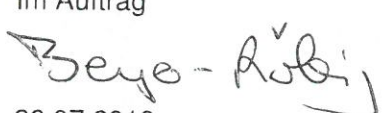


HERSTELLUNGSERLAUBNIS

- | | |
|---|---|
| 1. Nummer der Erlaubnis/Aktenzeichen | DE_HE_01_MIA_2018_0074/II 23.2 (Bey) -18 I 02
(001)- H 16 |
| 2. Name des Erlaubnisinhabers | Jacobi Pharma-Service GmbH & Co. KG |
| 3. Anschrift/en der Betriebsstätte/n des
Herstellers / des Einführers | Jacobi Pharma-Service GmbH & Co. KG
Benzstraße 8
64646 Heppenheim |
| 4. Eingetragene Anschrift des Erlaubnisinhabers | Benzstraße 8
64646 Heppenheim |
| 5. Umfang der Erlaubnis sowie
Darreichungsformen | ANLAGE 1 |
| 6. Rechtsgrundlage der Erlaubniserteilung | § 13 Absatz 1 des Gesetzes über den Verkehr mit
Arzneimitteln (Arzneimittelgesetz - AMG) in
gültiger Fassung |
| 7. Name des verantwortlichen Bearbeiters der
zuständigen Behörde des Mitgliedstaates, der
die Erlaubnis erteilt | Doris Beyer-Röbig |
| 8. Unterschrift | Im Auftrag
 |
| 9. Datum | 26.07.2018 |
| 10. Anlagen | Anlage 1
Anlage 4 (Anschrift/en beauftragter Prüfbetriebe)
Anlage 8 (Liste der Produkte, auf die sich die
Herstellungserlaubnis erstreckt) |



MANUFACTURER'S AUTHORISATION

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

- | | |
|--|---|
| 1. Authorisation number/file number | DE_HE_01_MIA_2018_0074/II 23.2 (Bey) -18 I 02
(001)- H 16 |
| 2. Name of authorisation holder | Jacobi Pharma-Service GmbH & Co. KG |
| 3. Address(es) of manufacturing site(s) | Jacobi Pharma-Service GmbH & Co. KG
Benzstraße 8
64646 Heppenheim |
| 4. Legally registered address of authorisation holder | Benzstraße 8
64646 Heppenheim |
| 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 | Doris Beyer-Röbig |
| 8. Signature | On behalf |
| 9. Date | 26/07/2018 |
| 10. Annexes attached | Annex 1
Annex 4 (Addresses of Contract Laboratories)
Annex 8 (Manufactured products authorised) |

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

Jacobi Pharma-Service GmbH & Co. KG, Benzstraße 8, 64646 Heppenheim

Human Medicinal Products

AUTHORISED OPERATIONS
Manufacturing Operations (according to part 1)

Part 1 - MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i>
	1.2.1.8 Other solid dosage forms
	1.2.1.13 Tablets
1.4	Other products or manufacturing activity
	<i>1.4.1 Manufacture of:</i>
	1.4.1.2 Homeopathic products
1.5	Packaging
	<i>1.5.1 Primary Packing</i>
	1.5.1.8 Other solid dosage forms
	1.5.1.13 Tablets
	<i>1.5.2 Secondary packing</i>
1.6	Quality control testing
	<i>1.6.3 Chemical/Physical</i>

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

List of products and manufacturing steps see current annex 8.
 1.3.1.5 (Homeopathic products) in the context of dosage forms of 1.2.1.13 (Bulkware).
 Ref. to 1.2.1.8: Powder
 Ref. to 1.6.3: Only physical testing

Address(es) of Contract Laboratories

Labor L + S AG
Mangelsfeld 4
97708 Bad Bocklet-Großenbrach
Batch release relevant testing:
- Microbiological testing of non-sterile products

BLS-Analytik GmbH & Co. KG
Columbiastraße 14
97688 Bad Kissingen
batch release relevant testing:
- chemical/physical

Annex 8

Products authorised to be manufactured (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).

siehe aktuelle Anlage 8