LAND BRANDENBURG

Landesamt für Arbeitsschutz,
Verbraucherschutz und
Gesundheit
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_BB_01_MIA_2016_0022/G3-5421.05-Faller/04/31.08.2016
2. Name of authorisation holder	August Faller GmbH & Co. KG
3. Address(es) of manufacturing site(s)	August Faller GmbH & Co. KG Am Wall 5 14979 Großbeeren
4. Legally registered address of authorisation holder	Freiburger Straße 25 79183 Waldkirch
5. Scope of authorisation and dosage forms	ANNEX 1 and 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	Volker Gieskes
8. Signature	On behalf
9. Date	10/17/2016
10. Annexes attached	Annex 1 and Annex 2

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SCOPE OF AUTHORISATION **Annex 1**

Name and address of the site:
August Faller GmbH & Co. KG, Am Wall 5, 14979 Großbeeren

Human 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)

1.5	**Packaging only**
	1.5.2 Secondary packing

SCOPE OF AUTHORISATION **Annex 2**

Name and address of the site:
August Faller GmbH & Co. KG, Am Wall 5, 14979 Großbeeren

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)

1.5	**Packaging only**
	1.5.2 Secondary packing

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