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 Engeländer
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