



Certificate of Analysis

Product name: Erythromycinum
Batch number: 19A11-B06--190641
Base unit: 25g
Expiration date: 22.09.2022
Quality: Ph.Eur.
Manufacturing date: 11.03.2019
Inspection report no.: INS-19-00340
IIN: 100439-114-91

Description	Claim	Result	Unit	Laboratory
Appearance	white or slightly yellow powder or colourless or slightly yellow crystals, slightly hygroscopic	conform		
Identification A	acc. to Ph. Eur.	conform		
Related substances	-impurity C: max. 3,0% -impurity A, B: max. 2,0% -impurity D, E, F, H, M: max. 1,0% -impurity L: max. 0,4% -any other impurity: max. 0,4% -total: max. 7,0%	<0,2 <0,2 <0,2 <0,2 <0,2 <0,2	%	Quercus Labo
Thiocyanate	max. 0,3%	0,02	%	Quercus Labo
Water	max. 6,5%	0,9	%	Quercus Labo
Sulfated ash	max. 0,2%	0,03	%	Quercus Labo
Assay	-sum of erythromycins A, B and C: 93,0 – 102,0% -erythromycin B: max. 5,0% -erythromycin C: max. 5,0%	95,6 0,4 0,8	%	Quercus Labo
Elemental impurities	CHMP/ICH/353369/2013	conform		data producer
Residual solvents	CPMP/ICH/82 260/06	conform		data producer
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	conform		data producer

Analysis performed by the laboratory: Quercus Labo and Fagron Poland.

Release:
Aleksandra Mazanek
Qualified Person

Date of releasing: 15.03.2019

Conclusion: Approved

 Fagron sp. z o.o.
Aleksandra Mazanek
Aleksandra Mazanek
Qualified Person

fagron.pl

Fagron sp. z o.o.
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Sąd Rejonowy dla Krakowa-Śródmieścia XI Wydział Gospodarczy KRS 0000405946 Wysokość kapitału zakładowego: 5050,00 PLN