

Specification

Item		Specification	Method
Characteristic	Appearance	White or off-white solid powder	Visual
	Solubility	Soluble in water	ChP
Identification	(1) In the chromatogram recorded in assay, the retention time of the main peak of the test solution shall be consistent with that of the control solution.	Internal standard	
	(2) Shall show the identifying reaction of potassium salt.	ChP	
Acidity	The pH value shall be 5.5-6.5	ChP	
Clarity and color	Shall be clear and colorless. If color is developed, it shall not be darker than No. 0.5 yellow standard colorimetric solution.	ChP	
Chloride	$\cong 0.01\%$	Internal standard	
Sulfate	$\cong 0.01\%$	ChP	
Related substance	Sucrose heptasulfate potassium salt $\cong 0.10\%$	Internal standard	
Residual solvents	Methanol $\cong 0.3\%$ Acetonitrile $\cong 0.041\%$ Pyridine $\cong 0.02\%$ 2-methylpyridine $\cong 0.02\%$	Internal standard	
Water content	$\cong 10.0\%$	ChP	
Heavy metal	$\cong 5\text{ppm}$	ChP	
Arsenate	$\leq 0.0002\%$	ChP	
Microbial limit	Total count of aerobic bacteria $\cong 10^3\text{cfu/g}$ Total count of mold and yeast $\cong 10^2\text{cfu/g}$ Escherichia coli shall not be detected per 1g	ChP	
Bacterial endotoxin	$< 100\text{EU/g}$	ChP	
Assay	On anhydrous basis, the content of $\text{C}_{12}\text{H}_{14}\text{K}_8\text{O}_{35}\text{S}_8$ shall be 95.0% ~ 105.0%	Internal standard	