicinal Products (according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i>
	1.2.1.1 Capsules, hard shell
	1.2.1.2 Capsules, soft shell
	1.2.1.8 Other solid dosage forms
	1.2.1.13 Tablets
	<i>1.2.2 Batch certification</i>
1.3	Biological medicinal products
	<i>1.3.1 Biological medicinal products</i>
	1.3.1.8 Other Medicinal products consisting of enzyme preparations of microbial origin
	<i>1.3.2 Batch certification</i>
	1.3.2.8 Other Medicinal products consisting of enzyme preparations of microbial origin
1.4	Other products or manufacturing activity
	<i>1.4.1 Manufacture of:</i>
	1.4.1.1 Herbal products
	1.4.1.2 Homeopathic products
	1.4.1.3 Other Grinding of a dry extract (API)
	<i>1.4.3 Other</i> final adjustment of the activity of the active substances amylase, protease and lipase
1.5	Packaging

	<i>1.5.1 Primary Packing</i>
	1.5.1.1 Capsules, hard shell
	1.5.1.2 Capsules, soft shell
	1.5.1.8 Other solid dosage forms
	1.5.1.13 Tablets
	<i>1.5.2 Secondary packing</i>

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

regarding point 1.2.1.2: only coating and packaging

regarding point 1.2.1.8: also granules

regarding point 1.2.1.13: also coated tablets

regarding point 1.2.1:
other dosage forms not mentioned under 1.2.1
only batch release and batch certification

regarding point 1.4.1.1 and 1.4.1.2:
solid dosage forms only

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.3	Other importation activities
	<i>2.3.1 Site of physical importation</i>

Any restrictions or clarifying remarks related to the scope of these Importation operations

Paracetamol 96% DC + 4% Maize Starch, lisencc holder Midas Pharma GmbH, Rheinstraße 49, 55218 Ingelheim, Germany

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

Wiewelhove GmbH, Dörnebrink 19, 49479 Ibbenbüren

Investigational Medicinal Products for Human Use

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>
	1.2.1.1 Capsules, hard shell
	1.2.1.2 Capsules, soft shell
	1.2.1.8 Other solid dosage forms
	1.2.1.13 Tablets
	<i>1.2.2 Batch certification</i>
1.3	Biological medicinal products
	<i>1.3.1 Biological medicinal products</i>
	1.3.1.8 Other Medicinal products consisting of enzym preparations of microbial origin
	<i>1.3.2 Batch certification</i>
	1.3.2.8 Other Medicinal products consisting of enzym preparations of microbial origin
1.4	Other products or manufacturing activity
	<i>1.4.1 Manufacture of:</i>
	1.4.1.1 Herbal products
	1.4.1.2 Homeopathic products
1.5	Packaging
	<i>1.5.1 Primary Packing</i>
	1.5.1.1 Capsules, hard shell

	1.5.1.2 Capsules, soft shell
	1.5.1.8 Other solid dosage forms
	1.5.1.13 Tablets
	<i>1.5.2 Secondary packing</i>

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

regarding point 1.2.1.2: only coating and packaging

regarding point 1.2.1.8: also granules

regarding point 1.2.1.13: also coated tablets

regarding point 1.2.1:
 other dosage forms not mentioned under 1.2.1
 only batch release and batch certification

regarding point 1.4.1.1 and 1.4.1.2:
 solid dosage forms only

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

Wiewelhove GmbH, Gildestraße 39, 49477 Ibbenbüren

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.2	Non-sterile products
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	1.2.1.13 Tablets
	<i>1.2.2 Batch certification</i>
1.3	Biological medicinal products
	<i>1.3.1 Biological medicinal products</i>
	1.3.1.8 Other Medicinal products consisting of enzym preparations of microbial origin
	<i>1.3.2 Batch certification</i>
	1.3.2.8 Other Medicinal products consisting of enzym preparations of microbial origin
1.4	Other products or manufacturing activity
	<i>1.4.1 Manufacture of:</i>
	1.4.1.1 Herbal products
	1.4.1.2 Homeopathic products
	1.4.1.3 Other Grinding of a dry extract (API)
	<i>1.4.3 Other</i> final adjustment of the activity of the active substances amylase, protease and lipase
1.6	Quality control testing

