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# CERTIFICATE OF GDP COMPLIANCE

We certify herewith

that the company **Unipharma SA, 6900 Lugano,** Authorisation No. 511517-102613927 with its site **Unipharma SA, Figino 6, 6917 Barbengo, Switzerland**, Site No. 1006048 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 Guidelines on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01) of the European Commission and with the requirements of the European GMP Part II (Basic Requirements for Active Substances used as Starting Materials);

that the company is subject to official periodic inspections; the last regular inspection has been performed on **21.03.2019** (dd.mm.yyyy).

| *No.* | *Operation* |
|---|---|
| **S.2** | **IMPORT OF MEDICINAL PRODUCTS (WITHOUT LABILE 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: |
| S.2.3.4.1 | the import for exclusive re-export |
| S.2.3.4.2 | the import on behalf of the marketing authorisation holder |
| 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.4.3** | **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.5.2** | **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 |



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Berne, **11.07.2019** (dd.mm.yyyy)
**No. GDP-CH-1000300**

Swiss Agency for Therapeutic Products swissmedic

Swissmedic, Swiss Agency for
Therapeutic Products

Rosmarie Neeser Zaugg

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
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