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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Centre hospitalier universitaire vaudois (CHUV), Rue du Bugnon 21, 1011 Lausanne,** Authorisation No. 511133-102637946 with its site **Centre hospitalier universitaire vaudois (CHUV), Service de pharmacie, Rue du Bugnon 46, 1011 Lausanne, Switzerland,** Site No. 1100213 has been duly authorised to perform the manufacturing activities according to the table below;

that the company is keeping the required level for Good Manufacturing Practices for Medicinal Products (GMP) according to the Swiss regulations in force. These regulations are in accordance with the requirements for good practices in the manufacture and quality control of the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) as well as with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada and Switzerland;

that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **16.10.2020** (dd.mm.yyyy).

No.	*Operation*	*Scope**
1	**MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)**	
1.1	**Sterile Products**	
1.1.1	Aseptically prepared (processing operations for the following dosage forms)	
1.1.1.1	Large volume liquids	H/V, I
1.1.1.3	Semi-solids	H/V, I
1.1.1.4	Small volume liquids	H/V, I
1.1.1.5	Solids and implants	H/V, I
1.1.2	Terminally sterilised (processing operations for the following dosage forms)	
1.1.2.1	Large volume liquids	H/V, I
1.1.2.2	Semi-solids	H/V, I
1.1.2.3	Small volume liquids	H/V, I
1.1.2.4	Solids and implants	H/V, I
1.1.3	Batch certification (technical release)	H/V, I
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	H/V, I
1.2.1.5	Liquids for external use	H/V, I
1.2.1.6	Liquids for internal use	H/V, I
1.2.1.7	Medicinal gases	H/V
1.2.1.8	Other solid dosage forms	H/V, I
1.2.1.11	Semi-solids	H/V, I
1.2.1.12	Suppositories	H/V, I
1.2.2	Batch certification (technical release)	H/V, I
1.3	**Biological medicinal products**	
1.3.1	Biological Medicinal Products	

Swissmedic | Hallerstrasse 7 | Postfach | CH-3000 Bern 9 | www.swissmedic.ch | Tel. +41 58 462 02 11 | Fax +41 58 462 02 12

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No.	Operation	Scope*
1.3.1.2	Immunological products	H/V, I
1.3.1.5	Biotechnology products	H/V, I
1.3.1.6	Human or animal extracted products	H/V, I
1.3.1.8	Other biological medicinal products: Fecal microbiota transplantation	H/V, I
1.3.2	Batch certification (technical release)	
1.3.2.2	Immunological products	H/V, I
1.3.2.5	Biotechnology products	H/V, I
1.3.2.6	Human or animal extracted products	H/V, I
1.3.2.8	Other biological medicinal products: Fecal microbiota transplantation	H/V, I
1.4	**Other products or manufacturing activity**	
1.4.1	Manufacture of:	
1.4.1.1	Herbal products	I
1.4.2	Sterilisation of active substances / excipients / finished product	
1.4.2.1	Filtration	H/V, I
1.4.2.2	Dry heat	H/V, I
1.4.2.3	Moist heat	H/V, I
1.5	**Packaging**	
1.5.1	Primary packing	
1.5.1.1	Capsules, hard shell	H/V, I
1.5.1.5	Liquids for external use	H/V, I
1.5.1.6	Liquids for internal use	H/V, I
1.5.1.7	Medicinal gases	H/V
1.5.1.8	Other solid dosage forms	H/V, I
1.5.1.11	Semi-solids	H/V, I
1.5.1.12	Suppositories	H/V, I
1.5.2	Secondary packing	H/V, I
1.6	**Quality control testing**	
1.6.1	Microbiological: sterility	H/V, I
1.6.2	Microbiological: non-sterility	H/V, I
1.6.3	Chemical/Physical	H/V, I
1.6.4	Biological	H/V, I
S.1.8	**Blinding of medicinal products for clinical trials**	

* Scope of authorisation:

H/V	Human and veterinary medicinal products, without investigational products
V	Veterinary medicinal products only, without investigational products
I	Human investigational medicinal products
–	Not specified

Berne, **17.12.2020** (dd.mm.yyyy)
No. GMP-CH-1001662

Swiss Agency for Therapeutic Products swissmedic

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M. Baumann

Marianne Baumann

Swissmedic | Hallerstrasse 7 | Postfach | CH-3000 Bern 9 | www.swissmedic.ch | Tel. +41 58 462 02 11 | Fax +41 58 462 02 12


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