

## Certificate of Analysis

**Product name:** Colistini sulfas  
**Batch number:** 20K06-B03-202356  
**Base unit:** 5g  
**Expiration date:** 31.03.2022  
**Quality:** Ph. Eur.  
**Manufacturing date:** 18.11.2020  
**Inspection report no.:** INS-20-04831  
**Manufacturer:** LAB. OFICHEM B.V.  
**Manufacturer's batch number:** 2003012.1224

Description	Claim	Result	Unit	Laboratory
Appearance	White to almost white hygroscopic powder	conform		
Identification B	acc. to Ph. Eur.	conform		
Identification C	acc. to Ph. Eur.	conform		
pH	4,0 – 6,0	4,32		
Related substances	- impurity B: $\leq 4,0\%$	0,00	%	
	- any other impurity: $\leq 2,5\%$	1,26		
	- total impurities: $\leq 11,0\%$	5,80		
Sulfate	16,0 – 18,0	17,12	%	
Loss on drying	$\leq 3,5\%$	2,2	%	data producer
Sulfated ash	$\leq 1,0\%$	0,35	%	
Polymixin E1-I	$\leq 8,5\%$	0,40	%	
Polymixin E3	$\leq 5,5\%$	2,50	%	
Polymixin E1-7MOA	$\leq 5,0\%$	3,64	%	
Polymixin E6	$\leq 4,5\%$	0,82	%	
Polymixin E1-Nva	$\leq 4,5\%$	<0,35	%	
Sum of polymyxins E4 and E2-Val	$\leq 3,0\%$	1,69	%	
Polymixin E2-I	$\leq 2,5\%$	0,76	%	
Polymixin 2,3-dehydro E1	$\leq 1,5\%$	<0,35	%	
Sum of polymyxins E1,E2,E3,E4,E6, E1-7MOA,E1-I,E1-Nva,E2-I,E2-Val and 2,3-dehydro E1	$\geq 86,0\%$	93,36	%	
Microbial contamination	-TAMC: $\leq 100$ CFU/g	<1	CFU/g	
	-TYMC: $\leq 10$ CFU/g	<1		
Assay Colistin sulphate	$\geq 19\,000$ IU/ mg	24 545	IU/ mg	data producer
Metallic residues	CHMP/ICH/353369/2013	conform		data producer
Residual solvents	CPMP/ICH/82 260/06	conform		data producer
Ethanol	< 5000 ppm	<252	ppm	data producer

Release:  
 Ewelina Gadzinowska  
 Qualified Person

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

Date of releasing: 23.11.2020  
 Conclusion: Approved