

CERTIFICATE OF GDP COMPLIANCE

We certify herewith

that the company **Doetsch Grether AG, Sternengasse 17, 4051 Basel**, Authorisation No. 511147-102687394 with its site **Doetsch Grether AG, Sternengasse 17, 4051 Basel, Switzerland**, Site No. 1000406 has been duly authorised to distribute medicinal products resp. API / intermediates according to the table below;

that the company is keeping the required level for Good Distribution Practices for Medicinal Products (GDP) according to the Swiss regulations in force. These regulations are in accordance with the requirements of the following documents:

- Guidelines of the European Commission on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01)
- Commission Implementing Regulation (EU) 2021/1248 on Good Distribution Practice for Veterinary Medicinal Products
- Guidelines of the European Commission on Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01)
- Commission Implementing Regulation (EU) 2021/1280 on Good Distribution Practice for active substances for veterinary medicinal products

that the company is subject to official periodic inspections; the last regular inspection has been performed on **14.06.2022** (dd.mm.yyyy).

No.	Operation	Scope*
S.2	IMPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	
S.2.2	Import of ready-to-use medicinal products, including market release	
S.2.2.1	Medicinal products (without immunological and blood products)	H/V, I
S.2.3	Import of ready-to-use medicinal products, excluding market release	
S.2.3.1	Medicinal products (without immunological and blood products)	H/V
S.2.3.4	The import of ready-to-use medicinal products, excluding market release, is restricted to:	
S.2.3.4.2	the import on behalf of the marketing authorisation holder	H/V, I
S.2.5	Storage of medicinal products by sales representatives	H/V, I
The authorised activities do not include the storage of medicinal products		
S.4	WHOLESALE DISTRIBUTION OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	
S.4.2	Wholesale distribution of ready-to-use medicinal products, including market release	
S.4.2.1	Medicinal products (without immunological and blood products)	H/V, I

No.	Operation	Scope*
S.4.5	Storage of medicinal products by sales representatives	H/V, I
S.4.6	Outsourcing of manufacture of medicinal products as contract giver	H/V, I

The authorised activities do not include the storage of medicinal products

* 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, **01.10.2022** (dd.mm.yyyy)
No. GDP-CH-1003558

Swissmedic, Swiss Agency for
 Therapeutic Products



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Jacqueline Büchi

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