



## SPECIFICATION

### Gentamicin sulphate (EP8.0)

<b>Aspect</b>	White or almost white powder
<b>Formula</b>	$C_{22}H_{24}N_2O_9 \cdot HCl$

<b>Properties</b>	
Identification	B)The chromatogram obtained with the test solution shows 5 principal peak having the same retention times as the 5 principal peaks in the chromatogram obtained with reference solution
	C)It gives reaction (a) of sulfates
Specific optical rotation	$+107^\circ \sim +121^\circ$
pH	3.5 – 5.5
Appearance of solution	Clarity :clear
	Colour : Not more intensely coloured than intensity 6 of the range of reference solutions of the most appropriate colour.
Methanol	Maximum 1.0 %
Composition(HPLC)	C1: 25.0%-45.0%
	C <sub>1a</sub> : 10.0%-30.0%
	C <sub>2a</sub> +C <sub>2</sub> +C <sub>2b</sub> : 35.0%-55.0%
Water	Maximum 15.0%
Sulphated ash	Maximum 1.0 %
Sulphate (anhydrous)	32.0 – 35.0 %
Related Substances	Impurities A: Max 3.0%
	Impurities B: Max 3.0%
	Any other impurity: Max 3.0%
	Total: Max 10.0%
Assay	$\geq 590$ IU/mg (anhydrous)
Solubility	Freely soluble in water, practically insoluble in alcohol and in ether..



Expiry Date	Four years after production date
Storage	In an airtight container
Transport information	See our latest safety data sheet
Safety data sheet	Yes
Classified as hazardous as per EU regulation	See our latest safety data sheet