



Specification

Gentamicin Sulfate USP/EP

Catalog Number:	GS1006
CAS Number:	1405-41-0
Molecular Formula:	C ₂₁ H ₄₃ N ₅ O ₇
Molecular Weight:	477.60
Storage:	2°C – 8°C
Retest Period:	Four years from the date of manufacture

Test	Specification
Appearance (EP)	White to off-white, hygroscopic powder.
Potency (Dry Basis, USP)	≥ 590µg/mg
Potency (Dry Basis, EP)	≥ 590IU/mg
Identification A (FTIR, USP)	To match reference spectra
Identification B (Sulfates, USP)	Reaction indicative of sulfates.
First Identification (EP) B Chromatography	5 principal peaks on the chromatogram match the reference solution.
C Sulfates	Reaction indicative of sulfates.
Second Identification (EP) A TLC	3 principal spots on the chromatogram match the reference solution.
C Sulfates	Reaction indicative of sulfates.
Sulfate (EP)	32.0 – 35%
Solubility (EP)	Freely soluble in water, practically insoluble in ethanol
Appearance of Solution (EP)	Clear, color intensity ≤ 6 of the range of reference solutions.
Specific Rotation (c=1, USP/EP)	+107.0 to +121.0°
pH (40mg/mL, USP/EP)	3.5 – 5.5
Composition:	
C1a (USP)	10 – 35%
C2+C2a (USP)	25 – 53%
C2b+C1 (USP)	25 – 50%
C1 (EP)	25 – 45%
C1a (EP)	10 – 30%
C2+C2a+C2b (EP)	35 – 55%
Moisture (LOD, USP)	≤ 18%
Moisture (LOD, EP)	≤ 15%
Residue on Ignition (USP)	≤ 1.0%
Sulfated Ash (EP)	≤ 1.0%
Limit of Methanol (USP/EP)	≤ 1.0%



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Related Substances (EP)	
Impurity A (Sisomicin)	≤ 3.0%
Impurity B (Garamine)	≤ 3.0%
Any other Impurity	≤ 3.0%
Total impurities	≤ 10.0%
Endotoxin (USP/EP)	≤ 0.71IU/mg
Total Microbial Count EP (Aerobic+Yeast+Mold)	≤ 100cfu/g
Particle Size	< 10 mm > 60% < 20 mm > 75%
This lot meets the specifications for USP40 and EP9.0.	

Approved:

Date: September 12, 2018

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