

PRODUCT: GENTAMYCIN SULFATE

ITEMS	SPECIFICATIONS
CHARACTERISTICS	White or almost white, hygroscopic powder, freely soluble in water, practically insoluble in ethanol
IDENTIFICATION	C. The chromatogram obtained with test solution (b) shows 5 principal peaks having the same retention times as the 5 principal peaks in the chromatogram obtained with reference solution (a) D. It gives reaction (a) of sulphates
APPEARANCE OF SOLUTION	Solution S is clear and not more intensely coloured than intensity 6 of the reference solution
PH	3.5~5.5 (40mg/ml solution)
SPECIFIC OPTICAL ROTATION	+107° ~ +121° (anhydrous substance)
COMPOSITION	
<ul style="list-style-type: none"> ➤ Gentamicin C1 ➤ Gentamicin C1a ➤ Gentamicin C2+C2a+C2b 	<p>25.0%~45.0%</p> <p>10.0%~30.0%</p> <p>35.0%~55.0%</p>
RELATED SUBSTANCES	
<ul style="list-style-type: none"> ➤ Impurity A (Sisomicin) ➤ Impurity B (Garamine) ➤ Any other impurity ➤ Total impurities 	<p>NMT 3.0%</p> <p>NMT 3.0%</p> <p>NMT 3.0%</p> <p>NMT 10.0%</p>

METHANOL	NMT 1.0%
SULPHATE	32.0% ~ 35.0% (anhydrous substance)
WATER	NMT 15.0%
SULPHATED ASH	NMT 1.0%
BACTERIAL ENDOTOXINS	Less than 0.71 IU/mg
ASSAY (anhydrous substance)	Not less than 590 IU/mg
MICROBIAL LIMIT	
a) Total aerobic microbial count	NMT 100 cfu/g
b) Total yeast and mould count	NMT 10 cfu/g