



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:

10. Signature:





Certificate of a Pharmaceutical Product¹

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☐ withdrawn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)



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

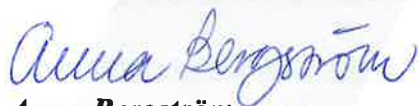
If no, explain:

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

