

License no. 512123-102700549

## OFFICIAL DECISION

### Establishment license for medicinal products

#### Circumstances

1. Application dated March 9, 2023, number 102700549
2. Applicant: BACHEM AG
3. Reason for the application:
  - Change of the scope of the license
  - Change of Responsible Person
4. Number of the previous license: 512123-102655296

#### Legal bases

- Therapeutic Products Act (TPA, SR 812.21)
- Ordinance on Licensing in the Medicinal Products Sector (MPLO; SR 812.212.1)
- Therapeutic Products Ordinance (TPO; SR 812.212.21)
- Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products (FeeO-Swissmedic, SR 812.214.5)

#### Swissmedic has decided the following:

1. Holder of the establishment license  
**BACHEM AG**  
**Hauptstrasse 144**  
**4416 Bubendorf**
2. This license is numbered 512123-102700549.
3. The license is granted for the following activities:
  - Import of medicinal products
  - Manufacture of medicinal products
  - Wholesale trading in medicinal products
  - Export of medicinal products
  - Trading in medicinal products in foreign countries
4. Number of operating sites: 1
5. The circumstances described in the annexes also apply.
6. The license is valid for an unlimited period from October 26, 2023.
7. Fee: CHF 4000.00

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8. This license replaces the license referred to in the subject line as of the validity date specified in point 6 above.

Berne, October 26, 2023

Swissmedic, Swiss Agency for Therapeutic Products

[signed]

Kathrin Aebischer  
Central Dispatch

**Your contact:**

Inspectorates and Licences Division  
Telephone no. of the secretariat: +41 58 462 04 55

**Information on the right of appeal:**

An appeal against this decision may be lodged within 30 days of notification with the Federal Administrative Court (address: Bundesverwaltungsgericht, Postfach, 9023 St. Gallen) (Art. 31 and 33 (e) of the Federal Law of 17 June 2005 on the Federal Administrative Court; SR 173.32). The appeal document should include the conclusions, the reasons for the remedy being sought with material cited in evidence and the signature of the appellant or the appellant's representative. The disputed decision and the material cited in evidence should be enclosed (Art. 52 of the Federal Law of 20 December 1968 on Administrative Procedure; SR 172.021).

Copies for information:

- Regional Medicines Inspectorate of Northwest Switzerland (RMI)
- Cantonal Pharmacist, Basel-Landschaft

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**Approved activities / Conditions / Restrictions**

| No.          | Designation   | Scope* | RP |
|--------------|---|--------|----|
| <b>S.2</b>   | <b>IMPORT OF MEDICINAL PRODUCTS (EXCLUDING LABILE BLOOD PRODUCTS)</b>   |        |    |
| <b>S.2.1</b> | <b>Import of non-ready-to-use medicinal products</b>  |        |    |
| S.2.1.2      | Immunological medicinal products (intermediates)  | H/V, I | 2  |
| S.2.1.4      | Active substances   | H/V, I | 2  |
| <b>3</b>     | <b>MANUFACTURE OF ACTIVE PHARMACEUTICAL INGREDIENTS</b>   |        |    |
| <b>3.1</b>   | <b>Manufacture of active pharmaceutical ingredients by chemical synthesis</b>   |        |    |
| 3.1.1        | Manufacture of active ingredient intermediates  | H/V, I | 1  |
| 3.1.2        | Manufacture of raw active pharmaceutical ingredients  | H/V, I | 1  |
| 3.1.3        | Salt formation / purification steps: preparative HPLC, ultrafiltration, crystallization, countercurrent distribution  | H/V, I | 1  |
| <b>3.5</b>   | <b>Final production steps</b>   |        |    |
| 3.5.1        | Physical processing steps, lyophilization, drying, milling  | H/V, I | 1  |
| 3.5.2        | Primary packaging   | H/V, I | 1  |
| 3.5.3        | Secondary packaging   | H/V, I | 1  |
| <b>3.6</b>   | <b>Quality control</b>  |        |    |
| 3.6.1        | Chemical/physical analysis  | H/V    | 1  |
| 3.6.2        | Microbiological analysis without sterility control  | H/V    | 1  |
| 3.8          | List of active ingredients: antazoline hydrochloride, antazoline phosphate, antazoline sulfate, aprotinin acetate, atosiban acetate, bivalirudin, buserelin, calcitonin (salmon), deslorelin high acetate, glucagon, gonadorelin acetate, goserelin acetate, histrelin acetate, icatibant acetate, leuprolide acetate, nitisinone, octreotide acetate, somatostatin, tetracosactide, triptorelin acetate, triptorelin pamoate | H/V    |    |
| <b>S.4</b>   | <b>WHOLESALE TRADING (EXCLUDING LABILE BLOOD PRODUCTS)</b>  |        |    |
| <b>S.4.1</b> | <b>Wholesale trading in non-ready-to-use medicinal products</b>   |        |    |
| S.4.1.2      | Immunological medicinal products (intermediates)  | H/V, I | 2  |
| S.4.1.4      | Active ingredients  | H/V, I | 2  |
| <b>S.5</b>   | <b>EXPORT OF MEDICINAL PRODUCTS (EXCLUDING LABILE BLOOD PRODUCTS)</b>   |        |    |
| <b>S.5.1</b> | <b>Export of non-ready-to-use medicinal products</b>  |        |    |
| S.5.1.2      | Immunological medicinal products (intermediates)  | H/V, I | 2  |
| S.5.1.4      | Active ingredients  | H/V, I | 2  |
| <b>S.6</b>   | <b>TRADING IN MEDICINAL PRODUCTS IN FOREIGN COUNTRIES (EXCLUDING LABILE BLOOD PRODUCTS)</b>   |        |    |
| <b>S.6.1</b> | <b>Trading in non-ready-to-use medicinal products in foreign countries, without storage in Switzerland</b>  |        |    |
| S.6.1.2      | Immunological medicinal products (intermediates)  | H/V, I | 2  |
| S.6.1.4      | Active ingredients  | H/V, I | 2  |

\*see last page

**Scope of approved activities (for all annexes)**

- H/V Medicinal products for human or veterinary use, excluding medicinal products for clinical trials
- V Exclusively medicinal products for veterinary use
- I Human medicinal products for clinical trials
- Not specified

## **Annex 1**

### **Operating site 1001480**

BACHEM AG  
Hauptstrasse 144  
4416 Bubendorf

### **Responsible Person(s):**

QP 1  
Morales Rodriguez Peterli Nubia Stella  
Dr. rer. nat., Pharmacist

QP2  
Milejski Dawid  
Pharmacist

## CONFIRMATION

This is to confirm that the English translation of the following document:

Betriebsbewilligung Arzneimittel  
Bewilligung Nr. 512123 -102700549  
Bern, 26.10.2023

is, to the best of my knowledge and ability, a faithful and accurate rendering of the original German text. The translation corresponds in all respects to the wording of the original.

bnp translations ag



Susan Worthington

Basel, 13 November 2023

### LEGALISATION

We hereby certify that the signature of

#### **BMP Translations AG**

of Basel (Switzerland), which is known to us, is genuine, and that the person/s, who signed on its behalf, viz.

#### **Worthington Susan translator**

who is/are personally known to us, is/are authorized to sign jointly/individually.

No. **264789**

tax: **CHF 15.00**

Basel, **13.11.2023**



**LEGALISATION OFFICE OF THE  
CANTON OF BASEL-CITY**

**Nicolas Stucky**



The certification refers exclusively to the signature and not the content or the authenticity of the signed document.