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# CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Lonza AG, Lonzastrasse, 3930 Visp,** Authorisation No. 511385-102705531 with its site **Lonza AG, Lonzastrasse, 3930 Visp, Switzerland,** Site No. 1001425 has been duly authorised to perform the manufacturing activities according to the table below;

that the company is keeping the required level for Good Manufacturing Practices for Medicinal Products (GMP) according to the Swiss regulations in force. These regulations are in accordance with the requirements for good practices in the manufacture and quality control of the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) as well as with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada and Switzerland;

that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **19.08.2022** (dd.mm.yyyy).

| *No.* | *Operation* | *Scope** |
|---|---|---|
| **1** | **MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)** | |
| **1.6** | **Quality control testing** | |
| 1.6.2 | Microbiological: non-sterility | H/V, I |
| 1.6.3 | Chemical/Physical | H/V, I |
| 1.6.4 | Biological | H/V, I |
| **3** | **MANUFACTURE OF ACTIVE SUBSTANCES** | |
| **3.1** | **Manufacture of active substance by chemical synthesis** | |
| 3.1.1 | Manufacture of active substance intermediates | H/V, I |
| 3.1.2 | Manufacture of crude active substance | H/V, I |
| 3.1.3 | Salt formation / Purification steps: charcoal treatment, filtration, destillation, centrifugation, crystallization, chromatography | H/V, I |
| **3.3** | **Manufacture of active substance using biological processes** | |
| 3.3.1 | Fermentation | H/V, I |
| 3.3.2 | Cell culture: Mammalian cells | H/V, I |
| 3.3.3 | Isolation / Purification | H/V, I |
| 3.3.4 | Modification | H/V, I |
| 3.3.5 | Other: biotechnology-derived subunit or conjugate vaccines | H/V, I |
| **3.5** | **General finishing steps** | |
| 3.5.2 | Primary packaging | H/V, I |
| 3.5.3 | Secondary packaging | H/V, I |
| **3.6** | **Quality control testing** | |
| 3.6.1 | Physical / Chemical testing | H/V, I |
| 3.6.2 | Microbiological: testing (excluding sterility testing) | H/V, I |
| 3.6.4 | Biological Testing | H/V, I |



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| No. | Operation | Scope* |
|---|---|---|
| 3.8 | List of active substances: afoxolaner, apremilast, avacopan, brentuximab vedotin, brolucizumab, certolizumab pegol, dapaglifiozin propanediol, enfortumab vedotin, esafoxolaner, eslicarbazepine acetate, firocoxib, fluvoxamine maleate, FRPA (GMP intermediate), L-asparaginase (GMP intermediate), lenalidomide, lonapegsomatropin, lufenuron, lumateperone, macitentan, mecasermin, miglustat, momelotinib, olaparib, opicapone, osimertinib mesylate, polatuzumab vedotin, pomalidomide, ranibizumab biosimilar, recombinant adenosine deaminase (GMP Intermediate), repotrectinib, risedronate sodium, rosuvastatin calcium, rucaparib camsylate, saxagliptin, sirolimus, sonidegib diphosphate, tesirine, ticagrelor, tildipirosin, tisotumab vedotin, trastuzumab deruxtecan, trastuzumab emtansine, vandetanib. voclosporin | - |

* 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, **15.06.2023** (dd.mm.yyyy)
**No. GMP-CH-1004462**

Swissmedic, Swiss Agency for Therapeutic Products

Swiss Agency for Therapeutic Products swissmedic

M. Baumann

Marianne Baumann

For certified copy
Visp, 4/10/2023

REPUBLIK UND KANTON WALLIS Marc WYSSEN- Notar VISP

CANTON DU VALAIS
KANTON WALLIS

Présidence du Conseil d'Etat - Chancellerie d'Etat - Unité Logistique

Präsidium des Staatsrates - Staatskanzlei - Abteilung Logistik

# APOSTILLE

(Convention de la Haye du 05 octobre 1961)

1. Country: **Switzerland – State of Valais**

**This public document**

2. has been signed by Me Marc Wyssen

3. acting in the capacity of Notar

4. bears the seal/stamp of Notar in Visp

## CERTIFIED

5. in Sion

6. the 20 October 2023

7. by Carmen Zuber
Assistent of the logistics unit, State office

8. registered under the number **207884**

9. Seal/Stamp:

10. Signature .....

State office of Valais


CHANCELLERIE DU CANTON