

ZHEJIANG HUAKANG PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS



NUMBER: ZC221513

Product		SORBITOL (HKSD40)		Batch No.	SD2253704
Quantity				Production date	15 Nov 2025
Expiry date		14 Nov 2028		Test date	16 Nov 2025
Items			Specification		Result of inspection
Appearance			white or almost white, crystalline powder.		white crystalline powder.
Solubility			Very soluble in water, practically insoluble in 96% ethanol		Conforms
Appearance of solubility			Clear and colourless		Conforms
Identification			The principal peak is similar with the reference		Conforms
Assay		%	97.0~102.0		98.0
Related substances	Any impurity	%	≤ 2.0		1.4
	Total	%	≤ 3.0		2.5
Water		%	≤ 1.5		0.21
Reducing sugars		%	≤ 0.2		0.06
Chloride		%	≤ 0.0050		< 0.0050
Sulfate		%	≤ 0.01		< 0.01
Conductivity		$\mu\text{S}/\text{cm}$	≤ 10		2.2
pH			3.5-7.0		5.50
Nickel		ppm	≤ 1		< 1
Lead		ppm	≤ 0.5		< 0.5
TAMC		cfu/g	≤ 1000		< 10
TYMC		cfu/g	≤ 100		< 10
Bacterial endotoxin		IU/g	≤ 4.0		< 4.0
Consult Standard			Conforms to USP41/EP9.0		

Approved by: *Yuhua Zhu* Reviewed by: *Lingmei You* Prepared by: *Kaili Jiang*