1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

regarding point 1.2.1.2: only coating

regarding point 1.2.1.8 : also granules

regarding point 1.2.1.13: also coated tablets

regarding point 1.2.1:
other dosage forms not mentioned under 1.2.1
only batch release and batch certification

regarding point 1.4.1.1 and 1.4.1.2:
solid dosage forms only

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

Wiewelhove GmbH, Gildestraße 39, 49477 Ibbenbüren

Investigational Medicinal Products for Human Use

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>
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	1.3.1.8 Other Medicinal products consisting of enzyme preparations of microbial origin
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	1.3.2.8 Other Medicinal products consisting of enzyme preparations of microbial origin
1.4	Other products or manufacturing activity
	<i>1.4.1 Manufacture of:</i>
	1.4.1.1 Herbal products
	1.4.1.2 Homeopathic products
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

regarding point 1.2.1.2: only coating

regarding point 1.2.1.8: also granules

regarding point 1.2.1.13: also coated tablets

regarding point 1.2.1:
other dosage forms not mentioned under 1.2.1
only batch release and batch certification

regarding point 1.4.1.1 and 1.4.1.2:
solid dosage forms only

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

Wiewelhove GmbH, Wilhelmstraße 248, 49479 Ibbenbüren

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

1.6	Quality control testing
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	<i>1.6.3. Chemical/Physical</i>
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SCOPE OF AUTHORISATION

Name and address of the site:

Wiewelhove GmbH, Wilhelmstraße 248, 49479 Ibbenbüren

Investigational Medicinal Products for Human Use
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AUTHORISED OPERATIONS Manufacturing Operations (according to part 1)
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Part 1 - MANUFACTURING OPERATIONS	
1.6	Quality control testing
	<i>1.6.3 Chemical/Physical</i>

SCOPE OF AUTHORISATION

Name and address of the site:

Lager Kamp, Gildestraße 28, 49477 Ibbenbüren

Human Medicinal Products

AUTHORISED OPERATIONS
Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.4	Other products or manufacturing activity
	<i>1.4.3 Other</i>

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

no manufacture, storage of GMP documentation, primary packaging material and secondary packaging material

SCOPE OF AUTHORISATION

Name and address of the site:
Lager Kamp, Gildestraße 28, 49477 Ibbenbüren

Investigational Medicinal Products for Human Use

AUTHORISED OPERATIONS
Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.4	Other products or manufacturing activity
	<i>1.4.3 Other</i>

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations
no manufacture, storage of GMP documentation, primary packaging material and secondary packaging material

SCOPE OF AUTHORISATION

Name and address of the site:
Wiewelhove GmbH, Gildestraße 4, 49477 Ibbenbüren

Human Medicinal Products

AUTHORISED OPERATIONS Manufacturing Operations (according to part 1)
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Part 1 - MANUFACTURING OPERATIONS	
1.4	Other products or manufacturing activity
	1.4.3 <i>Other</i>

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

no manufacture; Storage of raw materials, intermediate and finished products, primary packaging material and secondary packaging material

SCOPE OF AUTHORISATION

Name and address of the site:
Wiewelhove GmbH, Gildestraße 4, 49477 Ibbenbüren

Investigational Medicinal Products for Human Use

AUTHORISED OPERATIONS
Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.4	Other products or manufacturing activity
	<i>1.4.3 Other</i>

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations

no manufacture; Storage of raw materials, intermediate and finished products, primary packaging material and secondary packaging material

Address(es) of Contract Laboratories

Umweltlabor ACB GmbH
Albrecht-Thaer-Straße 14
48147 Münster
Microbiological: non-sterile products
chemical/physical

PhytoLab GmbH & Co. KG
Dutendorfer Straße 5-7
91487 Vestenbergsgreuth
Microbiological: non-sterile products
chemical/physical

Agon Pharma GmbH
Stuttgarter Str. 2
73240 Wendlingen
chemical/physical

Institut Kuhlmann GmbH
Hedwig-Laudien-Ring 3
67071 Ludwigshafen
chemical/physical

Particle Analytical ApS.
Agern Allè
2970 Hørsholm
Dänemark
physical

TECHPharm GmbH
Draisstraße 14
76646 Bruchsal
chemical/physical