

Certificate of Analysis

Product name: Colistini sulfas
Batch number: 21D20-B02-204400
Base unit: 100g
Expiration date: 31.08.2023
Quality: Ph. Eur.
Manufacturing date: 06.05.2021
Inspection report no.: INS-21-1983
Manufacturer: LAB. OFICHEM B.V.
Manufacturer's batch number: 2102027.1224

Description	Claim	Result	Unit	Laboratory
Appearance	White to almost white hygroscopic powder	conform		Fagron Poland
Identification B	acc. to Ph. Eur.	conform		Fagron Poland
Identification E	acc. to Ph. Eur.	conform		Fagron Poland
pH	4,0 – 6,0	4,39		Fagron Poland
Related substances	- impurity B: $\leq 4,0\%$ - any other impurity: $\leq 2,5\%$ - total impurities: $\leq 11,0\%$	<0,35 1,16 5,05	%	Fagron Poland
Sulfate	16,0 – 18,0	16,13	%	Fagron Poland
Loss on drying	$\leq 3,5\%$	2,7	%	data producer
Sulfated ash	$\leq 1,0\%$	0,07	%	Fagron Poland
Polymixin E1-I	$\leq 8,5\%$	0,42	%	Fagron Poland
Polymixin E3	$\leq 5,5\%$	3,05	%	Fagron Poland
Polymixin E1-7MOA	$\leq 5,0\%$	4,12	%	Fagron Poland
Polymixin E6	$\leq 4,5\%$	0,96	%	Fagron Poland
Polymixin E1-Nva	$\leq 4,5\%$	0,00	%	Fagron Poland
Sum of polymyxins E4 and E2-Val	$\leq 3,0\%$	1,89	%	Fagron Poland
Polymixin E2-I	$\leq 2,5\%$	0,79	%	Fagron Poland
Polymixin 2,3-dehydro E1	$\leq 1,5\%$	<0,35	%	Fagron Poland
Sum of polymyxins E1,E2,E3,E4,E6, E1-7MOA,E1-I,E1-Nva,E2-I,E2-Val and 2,3-dehydro E1	$\geq 86,0\%$	94,05	%	Fagron Poland
Microbial contamination	-TAMC: ≤ 100 CFU/g -TYMC: ≤ 10 CFU/g	<1 <1	CFU/g	CBMiA
Assay Colistin sulphate	$\geq 19\,000$ IU/ mg	23 392	IU/ mg	data producer
Metallic residues	CHMP/ICH/353369/2013	conform		data producer
TSE/BSE-statement	no contamination with TSE/BSE-risk materials	conform		data producer
Residual solvents	CPMP/ICH/82 260/06	conform		data producer

Release:
 Ewelina Gadzinowska
 Qualified Person



Fagron sp. z o.o.
Ewelina Gadzinowska
 osoba wykwalifikowana
 qualified person

Date of releasing: 12.05.2021
 Conclusion: Approved

fagron.pl

Fagron sp. z o.o.
 ul. Pasternik 26, 31-354 Kraków, NIP: 679 002 64 73, Regon 350013075, BDO 000031662 tel.: (+48) 12 3343 512,
 e-mail: biuro@fagron.pl Konto ING Bank Śląski S.A. nr 36 1050 0086 1000 0090 3014 8499
 Sąd Rejonowy dla Krakowa-Sródmieścia XI Wydział Gospodarczy KRS 0000405946 Wysokość kapitału zakładowego: 5050,00 PLN