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CERTIFICATE OF GDP COMPLIANCE

We certify herewith

that the company **KA Pharmaceuticals SA, , 6900 Lugano,** Authorisation No. 513145-102734124 with its site **KA Pharmaceuticals SA, Via Luganetto 4, 6962 Viganello, Switzerland,** Site No. 1107695 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 **11.10.2024** (dd.mm.yyyy);

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

The authenticity of this certificate may be verified in SwissGMDP. If it does not appear, please contact Swissmedic.

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
S.2.3.4.3	the import of preparations not authorised in Switzerland on behalf of the ordering healthcare professional	H/V

No.	Operation	Scope*
S.2.6	**Outsourcing of manufacture of medicinal products as contract giver**	H/V
The authorised importation operations 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
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
S.4.6	**Outsourcing of manufacture of medicinal products as contract giver**	H/V
The authorised wholesale operations 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.5.3	**Outsourcing of manufacture of medicinal products as contract giver**	H/V
The authorised exportation operations do not include the storage of medicinal products		

* Scope of authorisation:

H/V	Prefix S: Human and veterinary medicinal products/ Prefix ST: Human TpP/GT/GVO, without investigational products
V	Veterinary medicinal products only, without investigational products
I	Prefix S: Human investigational medicinal products/ Prefix: ST: Human Investigational TpP/GT/GVO
-	Not specified

Bern, **07.11.2024** (dd.mm.yyyy)

No. GDP-CH-1006308

Swissmedic, Swiss Agency for Therapeutic Products.