

**SOMATOSTATIN
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 1638.1 (free peptide)

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

Last update: 08 SEP 2020

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	<table border="0"> <tr><td>Asx</td><td>0.90-1.10</td></tr> <tr><td>Thr</td><td>1.4-2.1</td></tr> <tr><td>Ser</td><td>0.7-1.05</td></tr> <tr><td>Gly</td><td>0.90-1.10</td></tr> <tr><td>Ala</td><td>0.90-1.10</td></tr> <tr><td>Cys</td><td>1.4-2.1</td></tr> <tr><td>Phe</td><td>2.7-3.3</td></tr> <tr><td>Lys</td><td>1.8-2.2</td></tr> </table>	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	Ph. Eur.
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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 ¹	≤ 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																

¹ Detailed impurity specification not provided

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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 Organic Solvents, GC/HS		In-house
Methanol	≤ 1000 ppm	
Ethanol	≤ 1000 ppm	
Acetonitrile	≤ 400 ppm	
Triethylamine	≤ 500 ppm	
<i>N,N</i> -Dimethylformamide	≤ 880 ppm	
Trifluoroacetic acid, HPLC	≤ 0.25 %	In-house
Phosphate, IC	≤ 0.1 %	In-house
Bacterial endotoxins	≤ 10 EU/mg	Ph. Eur.