

Items	Specification	Testing result
Identification	Infrared Absorption: Corresponding to the Spectrum of Reference standard HPLC: The retention time of major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay	Conform
Appearance	White to off-white powder	Conform
Specific rotation	+13° ~ +18°	+13.8°
Residue on ignition	0.5%max	0.08%
S-Isomers (HPLC)	0.5%max	0.03%
Related substance		
-SUIb-0	0.5%max	0.35%
-Individual unspecified impurity	0.1%max	0.04%
-Total impurities	1.0%max	0.39%
Loss on drying	1.0%max	0.21%
Assay(Dried basis)/HPLC	98.0% ~ 102.0%	99.5%
Residual solvents/ <u>GC-HS</u>		
-Toluene	890ppm max	270ppm
- <u>Dichloromethane</u>	600ppm max	ND
Conclusion	Conform to quality specification.	