APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. **Country:** Sweden

   This public document

2. **has been signed by** Gabriel Rudbeck
3. **acting in the capacity of** Notary Public
4. **bears the seal/stamp of** Notary Public in Stockholm

Certified

5. **at** Stockholm
6. **the** 2019-05-16
7. **by** Adrienne Bonde

   Deputy Notary Public
8. **No.** 4267
9. **Seal/stamp:**

ADRIENNE BONDE * BITR NOTARIUS PUBLICUS I STOCKHOLM * BNR * 2012

10. **Signature:**

LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Medical Products Agency

CERTIFICATE NUMBER: ***6.2.1-2017-067843***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Sweden confirms the following:
The manufacturer: ***Recipharm Uppsala AB***
Site address: ***Björkgatan 30, Uppsala, 751 82 Uppsala, Sweden***

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-10-18*** , it is considered that it complies with :

- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/EC .

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

---

[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

LÄKEMEDELSVERKET · MEDICAL PRODUCTS AGENCY

LUDBECK * NOTARIUS PUBLICUS I STOCK

Part 2

Manufacture of active substance. Names of substances subject to inspection :
SULFASALAZINE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES Active Substance : SULFASALAZINE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation Purification steps : drying and milling
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Addition of Povidone and spraydrying 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Clarifying remarks (for public users)

Quality control can also be performed in building 22, Rapsgatan 7, Uppsala. (Analysverksamhet kan även utföras i hus 22, Rapsgatan 7, Uppsala.) Warehousing can also be done at Hyvelgatan 26, Knivsta. (Lagerhållning kan även ske på Hyvelgatan 26, Knivsta.)

2018-01-12

LÄKEMEDELSVERKET MEDICAL PRODUCTS AGENCY

Name and signature of the authorised person of the Competent Authority of Sweden

Bengt Berglund

Mr. Bengt Berglund
Medical Products Agency
Tel: *+46 18 174600*
Fax: *+46 18 548566*

NOTARIUS PUBLICUS I STOCKHOLM