

Bezirksregierung Detmold

Leopoldstraße 15

32756 Detmold

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Manufacturing Authorisation

1. Authorisation reference number

24.31.01 - 05

2. Name of the manufacturing authorisation holder

Bibitec Gesellschaft für Prozessentwicklung mbH

3. Address of the manufacturing site

**Universität Bielefeld
Technischen Fakultät der Universität Bielefeld
Abteilung Zellkulturtechnik
Universitätsstr. 25
33615 Bielefeld**

4. Legally registered address of the manufacturing authorisation holder

**Meisenstr. 96
33607 Bielefeld**

5. Scope of the manufacturing authorisation

see Annex 2

6. Manufacturing authorisation for medicinal products for human use according to sect

§ 13 (1)

§ 72 (1)

of the German Drug Law (AMG).

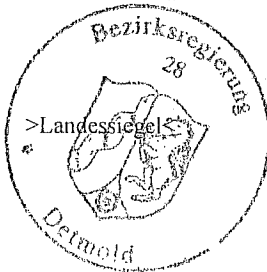
7. Name of the authorised person of the Competent Authority of Germany

Martin Sieling

8. Signature

9. Date

07. Dezember 2007



10. Attached Annexes

Annex 2 Scope of the manufacturing authorisation

Annex 4 Laboratories contracted for partial testing of medicinal products

ANNEX 2

Scope of the manufacturing authorisation

Name and address of the manufacturing site

Universität Bielefeld
Technischen Fakultät der Universität Bielefeld
Abteilung Zellkulturtechnik
Universitätsstr. 25
33615 Bielefeld

Clinical trial samples

Phase I Phase II Phase III

Authorised activities

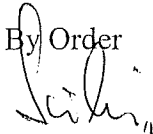
- Manufacturing of clinical trial samples**
- Import of clinical trial samples**

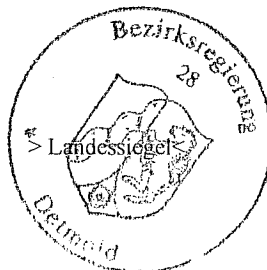
Part I Manufacturing

1.3	Biological clinical trial samples
	<ul style="list-style-type: none">• Production of active pharmaceutical ingredients derived from eucaryotic cell lines for use in human drug products intended for clinical trials

24.31.01 – 07

Detmold, 07. Dezember 2007

By Order

(Sieling)



ANNEX 4


Contract laboratories for quality control according to Sect. 14 Para. 4 of German Drug Law

contract accepting site	type of testing
NewLab BioQuality AG, Max-Planck-Str. 15a, 40699 Erkrath	Endotoxin, Bioburden (Subkontraktor: MicroSafe BV in Leiden), Mycoplasmen (Subkontraktor: MicroSafe BV in Leiden), In Vitro virus: -adventitious viruses in vitro, RP-HPLC
Nordmark Arzneimittel GmbH & Co. KG, Pinnauallee 4 25436 Uetersen	Bioburden
Zentrum für Ultrastrukturelle Diagnostik in dem Institut für Innovationstransfer (ITT) GmbH, Universitätsstraße 25, 33615 Bielefeld	In vitro virus: - adventitious viruses TEM (Transmissionelectronmicroscope)

24.31.01 – 07

Detmold, 07. Dezember 2007

By Order


(Sieling)

