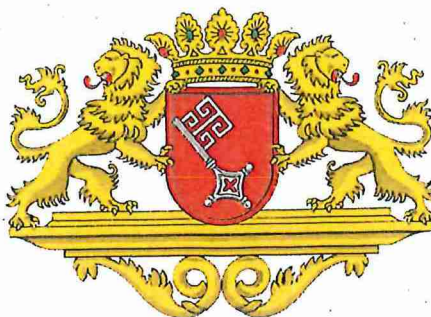




FREIE HANSESTADT BREMEN

**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.)

- | | |
|--|---|
| 1. Authorisation number/file number | DE_HB_02_MIA_2025_0001 |
| 2. Name of authorisation holder | GfM Gesellschaft für Micronisierung mbH
(LOC-100022007) |
| 3. Address(es) of manufacturing site(s) | GfM Gesellschaft für Micronisierung mbH
Lesumer Heerstraße 30
28717 Bremen
(LOC-100022007) |
| 4. Legally registered address of authorisation holder | Lesumer Heerstraße 30
28717 Bremen |
| 5. Scope of authorisation and dosage forms | ANNEX 1 |
| 6. Legal basis of authorisation | Art. 88 of Regulation (EU) 2019/6 and Sect 28
para 1 German Veterinary Medicinal Products Law |
| 7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation | Lena Engländer |
| 8. Signature | On behalf |
| 9. Date | 09/05/2025 |
| 10. Annexes attached | Annex 1
Annex 7 (Date of inspection on which authorisation
granted, scope of last inspection)
Annex 8 (Manufactured/ imported products authorised) |

SCOPE OF AUTHORISATION**Annex 1**

Name and address of the site:

GfM Gesellschaft für Micronisierung mbH, Lesumer Heerstraße 30, 28717 Bremen

Veterinary 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*

- Micronization, sieving, mixing and filling of active ingredients of animal or microbial origin or produced by genetic engineering
- Micronization, sieving, mixing and filling of bulk pharmaceuticals
- Sterile micronization in chamber KS7 and KS8
- Sterilization 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 authorization includes

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

Supplement to section 1.6.3:

- Determination of particle size, identity and content

Annex 7

Date of Inspection on which
authorisation was granted

30/10/2024

Scope of last Inspection

GMP-Inspection

Annex 8

Products authorised to be manufactured/imported (in accordance with Article 41 and 42 of Directive 2001/83/EC and/or Article 89 and 90 of Regulation (EU) 2019/6, as amended).

Misoxam
S- Roxapin
Robenacoxib