



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_2023_0008/HE GfM_2023 |
| 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 and ANNEX 2 |
| 6. Legal basis of authorisation | Sect 13 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 | Katja Ahrens |
| 8. Signature | On behalf |
| 9. Date | 11/09/2023 |
| 10. Annexes attached | Annex 1 and Annex 2
Annex 4 (Addresses of Contract Laboratories)
Annex 7 (Date of inspection on which authorisation granted, scope of last inspection) |



SCOPE OF AUTHORISATION

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*

- Micronization, sieving, mixing and filling of active ingredients that are of human, animal or microbial origin or which have been produced by genetic engineering

- Micronization, sieving, mixing and filling of bulk drug products

1.6 Quality control testing*1.6.3 Chemical/Physical*

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

Addition to subclause 1.4.3:
Packing as transport packaging
Addition to 1.6.3:
Determination of particle size

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

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

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

1.4.3 Other

- Micronization, sieving, mixing and filling of active ingredients that are of human, animal or microbial origin or which have been produced by genetic engineering for the purpose of manufacturing

Phase I, II and III investigational medicinal products for human use

- Micronization, sieving, mixing and filling of bulk drug products for the manufacture of manufacturing of investigational medicinal products for human use of phases I, II and III

1.6 Quality control testing

1.6.3 Chemical/Physical

Address(es) of Contract Laboratories

WESSLING GmbH
Johann-Krane-Weg 42
48149 Münster
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

SGS INSTITUT FRESENIUS GmbH
Im Maisel 14
65232 Taunusstein
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

SGS Institut Fresenius GmbH
Tegeler Weg 33
10589 Berlin
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

Labor LS SE & Co. KG
Mangelsfeld 4, 5, 6
97708 Bad Bocklet-Großenbrach
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

TECHPharm GmbH
Draisstr. 14
76646 Bruchsal

Analytical tests:
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

Date of Inspection on which
authorisation was granted

22/03/2023

Scope of last Inspection

GMP full inspection