

Specification

Formula Hill: C₅₃H₁₀₂N₁₆O₁₇S
Molar Mass:
CAS N°: 1264-72-8

Print Date: 11 October 2022

104011 Colistin sulfate Ph. Eur.

	Specifications
Content (dried substance)	≥ 19.000 IU/mg
Identity	conforms
Composition	
- Polymyxin 2,3-dehydro E1	≤ 1,5 %
- Polymyxin E1-7MOA	≤ 5,0 %
- Polymyxin E1-I	≤ 8,5 %
- Polymyxin E1-Nva	≤ 4,5 %
- Polymyxin E2-I	≤ 2,5 %
- Polymyxin E3	≤ 5,5 %
- Polymyxin E6	≤ 4,5 %
- Sum of polymyxins	≥ 86,0 %
- Sum of polymyxins E4 and E2-Val	≤ 3,0 %
Appearance	
- White or almost white	conforms
- Hygroscopic powder	conforms
pH	4,0 - 6,0
Solubility	conforms
Sulfate (SO ₄)	16,0 - 18,0 %
Related substances	
- Impurity B	≤ 4,0 %
- Any other impurity (for each)	≤ 2,5 %
- Total impurities	≤ 11,0 %
- Impurities exceed 1.0%	≤ 4
Loss on drying	≤ 3,5 %
Sulfated ash	≤ 1,0 %

The product cannot be considered as an Active Pharmaceutical Ingredient (API)

Conforms to: Ph. Eur. specification