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浙江圣达药业有限公司
Zhejiang Shengda Pharmaceutical Co. Ltd.

CERTIFICATE OF ANALYSIS

Product name: D-Biotin

Batch number	20121035	Test No.	0212383
Expiry date	Oct.20,2015	Report date	Oct.27,2012
Manufacturing date	Oct.21,2012	Submitted date	Oct.24,2012
Package	10Kg per carton	Batch size	200Kg
Ref. pharmacopocia(s)	EP7	Quantity	100Kg

Test Items		Specification	Results
Characters		A white or almost white,crystalline powder or colourless crystals.	A white crystalline powder
Identification	A: IR spectrophotometry	To match with the reference IR spectrum	Conform
	B: Examine the chromatograms obtained in the test for related substances	The principal spot in the chromatogram obtained with test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution	Conform
	C: Color reaction	The bromine water is decolourised	Conform
Appearance of solution		Clear and colourless	Conform
Specific optical rotation		+89°~ +93°	+90.3°
Related substances		Meets EP requirement	Conform
Heavy metals		≤10ppm	<10ppm
Loss on drying		≤1.0%	0.04%
Sulphated ash		≤0.1%	0.07%
Assay		98.5% ~ 101.0%	100.2%
Mesh size		100% pass 300 Mesh	
Conclusion: This batch complies with the specification of EP7			

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