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CERTIFICATE OF GDP COMPLIANCE

We certify herewith

that the company **Mondial Pharma SA, Corso Elvezia 16, 6900 Lugano,** Authorisation No. 511499-102669186 with its site **Mondial Pharma SA, Via Dante Alighieri 10, 6830 Chiasso, Switzerland,** Site No. 1102850 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 **11.07.2024** (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 (without immunological and blood products)	-
S.2.1.2	Immunological products	-
S.2.1.3	Blood products	-
S.2.3	**Import of ready-to-use medicinal products, excluding market release**	
S.2.3.1	Medicinal products (without immunological and blood products)	-
S.2.3.2	Immunological medicinal products	-
S.2.3.3	Blood products	-
S.2.3.4	The import of ready-to-use medicinal products, excluding market release, is restricted to:	

No.	*Operation*	*Scope**
S.2.3.4.1	the import for exclusive re-export	-
S.2.3.4.3	the import of preparations not authorised in Switzerland on behalf of the ordering healthcare professional	-
S.2.3.4.4	the import of medicinal products for clinical trials on behalf of the sponsor for subsequent distribution to the trial centres	-
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 (without immunological and blood products)	-
S.4.1.2	Immunological products	-
S.4.1.3	Blood products	-
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)	-
S.4.3.2	Immunological products	-
S.4.3.3	Blood 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 (without immunological and blood products)	-
S.5.1.2	Immunological products	-
S.5.1.3	Blood products	-
S.5.2	**Export of ready-to-use medicinal products**	
S.5.2.1	Medicinal products (without immunological and blood products)	-
S.5.2.2	Immunological products	-
S.5.2.3	Blood 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, **10.11.2024** (dd.mm.yyyy)

No. GDP-CH-1006321

Swissmedic, Swiss Agency for Therapeutic Products.