**FREIE HANSESTADT BREMEN**

**Die Senatorin für Gesundheit, Frauen und Verbraucherschutz**

# MANUFACTURER'S AUTHORISATION

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

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|---|---|
| 1. Authorisation number/file number | DE_HB_01_MIA_2025_0001/HE GfM_2025 |
| 2. Name of authorisation holder | GfM Gesellschaft für Micronisierung mbH (LOC-100022007) |
| 3. Address(es) of manufacturing site(s) | GfM Gesellschaft für Micronisierung mbH<br>Lesumer Heerstraße 30<br>28717 Bremen<br>(LOC-100022007) |
| 4. Legally registered address of authorisation holder | Lesumer Heerstraße 30<br>28717 Bremen |
| 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)<br>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 | Katja Ahrens |
| 8. Signature | On behalf |
| 9. Date | 20/02/2025 |
| 10. Annexes attached | Annex 1 and Annex 2<br>Annex 4 (Addresses of Contract Laboratories)<br>Annex 7 (Date of inspection on which authorisation granted, scope of last inspection) |

Die Senatorin für Gesundheit, Frauen und Verbraucherschutz
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Bremen

**SCOPE OF AUTHORISATION** **Annex 1**

Name and address of the site:
GfM Gesellschaft für Micronisierung mbH, Lesumer Heerstraße 30, 28717 Bremen

Human Medicinal Products

**AUTHORISED OPERATIONS**
Manufacturing Operations (according to part 1)

| **Part 1 - MANUFACTURING OPERATIONS** | |
|---|---|
| **1.4** | **Other products or manufacturing activity** |
| | *1.4.3 Other*<br>- Micronisation, sieving, mixing and filling of active ingredients of human, animal or microbial origin or produced by genetic engineering, of human, animal or microbial origin or which have been produced by genetic engineering<br><br>- Micronisation, sieving, mixing and filling of bulk medicinal products<br><br>- Sterile micronisation in chamber KS7 and KS8<br><br>- Sterilisation of active ingredients |
| **1.6** | **Quality control testing** |
| | *1.6.3 Chemical/Physical* |

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

Supplement to section 1.4.3:

This authorisation includes

- Sterilisation of excipients, active substances or medicinal products
- Sterile micronisation in chamber KS7 and KS8
- Packaging as transport packaging

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Supplement to section 1.6.3:

- Determination of particle size, identity and content

**SCOPE OF AUTHORISATION** **Annex 2**

Name and address of the site:
GfM Gesellschaft für Micronisierung mbH, Lesumer Heerstraße 30, 28717 Bremen

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| Investigational Medicinal Products for Human Use |

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| **AUTHORISED OPERATIONS**<br>Manufacturing Operations (according to part 1) |

| **Part 1 - MANUFACTURING OPERATIONS** | |
|---|---|
| **1.4** | **Other products or manufacturing activity** |
| | *1.4.3 Other*<br>- Micronisation, sieving, mixing and filling of active substances of human, animal or microbial origin or produced by genetic engineering for the purpose of manufacturing investigational medicinal products for human use in phases I, II and III<br><br>- Micronisation, sieving, mixing and filling of bulk medicinal products for the manufacture of investigational medicinal products for human use of phases I, II and III<br><br>- Sterile micronisation in chambers KS7 and KS8<br><br>- Sterilisation of active ingredients |
| **1.6** | **Quality control testing** |
| | *1.6.3 Chemical/Physical* |

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

Supplement to section 1.4.3:

This authorisation includes

- Sterilisation of excipients, active substances or medicinal products
- Sterile micronisation in chamber KS7 and KS8
- Packaging as transport packaging

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Supplement to section 1.6.3:

- Determination of particle size, identity and content

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| Address(es) of Contract Laboratories | WESSLING GmbH<br>Johann-Krane-Weg 42<br>48149 Münster<br>Sterility, TOC, microbial count, microbial identification, chemical-physical analysis of active ingredients and and excipients according to pharmacopoeia methods or methods, mediafill, microbial growth control of nutrient microbial growth control of culture media, preservation of HPLC - content determinations and stability stability tests<br><br>Labor LS SE & Co. KG<br>Mangelsfeld 4, 5, 6<br>97708 Bad Bocklet-Großenbrach<br>Sterility, TOC, microbial count, microbial identification, chemical-physical analysis of active ingredients and and excipients according to pharmacopoeia methods or methods, mediafill, microbial growth control of nutrient microbial growth control of culture media, preservation of HPLC - content determinations and stability stability tests<br><br>TECHPharm GmbH<br>Draisstr. 14<br>76646 Bruchsal<br>Analytical tests:<br>TOC and other chemical-physical tests of active ingredients and excipients according to pharmacopoeia and in-house methods. Method development and -validation of HPLC methods, storage of stability stability samples according to ICH |

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| Date of Inspection on which authorisation was granted | 30/10/2024 |
| Scope of last Inspection | GMP-inspection |