

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



Molecular weight: 1084.2 (free peptide)

Page 1 of 2

Sequence: H-Cys-Tyr-Phe-Gln-Asn-Cys-Pro-Arg-Gly-NH₂

Last update: 07 JUN 2018

Available registration documents (CTD format): DMF

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE																
Appearance	White to off white powder or flakes	Visual inspection																
Identification, HPLC	The retention time of the vasopressin peak of the sample solution corresponds to that of the standard solution	In-house																
Identification, MS	Contain peaks with mass-to-charge ratios of 1084.4 ± 0.5 and 542. ± 0.5	USP																
Identification, AAA	<table style="margin-left: 40px; border: none;"> <tr><td>Asx</td><td>0.9 to 1.1</td></tr> <tr><td>Glx</td><td>0.9 to 1.1</td></tr> <tr><td>Gly</td><td>0.9 to 1.1</td></tr> <tr><td>Tyr</td><td>0.9 to 1.1</td></tr> <tr><td>Phe</td><td>0.9 to 1.1</td></tr> <tr><td>Arg</td><td>0.9 to 1.1</td></tr> <tr><td>Cys</td><td>Identified</td></tr> <tr><td>Pro</td><td>0.9 to 1.1</td></tr> </table>	Asx	0.9 to 1.1	Glx	0.9 to 1.1	Gly	0.9 to 1.1	Tyr	0.9 to 1.1	Phe	0.9 to 1.1	Arg	0.9 to 1.1	Cys	Identified	Pro	0.9 to 1.1	USP
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Arg	0.9 to 1.1																	
Cys	Identified																	
Pro	0.9 to 1.1																	
Vasopressin content calculated with reference to the anhydrous, acetic acid free substance ¹⁾	95.0-105.0%	Calculation																
Vasopressin content of the total mass of substance, HPLC	≥ 72.0%	In-house																
Purity related impurities, HPLC		In-house																
Total impurities	≤ 3.0%																	
Trifluoroacetic acid content, IC	≤ 0.3%	In-house																
Acetic acid content, IC	≤ 15.0%	In-house																
Water content, KF	≤ 8.0%	USP																

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TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Specific optical rotation [α] _D ²⁵ , 5 mg/mL, 1% acetic acid	-28 to -18	USP
Residual solvents, GC		In-house
Ethanol	≤ 5000 ppm	
Methanol	≤ 3000 ppm	
Total viable aerobic count (TAMC)	≤ 100 CFU/g	USP
Total yeast and mould count (TYMC)	≤ 50 CFU/g	USP
Bacterial endotoxins	≤ 100 EU/mg	USP

¹⁾ Vasopressin content calculated with reference to the anhydrous, acetic acid free substance (%) = Vasopressin content of the total mass of substance (%) / (100% – Acetic acid content (%) – Water content (%)) × 100.