

检验项目 Item	标准规定 Specification	检验结果 Results
性状 Appearance	白色或类白色粉末 White or off-white powder	白色粉末 white powder
鉴别 Identification	本品的红外吸收图谱应与对照品的图谱一致 The IR absorption spectrum of sample is concordant with the Reference Standard Spectrum	符合要求 Confirmed
水分 Water	不得过 0.5% NMT 0.5%	0.04%
比旋度 Specific optical rotation	-61° — -64° -61°to -64°	-61°
残留溶剂 Residual solvent	甲基叔丁基醚不得过 0.5% Tert-Butyl Methyl Ether NMT 0.5%	0.02%
	— 氯甲烷不得过 0.06% Dichloromethane NMT 0.06%	0.01%
炽灼残渣 Residue on ignition	不得过 0.1% Not more than 0.1%	0.08%
有关物质 Related substances	任意未知单杂不得过 0.1% Any unknown individual impurity NMT 0.1%	未检出 N.D
	R,R-异构体及 S,S-异构体之和不得过 0.3% Sum of (R,R-isomer and S,S-isomer) NMT 0.3%	0.07%
	总杂不得过 0.5% Total impurities NMT 0.5%	未检出 N.D
光学异构体 Optical isomer	R,S-异构体不得过 0.15% R,S-isomer NMT 0.15%	0.01%
	R,R-异构体不得过 0.15% R,R-isomer NMT 0.15%	0.01%
	S,S-异构体不得过 0.15% S,S-isomer NMT 0.15%	0.04%
重金属 Heavy metals	不超过 0.002% not more than 0.002%	符合要求 Confirmed
含量 Assay	98.0%至 102.0% 98.0 per cent to 102.0 per cent	99.3%