Dr. Falk Pharma GmbH

Certificate of Analysis

Product:	Salofalk 500 mg suppositories
Batch No.:	200173A
Manufacturing date:	02.2020
Expiry date:	02.2023
Production site:	Vifor AG, Zweigniederlassung Medichemie Ettingen Brühlstrasse 50 4107 Ettingen Switzerland
API; Batch No.:	6156

Test	Specification	Result
Appearance	white to cream-coloured torpedo shaped suppositories, even consistency and undamaged smooth surface	conforms
Colour of solution (Ph. Eur. 2.2.2)	not more than BY_3	BY_6
Uniformity of mass (Ph. Eur. 2.9.5)	≥ 18/20: mean value ± 5 % 20/20: mean value ± 10 % none: mean value ± more than 10 %	conforms conforms
Disintegration time (Ph. Eur. 2.9.2)	≤ 25 min	7 min.
Identification (UV)	UV-spectrum of reference solution corresponds to UV-spectrum of sample solution	conforms
Purity * (HPLC)	4-aminophenol ≤ 0.1 % 2,5-dihydroxybenzoic acid ≤ 0.1 % Any unspecified degradation product ≤ 0.1 % Total degradation products ≤ 0.3 %	not determined not determined not determined not determined
Assay (UV)	475-525 mg 5-ASA / suppository (95-105 %)	501 mg/Supp. (100 %)
Microbiological quality (Ph. Eur. 2.6.12/2.6.13)	Total viable aerobic count: Bacteria ≤ 10^3 CFU/g Fungi ≤ 10^2 CFU/g E. coli none/g (according to Ph. Eur. 5.1.4, category 3a)	 < 10 CFU/g < 10 CFU/g absent

* Purity testing is performed in frame of a quality monitoring every 10th batch, at least twice a year

Remarks: We herewith certify that this product is produced according to GMP

Result: ☒ approved ☐ not approved

Freiburg, 08. APR. 2020

Qualified Person

Dr. Falk Pharma GmbH

Batch Certificate

Name of product, strength, dosage form:	Salofalk 500mg Suppositories
Packaging size and type:	5 Suppositories
Importing country:	Chile
Marketing authorisation number:	F-9448/16
Batch number:	200173A
Date of manufacture:	02.2020
Expiry date:	02.2023
Manufacturing site:	Vifor SA, Zweigniederlassung Medichemie Ettingen Brühlstrasse 50 4107 Ettingen Switzerland
Certificate of GMP Compliance:	GMPE-CH-1000874 (Vifor Ettingen)
Results of analysis:	See CoA attached
Comments:	

Certification statement:
I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Dr. Falk Pharma GmbH
Qualified Person

- ☐ Dr. Thomas Fingerhut
- ☒ Dr. Thomas Uhlmann
- ☐ Dr. Rudolf Wilhelm

Date of signature: 08. APR. 2020