

**SOMATOSTATIN (CYCLIC)  
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 1638.1 (free peptide)

Page 1 of 3

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

Last update: 30 AUG 2007

Available registration documents (CTD format): EU DMF

Please note that regional minor differences in analytical procedures and acceptance criteria might occur.

TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
<b>CHARACTERS</b>		
Appearance	White to off-white amorphous powder	Visual inspection
Solubility	Soluble in water at a concentration of 6 mg/mL to give a clear colorless solution	Ph.Eur.
<b>IDENTIFICATION</b>		
Identification, MS	Monoisotopic mass 1636.7 ± 1	Ph.Eur.
Amino acid analysis	Asx: 0.90 to 1.10 Thr: 1.4 to 2.1 Ser: 0.7 to 1.05 Gly: 0.90 to 1.10 Ala: 0.90 to 1.10 Cys: 1.4 to 2.1 Phe: 2.7 to 3.3 Lys: 1.8 to 2.2 Trp: 0.3 to 1.1	Ph. Eur.
Identification, TLC	The R <sub>f</sub> value of the sample corresponds to the reference standard	Ph.Eur.
Identification, HPLC	Co-elutes with reference standard	In-house

**SOMATOSTATIN (CYCLIC)  
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 1638.1 (free peptide)

Page 2 of 3

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

Last update: 30 AUG 2007

Available registration documents (CTD format): EU DMF

Please note that regional minor differences in analytical procedures and acceptance criteria might occur.

TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
<b>PURITY</b>		
Peptide purity, HPLC:	≥ 98%	In-house
Related substances, HPLC:		In-house
Total amount	≤ 2%	
Any individual impurity	≤ 1%	
<b>ASSAY</b>		
Mass balance	95.0 to 103.0%	Calculation
<b>OTHER TESTS</b>		
Acetic acid	3.0 to 10.0%	In-house
Water	≤ 8%	USP/Ph.Eur.
Specific optical rotation [ $\alpha$ ] <sub>D</sub> <sup>20</sup> (c = 0.2, 1% acetic acid)	-37 to -47 (with reference to the anhydrous and acetic acid- free substance)	Ph.Eur.
UV absorbance (280 nm, 5 mg/100 mL, 0.9% NaCl)	≤ 0.20 (corrected for peptide content)	Ph.Eur.
Trifluoroacetic acid	≤ 0.25%	In-house
Inorganic fluoride	≤ 0.1%	In-house

**SOMATOSTATIN (CYCLIC)  
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 1638.1 (free peptide)

Page 3 of 3

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

Last update: 30 AUG 2007

Available registration documents (CTD format): EU DMF

Please note that regional minor differences in analytical procedures and acceptance criteria might occur.

<b>TEST</b>	<b>ACCEPTANCE CRITERIA</b>	<b>ANALYTICAL PROCEDURE</b>
<b>RESIDUAL SOLVENTS</b>		
Any individual residual solvent	≤ 0.1%	In-house
<b>MICROBIOLOGICAL TESTS</b>		
Total viable aerobic count	Report value (CFU/g)	In-house
Bacterial endotoxins	≤ 10 IU/mg	USP/Ph.Eur.