

SPECIFICATION

Tests	Specifications
Appearance	White powder
Clarity of solution	5 mmol in 10ml DMF clear solution
Identification (MS) (mu)	Monoisotopic mass 425.5 ± 0.5
Identification (UPLC)	Coelutes with reference standard when the sample and standard solutions are coinjected (1:1, v/v)
Purity(UPLC) (%)	≥99.0 N N N
Impurities (UPLC) (%)	Fmoc-β-Ala-OH≤0.3
	Fmoc-β-Ala-Glu(OtBu)-OH≤0.3
	Fmoc-Glu(OtBu)-Glu(OtBu)-OH≤0.3
	Fmoc-Glu-OH≤0.3
	each single unspecified≤0.5
Impurity (TLC) (%)	H-Glu(OtBu)-OH≤0.2
Specific Rotation[a] ²⁰	-18.0° ± 2.0° (C = 1 in DMF)
Chiral Impurity (HPLC) (%)	≤0.2
Water Content (K.F.) (%)	≤ 6.0 90.0-105.0
Assay (Titration) (%)	90.0-105.0 CAO
Ethyl Acetate (%)	≤0.5
Acetate (IC) (%)	≤0.2
Identification (MS)	In accordance with the standard
Identification (NMR)	In accordance with the standard

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