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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Lipomed AG, Fabrikmattenweg 4, 4144 Arlesheim,** Authorisation No. 512651-102669084 with its site **Lipomed AG, Fabrikmattenweg 4, 4144 Arlesheim, Switzerland,** Site No. 1000751 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 **13.01.2022** (dd.mm.yyyy).

No.	*Operation*	*Scope**
1	**MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)**	
1.1	**Sterile Products**	
1.1.3	Batch certification (technical release)	H/V, I
1.2	**Non-sterile products**	
1.2.2	Batch certification (technical release)	H/V, I
1.5	**Packaging**	
1.5.1	Primary packaging	
1.5.1.1	Capsules, hard shell	I
1.5.1.13	Tablets	I
1.5.2	Secondary packaging	H/V, I
1.6	**Quality control testing**	
1.6.3	Chemical/Physical	H/V, I
S.1.8	**Blinding of medicinal products for clinical trials**	-
3	**MANUFACTURE OF ACTIVE SUBSTANCES**	
3.1	**Manufacture of active substance by chemical synthesis**	
3.1.1	Manufacture of active substance intermediates	-
3.1.2	Manufacture of crude active substance	-
3.1.3	Salt formation / Purification steps: Cristallization, Destillation, Chromatography	-
3.2	**Extraction of active substance from natural sources**	
3.2.5	Modification of extracted substance: Plant origin	-
3.2.6	Purification of extracted substance: Plant origin	-

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No.	Operation	Scope*
3.5	**General finishing steps**	
3.5.2	Primary packaging	-
3.5.3	Secondary packaging	-
3.6	**Quality control testing**	
3.6.1	Physical / Chemical testing	-
3.8	List of active substances: Cladribine Deferiprone Canabidiol Lysergic acid diethylamide tartrate	-

* 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, **08.06.2022** (dd.mm.yyyy)
No. GMP-CH-1003265

Swiss Agency for Therapeutic Products
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[redacted]

Marianne Baumann

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