



Certificate of Analysis

Colistin Sulfate

Catalog Number: CS1005
Lot Number: 0818703
CAS Number: 1264-72-8
Synonym(s): Polymyxin E sulfate
Molecular Formula: $C_{45}H_{85}N_{13}O_{10} \cdot H_2SO_4$
Molecular Weight: 820.61
Storage: 2°C – 8°C
Date of Manufacture: April 6, 2017
Retest Date: April 5, 2020

Test	Specification	Result
Appearance	White to off-white powder	Conforms
Assay (Anhydrous)	≥ 19000 IU/mg	23053 IU/mg
Specific Rotation	-63° to -73°	-71°
Solubility	Freely soluble in water, practically insoluble in 96% ethanol	Conforms
pH	4.0 – 6.0	4.91
Moisture (LOD)	$\leq 3.5\%$	2.4%
Sulfated Ash	$\leq 1.0\%$	0.27%
Sulfate	16.0% - 18.0%	16.7%
Related Substances		
Total Impurities	$\leq 23\%$	15.6%
Any Single Impurity	$\leq 4.0\%$	3.3%
Impurity I	$\leq 3.0\%$	1.6%
Impurity II	$\leq 4.0\%$	1.7%
Impurity III	$\leq 3.0\%$	1.8%
Impurity IV	$\leq 3.0\%$	2.4%
Impurity V	$\leq 3.0\%$	1.2%
Impurity VI	$\leq 4.0\%$	3.3%
HPLC Composition (Anhydrous):		
Polymixins (E1,E2,E3,E1-1, E1-7MOA)	$\geq 77.0\%$	85.4%
Polymixin E3	$\leq 10.0\%$	5.2%
Polymixin E1-1	$\leq 10.0\%$	0.59%
Polymixin E1-7MOA	$\leq 10.0\%$	3.6%

Approved by:

John Grubb, PhD

Date: August 22, 2017



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