

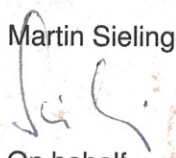


Bezirksregierung Detmold
Leopoldstr. 15
32756 Detmold

MANUFACTURER'S AUTHORISATION

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

- | | |
|--|--|
| 1. Authorisation number/file number | DE_NW_02_MIA_2012_0030/24.31.01-05-Bibitec |
| 2. Name of authorisation holder | Bibitec Gesellschaft für Prozessentwicklung mbH |
| 3. Address(es) of manufacturing site(s) | Bibitec Gesellschaft für Prozessentwicklung GmbH
Universitätsstraße 25
33615 Bielefeld

Bibitec Gesellschaft für Prozessentwicklung mbH
Almestraße 4-8
Archiv II der Firma Safebox GmbH
33649 Bielefeld |
| 4. Legally registered address of authorisation holder | Meisenstraße 96
33607 Bielefeld |
| 5. Scope of authorisation and dosage forms | ANNEX 2 |
| 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 | Martin Sieling
 |
| 8. Signature | On behalf |
| 9. Date | 09/13/2012 |
| 10. Annexes attached | |

Annex 2
Annex 4 (Addresses of Contract Laboratories)



SCOPE OF AUTHORISATION**Annex 2**

Name and address of the site:

Bibitec Gesellschaft für Prozessentwicklung GmbH, Universitätsstraße 25, 33615 Bielefeld

Human Investigational Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations of Investigational Medical Products (according to part 1)

Part 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

- 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)

1.3 Biological medicinal products*1.3.1 Biological medicinal products*

1.3.1.5 Biotechnology products

Recombinant proteins/DNA

Others

active pharmaceutical ingredients from transgenic cows

1.6 Quality control testing*1.6.3 Chemical/Physical**1.6.4 Biological*

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

only active pharmaceutical ingredients for sterile filling



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Human Investigational Medicinal Products

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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
storage of documents



Annex 4

Address(es) of Contract Laboratories

Nordmark Arzneimittel GmbH & Co. KG
Pinnauallee 4
25436 Uetersen
bioburden. RP-HPLC, ELISA, QPCR

Zentrum für Ultrastrukturelle Diagnostik im Institut für
Innovationstransfer
Universitätsstraße 25
33615 Bielefeld
in vitro virus by transmission electron microscope

L + S AG
Mangelsfeld 4
97708 Bad Bocklet-Großenbrach
endotoxin

Charles River Biopharmaceutical Services GmbH
Max-Planck-Straße 15 a
40699 Erkrath
endotoxin, Bioburden, In-Vitro-Virus, RP-HPLC

Richter-Helm BioTec GmbH & Co.KG
Suhrenkamp 59
22335 Hamburg
activity- and identitytests via cell cultures

