

**VASOPRESSIN, 8-L-ARGININE
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 1084.2 (free peptide)

Page 1 of 2

Sequence: H-Cys-Tyr-Phe-Glu(NH₂)-Asp(NH₂)-Cys-Pro-Arg-Gly-NH₂

Last update: 30 AUG 2007

Available registration documents (CTD format): None, the substance is sold based on its CoA
Please note that regional minor differences in analytical procedures and acceptance criteria might occur.

TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
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CHARACTERS

Appearance	White or almost white amorphous powder. A solution of the material in water must be clear and colourless.	Visual inspection
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IDENTIFICATION

Identification, HPLC	Retention time of the sample must be approximately the same as the retention time of the reference	USP
Amino acid analysis	Asp: 0.9 to 1.1 Glu: 0.9 to 1.1 Gly: 0.9 to 1.1 Pro: 0.9 to 1.1 Tyr: 0.9 to 1.1 Phe: 0.9 to 1.1 Arg: 0.9 to 1.1 Halfcysteine: Identified	In-house

PURITY

Peptide purity, HPLC:	> 95%	USP
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ASSAY

Potency, HPLC	≥ 300 IU/mg	USP
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TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
OTHER TESTS		
Acetic acid	≤ 15%	In-house
Water	≤ 8%	USP/Ph.Eur.
Trifluoroacetic acid	< 0.3%	In-house
RESIDUAL SOLVENTS		
Ethanol	≤ 0.5%	In-house
Methanol	≤ 0.3%	In-house
MICROBIOLOGICAL TESTS		
Total viable aerobic count	< 200 CFU/g	Ph.Eur.
Bacterial endotoxins	≤ 17.0 IU endotoxin/IU vasopressin	USP/Ph.Eur.