**APOSTILLE**

**(Convention de La Haye du 5 octobre 1961)**

1. **Country :** Sweden

   **This public document**

2. **has been signed by** Anna Bergström

3. **acting in the capacity of** Pharmaceutical Handling Officer

4. **bears the seal/stamp of** Medical Products Agency

**Certified**

5. **at** Stockholm

6. **the** 2020-03-04

7. **by** Adrienne Bonde

   Deputy Notary Public

8. **No.** 2063

9. **Seal/stamp:**

ADRIENNE BONDE * BITR. NOTARIUS PUBLICUS I STOCKHOLM * DNR

10. **Signature:**

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

# Certificate of a Pharmaceutical Product[1]

This certificate conforms, in general, to the format recommended by the World Health Organisation *(explanatory notes are attached)*



No. of Certificate: **5.8.1-2020-10853**

Exporting (certifying) country: **Sweden**

Importing (requesting) country: **Chile**

1. Name, dosage form and strength of the medicinal product:
**Salazopyrin®, tablet, 500 mg**

1.1 Active ingredient(s)[2] and amount(s) per unit dose:[3]

| **Active ingredient** | |
|---|---|
| sulfasalazine | 500,000 mg |

For complete qualitative composition including excipients, see attached.[4]

1.2 Is this product authorised to be placed on the market for use in the exporting country?[5] ☑ Yes ☐ No

If No, why is Marketing Authorisation lacking?

☐ *under consideration* ☐ *refused* ☐ *withdrawn*

2A.1 Marketing Authorisation number:[6] **3017**

Date of Marketing Authorisation: **27 September 1945**

2A.2 Marketing Authorisation Holder (name and address):

**Pfizer AB**
**191 90 Sollentuna**
**Sweden**

2A.3 Status of the Marketing Authorisation Holder:[7]

☐ *a* ☐ *b* ☐ *c* ☑ *d (key in appropriate category as defined in note 7)*

1002002

2A.3.1 For categories b, c and d the name and address of the manufacturing site producing the dosage form are:[8]

**Recipharm Uppsala AB**
**Björkgatan 30**
**751 82 Uppsala**
**Sweden**

2A.4 Is Summary Basis of Approval appended?[9] ☑ No

2A.5 Is the attached, officially approved product information complete and consonant with the Marketing Authorisation?[10] ☑ Yes ☐ Not provided

***The applicant assumes the whole responsibility for the accuracy of the translation of the text from Swedish into English.***

2A.6 Applicant for certificate if different from the Marketing Authorisation Holder (name and address):[11]

**FMD KL Europe LLC**
**3a Hakob Hakobyan Str.**
**Yerevan 0031**
**Republic of Armenia**

3. Does the certifying authority arrange for periodic inspection of the manufacturing site in Sweden in which the dosage form is produced?[12] ☑ Yes ☐ No ☐ N/A
If no or not applicable proceed to question 4.

3.1 Periodicity of routine inspections: Every two to three years

3.2 Has the manufacture of this type of dosage form been inspected? ☑ Yes

3.3 Do the facilities and operations in Sweden conform to GMP in the European Community. (The Commission: Guide to Good Manufacturing Practice for Medicinal Products in the European Community and directives 2003/94/EEC and 91/412/EEC) and as recommended by the World Health Organisation?[13] ☑ Yes ☐ No

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[14] ☑ Yes ☐ No

If no, explain:

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Address of certifying authority:
***Swedish Medical Products Agency***
***Box 26***
***Dag Hammarskjölds väg 42***
***751 03 Uppsala***
***Sweden***
Telephone number: ***+46 (0)18-17 46 00*** Fax number: ***+46(0)18-54 85 66***

On behalf of the Swedish Medical Products Agency

Signature:

Anna Bergström

***Anna Bergström***
***Pharmaceutical Handling Officer***
Stamp and date: ***5 February, 2020***

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY