Der Senator für Gesundheit 12 Bremen

Freie Hansestadt Bremen

Der Senator für Gesundheit

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_01_MIA_2014_0020/510-05-02/01 GfM
2. Name of authorisation holder	Gesellschaft für Micronisierung mbH
3. Address(es) of manufacturing site(s)	Gesellschaft für Micronisierung mbH Lesumer Heerstraße 30 28717 Bremen
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	Sect 13 para 1 Arzneimittelgesetz (German Drug Law)
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Dr. Heide Schütt
8. Signature	On behalf
9. Date	10/01/2014
10. Annexes attached	Annex 1 Annex 4 (Addresses of Contract Laboratories) Annex 7 (Date of inspection on which authorisation granted, scope of last inspection) Annex 8 (Manufactured/ imported products authorised)

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SCOPE OF AUTHORISATION **Annex 1**

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

Human Medicinal Products Veterinary Medicinal Products

AUTHORISED OPERATIONS Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;

- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;

- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form (applicable to all sections of Part 1 apart from sections 1.5.2 and 1.6)

1.4	**Other products or manufacturing activity** [any other relevant manufacturing activity/product type that is not covered above e.g. sterilisation of active substances, manufacture of biological active starting materials (when required by national legislation), herbal or homeopathic products , bulk or total manufacturing, etc].
	1.4.3 Others - micronisation of active pharmaceutical ingredients (API) (non-sterile and sterile) - sterilisation of APIs - sieving, blending and filling of APIs
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

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

Particle size analysis

Address(es) of Contract Laboratories	Fraunhofer Institut, IFAM Wiener Straße 12 28359 Bremen BET-Method DIN ISO 9277:2003-05 Labor L&S AG Mangelsfeld 4 97708 Bad Bocklet-Großenbach Sterility, Germ identification, chemical-physical and microbiological testing of water WESSLING GmbH Johann-Krane-Weg 42 48149 Münster sterility, endotoxins, Impinger-method, TOC, microbiological colony counting and germ identification, chemical-physical and microbiological testing of water, chemical-physical testing of APIs according to pharmacopoeia or registered methods Intertek Food Services GmbH Olof-Palme-Straße 8 28719 Bremen Content with HPLC, TOC, chemical-physical testing of APIs according to pharmacopoeia or registered methods

Date of Inspection on which authorisation was granted	07/16/2014
Scope of last Inspection	Fullinspektion

Products authorised to be manufactured/imported (in accordance with Article 41 and 42 of Directive 2001/83/EC and/or Article 45 and 46 of Directive 2001/82/EC, as amended).

Ergänzung zu Teil I (Anlage I) / Supplement to Part I

Produktgruppen mit speziellen Anforderungen /
Products with special requirements:

- Zytostatika / Cytotoxics

- Stoffe mit hormoneller Wirkung (Hormone) / Substances with hormonal activity

- Cephalosporine / Cephalosporins

- Sulfonamide / Sulfonamides