SOMATOSTATIN
DRUG SUBSTANCE SPECIFICATION

PolyPeptide GROUP

Molecular weight: 1638.1 (free peptide)

Sequence: H-Ala-Gly-Cys-Lys-Asn-Phe-Phe-Trp-Lys-Thr-Phe-Thr-Ser-Cys-OH

Last update: 09 JUN 2018

Available registration documents (CTD format): DMF, CEP/COS certificate

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Appearance	White to off-white powder	Visual inspection
Solubility	Soluble in water at a concentration of 6 mg/mL to give a clear, colorless solution	Visual inspection
Identity, AAA		Ph. Eur.
	Asx 0.90-1.10 Thr 1.4-2.1 Ser 0.7-1.05 Gly 0.90-1.10 Ala 0.90-1.10 Cys 1.4-2.1 Phe 2.7-3.3 Lys 1.8-2.2	
Identity, HPLC	Co-elutes with reference standard	Ph. Eur.
Peptide purity, HPLC	≥ 98 % (area %)	Ph. Eur.
Related substances, HPLC		Ph. Eur.
Total sum	≤ 2 %	
Any single impurity	≤ 0.5 %	
Assay, HPLC	For information	Ph. Eur.
Acetic acid, HPLC	3.0 % to 10.0 %	In-house
Water, Karl Fischer	≤ 8.0 %	Ph. Eur.
Somatostatin content (With reference to the anhydrous and acetic acid-free substance)	95.0 % to 104.0 %	Calculation

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TEST	**ACCEPTANCE CRITERION**	**ANALYTICAL PROCEDURE**
Specific optical rotation $[\alpha]_D^{20}$ (c = 0.2, 1% acetic acid) (with reference to the anhydrous and acetic acid-free substance)	-37 to -47	Ph. Eur.
Residual solvents, GC/HS		In-house
Methanol	≤ 1000 ppm	
Ethanol	≤ 1000 ppm	
Acetonitrile	≤ 400 ppm	
Triethylamine	≤ 500 ppm	
N,*N*-Dimethylformamide	≤ 880 ppm	
Trifluoroacetic acid, HPLC	≤ 0.25 %	In-house
Phosphate, IC	≤ 0.1 %	In-house
Bacterial endotoxins	≤ 10 EU/mg	Ph. Eur.