MANUFACTURER'S AUTHORISATION

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

1. Authorisation number/file number	DE_SN_01_MIA_2017_0001/ L24-5117/99
2. Name of authorisation holder	IPC Process-Center GmbH & Co. KG
3. Address(es) of manufacturing site(s)	IPC Process-Center GmbH & Co. KG Grunaer Weg 26 01277 Dresden
4. Legally registered address of authorisation holder	Grunaer Weg 26 01277 Dresden
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	Klaus Hartmann
8. Signature	
9. Date	03/14/2017
10. Annexes attached	Annex 1 Annex 4 (Addresses of Contract Laboratories) Annex 5 (Name of Qualified Person) Annex 8 (Manufactured/ imported products authorised)

SCOPE OF AUTHORISATION **Annex 1**

Name and address of the site:
IPC Process-Center GmbH & Co. KG, Grunaer Weg 26, 01277 Dresden

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)

1.2	**Non-sterile products**
	1.2.1 Non-sterile products
	1.2.1.8 Other solid dosage forms

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

The authorisation applies to premises in accordance wiht floor plans of the current Site Master File SMF-006-03 in a Version registered and approved by the authority.
SMF-006-01 in valid version

to 1.2.1.8
Granulates, coated granulates and pellets as intermediate products and bulkware, no manufacturing of finished dosage forms

Annex 4

Address(es) of Contract Laboratories	synlab Umweltinstitut GmbH Hauptstraße 105 04416 Markkleeberg - wet chemistry - microbiological tests of non-sterile medicinal products (according to monographs 2.6.12 and 2.6.13 of the European Pharmacopoeia) DSG Biotec Umwelt- und Pharmaanalytik GmbH Kirchstrasse 10 83229 Aschau - wet chemistry

Annex 5

Name(s) of Qualified Person(s)	Mr. PhR Eberhard Schubert