

Word-Link
Translations / Übersetzungen
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Translator's Certification

I certify herewith that the attached translation is identical in content to the original German document.

Translator's stamp:

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Translations / Übersetzungen
(europ. Sprachen/japanisch/chinesisch)
Dolmetscherservice / Sprachkurse
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Allgemein beeidigte Dolmetscherin / Übersetzerin für die
Gerichte und Notare des Landgerichtsbezirks Hannover

Date: 1st April 2010

signature: *Veronica Maguire*

Die Kopie stimmt mit dem Original überein

Hameln, den

13. AUG. 2010



Industrie- u. Handelskammer

Hameln
Beck
Bots

stamp with logo Trade Supervision
in Lower Saxony

Lower Saxon logo - horse on red shield

**State Factory Inspectorate
Hanover**

Office for Work, Environment and Consumer Protection
Am Liftholze 74
30177 Hanover

MANUFACTURING LICENCE

- | | |
|---|--|
| 1. Number of licence /ref | DE_NI_02_MIA_2010_0004/41401/H-14 |
| 2. Name of licence-holder | hameln pharmaceuticals gmbh |
| 3. Address/es of manufacturer's /
importer's business premises | hameln pharmaceuticals gmbh
Brekelbaumstr. 1
31789 Hameln

hameln pharmaceuticals gmbh
Langes Feld 13
31789 Hameln |
| 4. Registered address of licence-holder | Langes Feld 13
31789 Hameln |
| 5. Scope of licence, as well as the
proffered dosage forms | APPENDIX 1 and APPENDIX 2 |
| 6. Issue of licence based legally on | Section 13, paragraph 1 of the Law on Trade with
Drugs (Medical Drugs Regulatory Law -
Arzneimittelgesetz AMG), valid version |
| 7. Name of employee of member
state's authority responsible for
issuing licence | Dr Martin Melzer
pp |
| 8. Signature | signature stamp: Trade Supervision Hanover |
| 9. Date | 18.03.2010 |

10. Appendices

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Translations / Übersetzungen

(europ. Sprachen/japanisch/chinesisch)

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Appendix 1 and Appendix 2

Appendix 3 (Addresses of contract manufacturing
companies' business premises)

Appendix 4 (Addresses of companies engaged for
testing)

Appendix 7 (Date of inspection which served as the basis
for granting licence; extent of inspection)

SCOPE OF LICENCE

Appendix 1

Name and address of business premises:

hameln pharmaceuticals gmbh, Brekelbaumstraße 1, 31789 Hameln

Human Medical Products Animal Medical Products

ACTIVITIES PERMITTED

Manufacturing activities (according to Part 1)

Part 1 – MANUFACTURING ACTIVITIES

1.6 Quality control

1.6.3 Chemical / physical

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— Dolmetscherservice / Sprachkurse

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SCOPE OF LICENCE

Appendix 2

Name and address of business premises:

hameln pharmaceuticals gmbh, Brekelbaumstraße 1, 31789 Hameln

Testing compounds

ACTIVITIES PERMITTED

Manufacturing activities for testing compounds (according to Part 1)

Part 1 – MANUFACTURING ACTIVITIES FOR TESTING COMPOUNDS

1.6 Quality Control

1.6.3 Chemical /physical

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SCOPE OF LICENCE**Appendix 1**

Name and address of business premises:

hameln pharmaceuticals gmbh, Langes Feld 13, 31789 Hameln

Human Medical Products Animal Medical Products

ACTIVITIES PERMITTED

Manufacturing activities (according to Part 1)

