



CERTIFICATE OF GDP COMPLIANCE

We certify herewith

that the company **APR Applied Pharma Research SA, Via Giuseppe Corti 5, 6828 Balerna**, Authorisation No. 511474-102695437 with its site **APR Applied Pharma Research SA, Via Giuseppe Corti 5, 6828 Balerna, Switzerland**, Site No. 1000687 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 **18.04.2023** (dd.mm.yyyy).

No.	Operation	Scope*
S.2	IMPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	
S.2.1	Import of non- ready-to-use medicinal products	
S.2.1.1	Medicinal products (intermediates, without immunological and blood products)	H/V
S.2.1.4	Active substances	H/V
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.2.3.4.1	the import for exclusive re-export	H/V
S.2.3.4.2	the import on behalf of the marketing authorisation holder	H/V
The authorised import activities do not include the storage of medicinal products		
S.4	WHOLESALE DISTRIBUTION OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	
S.4.1	Wholesale distribution of non- ready-to-use medicinal products	
S.4.1.1	Medicinal products (intermediates, without immunological and blood products)	H/V

No.	Operation	Scope*
S.4.1.4	Active substances	H/V
S.4.3	Wholesale distribution of ready-to-use medicinal products, excluding market release	
S.4.3.1	Medicinal products (without immunological and blood products)	H/V
The authorised wholesale activities do not include the storage of medicinal products		
S.5	EXPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	
S.5.1	Export of non- ready-to-use medicinal products	
S.5.1.1	Medicinal products (intermediates, without immunological and blood products)	H/V
S.5.1.4	Active substances	H/V
S.5.2	Export of ready-to-use medicinal products	
S.5.2.1	Medicinal products (without immunological and blood products)	H/V
The authorised export 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, **06.06.2023** (dd.mm.yyyy)
No. GDP-CH-1004414

Swissmedic, Swiss Agency for
 Therapeutic Products



J. Büchi

Jacqueline Büchi