

SPECIFICATION

Framyctin sulfate (EP8.0)

Aspect	White or yellowish-white powder
Formula	$C_{23}H_{46}N_6O_{13} \cdot xH_2SO_4$

Properties	Properties	
Identification	A.(1)The retention time of a major peak meets the requirements. (2)Impurity C meets the requirements B: Positive	
рН	6.0 - 7.0	
Specific optical rotation	+52.5° - +55.5°	
Related substances	Impurity A: NMT 1.0 %	
	Impurity C: NMT 3.0 %	
	Total of other impurities: NMT 3.0 %	
Sulfate(anhydrous)	27.0% –31.0%	
Loss on drying	NMT 8.0 %	
Sulfated ash	NMT 1.0 %	
Sterility	Meets the requirements	
Bacterial endotoxins	Less than 1.3 IU/mg	
Potency	NLT 630 IU/mg (dried substance)	
Solubility	Very soluble in water, very slightly soluble in alcohol, practically insoluble in acetone.	
Expiry Date	Tree and a half years after production date	
Storage	In an airtight container, protected from light.	
Transport information	See our latest safety data sheet	
Safety data sheet	Yes	



Classified as hazardous	Saa our latest safety data sheet
as per EU regulation	See our latest safety data sheet