Part 1 – MANUFACTURING ACTIVITIES	
1.1	Sterile products
	<i>1.1.1 Aseptically manufactured</i>
	1.1.1.1 Large volume liquid dosage forms
	1.1.1.2. Lyophilisates
	1.1.1.4 Small volume liquid dosage forms
	1.1.1.6 Other aseptically manufactured products Suspensions
	<i>1.1.2 Sterilised in end-product container</i>
	1.1.2.1 Large volume liquid dosage forms
	1.1.2.3 Small volume liquid dosage forms
1.3	Biological drugs
	<i>1.3.1 Biological drugs</i>
	1.3.1.2 Immunological products Inactivated viral vaccines
1.6	Quality control
	<i>1.6.1 Microbiological: sterility</i>
	<i>1.6.2 Microbiological: testing of non-sterile products</i>
	<i>1.6.3 Chemical / physical</i>
	<i>1.6.4 Biological</i>
	Restrictions or clarifications with regard to the manufacturing activities
	Re: 1.1.1.2 Lyophilisates: valid solely for packing, labelling and release, according to the concept of Section 14, paragraph 14 of the Law on Trade with Drugs
	Manufacturing only status does NOT include import.

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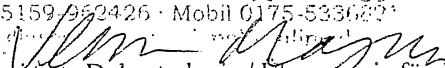
(europ. Sprachen/japanisch/chinesisch)

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SCOPE OF LICENCE

Appendix 2

Name and address of business premises:

hameln pharmaceuticals gmbh, Langes Feld 13, 31789 Hameln

Testing compounds

ACTIVITIES PERMITTED

Manufacturing activities for testing compounds (according to Part 1)

Part 1 – MANUFACTURING ACTIVITIES FOR TESTING COMPOUNDS	
1.1	Sterile Products
	<i>1.1.1 Aseptically manufactured</i>
	1.1.1.1 Large volume liquid dosage forms
	1.1.1.4 Small volume liquid dosage forms
	1.1.1.6 Other aseptically manufactured products Suspensions
	<i>1.1.2 Sterilised in end-product container</i>
	1.1.2.1 Large volume liquid dosage forms
	1.1.2.3 Small volume liquid dosage forms
1.6	Quality control
	1.6.1 Microbiological: sterility
	1.6.2 Microbiological: testing of non-sterile products
	1.6.3 Chemical / physical
	1.6.4 Biological
	Restrictions or clarifications with regard to the manufacturing activities
	Manufacturing only status does NOT include import.

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Allgemein bestellte Dolmetscherin / Übersetzerin für die
Legation und Konsulate des Landes niedersächsisches Hannover

Appendix 3

Addresses of contract manufacturing
companies' business premises

Stegemann Lohnverpackungen &
Logistischer Service e. K.
Up `n Nien Esch 14
48268 Greven

Only packing – secondary packing
(Scope of activity as in Manufacturing
Licence of Stegemann Lohnverpackungen
& Logistischer Service e. K.)

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Appendix 4

Addresses of companies engaged for testing

Labor L+S AG
Gesellschaft für Mikrobiologie und
biologische Qualitätsprüfung
Mangelsfeld 4
97708 Bad Bocklet

Type of test :

- Biological and microbiological level determination
- microbiological determination procedures (total microbial count)
- sterility
- pyrogens
- bacterial endotoxins
- preservation stress test
- identification of micro-organisms
- quality testing of sterile drugs according to pharmacopoeia or authorisation methods
- chemo-physical testing of drugs according to pharmacopoeia or authorisation methods

BioChem GmbH
Labor für biologische und chemische
Analytik GmbH
Daimlerstraße 5b
79185 Karlsruhe

Type of tests:

- Chemo-physical testing of drugs according to pharmacopoeia or authorisation methods.

Currenta GmbH & Co. oHG
CHEMPARK - SUA-BM-SM Geb. Q21
51368 Leverkusen

Type of tests:

- Chemo-physical analyses of sterile drugs according to pharmacopoeia or authorisation methods.

Hameln rds a.s.
Horná 36
90001 Modra
Slovakia

Type of tests:

- Chemo-physical and microbiological analyses of finished products according to pharmacopoeia or stipulated methods, and also stability tests

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Gerichte und Notare des Landgerichtsbezirks Hannover

Appendix 7

Date of the inspection which served
as the basis for granting the licence

14.01.2010

Extent of last inspection

Inspection to establish the filling and packing
of CELVAPAN® influenza vaccine for Baxter (the
company).

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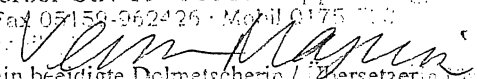
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