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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Cilag AG, Hochstrasse 201, 8200 Schaffhausen,** Authorisation No. 511726-102708351 with its site **Cilag AG, Hochstrasse 201, 8200 Schaffhausen, Switzerland,** Site No. 1000440 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 from the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **18.11.2022** (dd.mm.yyyy) , it is considered that it complies with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada and Switzerland.

That this certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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)	
1.1.1.2	Lyophilisates	H/V, I
1.1.1.4	Small volume liquids	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
1.2.1.13	Tablets	H/V, I
1.2.2	Batch certification (technical release)	H/V, I
1.3	**Biological medicinal products**	
1.3.1	Biological Medicinal Products	
1.3.1.5	Biotechnology products	H/V, I
1.3.2	Batch certification (technical release)	
1.3.2.5	Biotechnology products	H/V, I

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No.	Operation	Scope*
1.4	**Other products or manufacturing activity**	
1.4.2	Sterilisation of active substances / excipients / finished product	
1.4.2.1	Filtration	H/V, I
1.5	**Packaging**	
1.5.1	Primary packaging	
1.5.1.1	Capsules, hard shell	H/V, I
1.5.1.13	Tablets	H/V, I
1.5.2	Secondary packaging	H/V
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
3	**MANUFACTURE OF ACTIVE SUBSTANCES**	
3.1	**Manufacture of active substance by chemical synthesis**	
3.1.1	Manufacture of active substance intermediates	H/V, I
3.1.2	Manufacture of crude active substance	H/V, I
3.1.3	Salt formation / Purification steps: Ultrafiltration, crystallisation, salt formation	H/V, I
3.5	**General finishing steps**	
3.5.1	Physical processing steps: Delumping and homogenisation of intermediates and delumping and homogenisation of active ingredients	H/V, I
3.5.2	Primary packaging	H/V, I
3.5.3	Secondary packaging	H/V, I
3.6	**Quality control testing**	
3.6.1	Physical / Chemical testing	H/V, I
3.6.2	Microbiological: testing (excluding sterility testing)	H/V, I
3.8	List of active substances: Alcaftadine, Amorolfine hydrochloride, Bortezomib, Cladribine, Decitabine, Dimethylfumarate, Dronabinol in sesam oil, Erdafitinib, Iron Sucrose, Remifentanil hydrochloride	-

* 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, **11.08.2023** (dd.mm.yyyy)
No. GMP-CH-1004711

Swissmedic, Swiss Agency for Therapeutic Products

Swiss Agency for Therapeutic Products swissmedic

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