VASOPRESSIN, 8-L-ARGININE
DRUG SUBSTANCE SPECIFICATION

PolyPeptide GROUP

Molecular weight: 1084.2 (free peptide)

Sequence: H-Cys-Tyr-Phe-Gln-Asn-Cys-Pro-Arg-Gly-NH_2

Last update: 19 SEP 2019

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 542.7 ± 0.5	USP
Identification, AAA	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
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	≥ 78.0%	In-house
Purity related impurities, HPLC		In-house
Total impurities	≤ 3.0%	
endo-Gly^{9a}-vasopressin	≤ 0.50%	
des-Gly-vasopressin	≤ 0.30%	
N-acetyl vasopressin	≤ 1.0%	
Any unspecified impurity	≤ 0.10%	

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Trifluoroacetic acid content, IC	≤ 0.3%	In-house
Acetic acid content, IC	≤ 15.0%	In-house
Water content, KF	≤ 8.0%	USP
Specific optical rotation $[\alpha]_D^{25}$, 5 mg/mL, 1% acetic acid	-26 to -20	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.