MANUFACTURER'S AUTHORISATION

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

1. Authorisation number/file number	DE_BW_01_MIA_2019_0103/DE_BW_01_HWI development
2. Name of authorisation holder	HWI development GmbH
3. Address(es) of manufacturing site(s)	HWI development Straßburger Str. 77 77767 Appenweier
4. Legally registered address of authorisation holder	Straßburger Str. 77 77767 Appenweier
5. Scope of authorisation and dosage forms	ANNEX 1 and ANNEX 2
6. Legal basis of authorisation	Sect 13 para 1 and sect 72 para 1 Arzneimittelgesetz (German Drug Law)
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Dr. Manfred Franck
8. Signature	
9. Date	17/10/2019
10. Annexes attached	Annex 1 and Annex 2 Annex 4 (Addresses of Contract Laboratories)

SCOPE OF AUTHORISATION **Annex 1**

Name and address of the site:
HWI development, Straßburger Str. 77, 77767 Appenweier

Human Medicinal Products Veterinary Medicinal Products

AUTHORISED OPERATIONS Manufacturing Operations (according to part 1) Importation of Medicinal Products (according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms)
	1.2.1.1 Capsules, hard shell
	1.2.1.5 Liquids for external use
	1.2.1.6 Liquids for internal use
	1.2.1.8 Other solid dosage forms
	1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packing
	1.5.1.1 Capsules, hard shell
	1.5.1.5 Liquids for external use
	1.5.1.6 Liquids for internal use
	1.5.1.8 Other solid dosage forms
	1.5.1.13 Tablets
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

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

The authorisation is based on floor plans included in appendix 7 V-02 of SMF V-11.
Retention samples, stability samples and GMP-related documents (including batch records) are kept at the Rastatt facility, Im Steingeruest 30, 76437 Rastatt, as described in appendix 8 V-01 of SMF V-11, too.
Authorised manufacturing covers coated tablets. Other solid dosage forms: powders, granules.
Production of liquid dosage forms is limited to 10 kg batch size.
Authorised secondary packaging also covers other dosage forms except for advanced therapy medicinal products, xenogeneic products, tissue and cell products, medicinal products for use in in-vivo diagnosis by means of marker genes and radiopharmaceuticals.

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS	
2.3	**Other importation activities**
	2.3.1 Site of physical importation

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

Importation activities are restricted to receipt and storage of imported drug products as well as sampling until the responsible importer decides on usage (release).

SCOPE OF AUTHORISATION **Annex 2**

Name and address of the site:
HWI development, Straßburger Str. 77, 77767 Appenweier

Investigational Medicinal Products for Human Use

AUTHORISED OPERATIONS Manufacturing Operations (according to part 1) Importation of Investigational Medicinal Products (according to part 2)

Part 1 - MANUFACTURING OPERATIONS	
1.1	**Sterile Products**
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms)
	1.2.1.1 Capsules, hard shell
	1.2.1.5 Liquids for external use
	1.2.1.6 Liquids for internal use
	1.2.1.8 Other solid dosage forms
	1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packing
	1.5.1.1 Capsules, hard shell
	1.5.1.5 Liquids for external use
	1.5.1.6 Liquids for internal use
	1.5.1.8 Other solid dosage forms
	1.5.1.13 Tablets
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

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

The authorisation is based on floor plans included in appendix 7 V-02 of SMF V-11.
Retention samples, stability samples and GMP-related documents (including batch records) are kept at the Rastatt facility, Im Steingeruest 30, 76437 Rastatt, as described in appendix 8 V-01 of SMF V-11, too.
Authorised manufacturing covers coated tablets. Other solid dosage forms: powders, granules.
Production of liquid dosage forms is limited to 10 kg batch size.
Authorised secondary packaging also covers other dosage forms except for advanced therapy medicinal products, xenogeneic products, tissue and cell products, medicinal products for use in in-vivo diagnosis by means of marker genes and radiopharmaceuticals.

Part 2 - IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported investigational medicinal products**
	2.1.3 Chemical/Physical
2.2	**Batch certification of imported investigational medicinal products**
	2.2.1 Sterile products
	2.2.1.1 Aseptically prepared
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation

Annex 4

Address(es) of Contract Laboratories	HWI ANALYTIK GmbH Rheinzaberner Str. 8 76761 Rülzheim Chemical/physical testing: GC, GC-MS, MS BAV Institut für Hygiene und Qualitätssicherung GmbH Hanns-Martin-Schleyer-Str. 25 77656 Offenburg Microbiological testing BioChem Labor für biologische und chemische Analytik GmbH Daimlerstr. 5b 76185 Karlsruhe Chemical/physical testing Labor LS SE & Co. KG Mangelsfeld 4, 5, 6 97708 Bad Bocklet-Großenbrach Microbiological testing Biological assays Sterility testing Endotoxin testing