Certificate of Analysis

Global name of Pharmaceutical product:	Batch. No.	Page
Mesalazine (30214)	**B39864**	**1 / 2**

Production date	Dispositioned on	Retest date
15 September 2018	**26 September 2018**	**14 September 2021**

Manufacturer	Manufacturing authorization number
Syntese A/S **Industriholmen 11-13** **DK-2650 Hvidovre**	**254604**

Market: **Ferring International Center SA**

Conformity Statement: This product complies with the Ph. Eur. monograph of Mesalazine.

Sealing Numbers:

1/2 119394
2/2 119395

Dispositionstatement: Approved

Test	Test-Method	Specification	Result
Visual appearance	Visual inspection	Almost white, light grey or light pink powder or crystals	Complies
Clarity	Ph. Eur Mesalazine monograph	Clear solution	Solution is clear
Absorbency 440 nm	Ph. Eur Mesalazine monograph	≤ 0.15	< 0.15
Absorbency 650 nm	Ph. Eur Mesalazine monograph	≤ 0.10	< 0.10
Identification	Ph. Eur. Mesalazine monograph	IR spectrum conforms with reference spectrum	Spectra equal to reference standard
Reducing substances	Ph. Eur. Mesalazine monograph	Solution is blue or violetbrown	Blue
Loss on drying	Ph. Eur. Mesalazine monograph	≤ 0.5%	0.15 %
Chloride	Ph. Eur. Mesalazine monograph	≤ 0.1%	0.05 %
Sulphates	Ph. Eur Mesalazine monograph	≤ 200 ppm	≤ 200 ppm

Print Date: 22/02/2019

Dispositionstatement: Approved

Test	Test-Method	Specification	Result
Heavy metals	USP Monograph	≤ 10 ppm	≤ 10 ppm
Sulphated ash	Ph. Eur. Mesalazine monograph	≤ 0.2%	≤ 0.2 %
Assay (calculated on dried basis)	Ph. Eur. Mesalazine monograph	98.5 - 101.5%	100.3 %
Aniline (K)	Manufacturers method 08. 4000.10.10.04	≤ 10 ppm	< LOD
2-Aminophenol (C)	Ph. Eur Mesalazine monograph (HPLC)	≤ 200 ppm	< LOD
4-Aminophenol (A)	Ph. Eur Mesalazine monograph (HPLC)	≤ 200 ppm	< LOD
3-aminosalicylic acid (Impurity F)	Ph. Eur Mesalazine monograph (HPLC)	≤ 0.1%	0.08 %
2,5-dihydroxybenzoic acid (Impurity G)	Ph. Eur Mesalazine monograph (HPLC)	≤ 0.05%	N.D.
Salicylic acid (Impurity H)	Ph. Eur Mesalazine monograph (HPLC)	≤ 0.3%	N.D.
3,5-Diaminosalicylic acid (Impurity J)	Ph. Eur Mesalazine monograph (HPLC)	≤ 0.1%	N.D.
Unspecified impurities	Ph. Eur Mesalazine monograph (HPLC)	≤ 0.05%	N.D.
Total impurities	Ph. Eur Mesalazine monograph (HPLC)	≤ 0.5%	0.08 %

This statement certifies that the above mentioned product has been manufactured and inspected in accordance with the principles defined in the European Commision Guide to Good Manufacturing Practice, Eudralex, vol. 4, GMP part II, the equivalent to ICH Q7.

Warehouse: **Syntese Warehouse** (**SYNT**)

Released by	Release status	Released on	on Location
Karoline Marie Hansen(KARH)	*Approved(A)*	*19/10/2018*	*IN-HOUSE*

The electronic authorisation is the legally binding equivalent of a hand-written signature and done by Qualified Person or person authorised for signature