DESMOPRESSIN US
DRUG SUBSTANCE SPECIFICATION

PolyPeptide GROUP

Molecular weight: 1069 (as free base)

Sequence: SCH_2CH_2CO-Tyr-Phe-Gln-Asn-Cys-Pro-D-Arg-Gly-NH_2 Acetate salt

Last update: 09 JUN 2018

Available registration documents (CTD format): US DMF

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Appearance	A white powder	Visual inspection
Identity, Monoisotopic mass	1069.4 ± 0.5	USP
Identity, HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution. The major peaks of the identity sample solution co-elute	In-house
Peptide content, HPLC	95.0-105.0% of Desmopressin calculated with reference to the anhydrous, acetic acid/acetate free substance	In-house
Peptide related impurities, HPLC		In-house
[Asp^5]desmopressin	≤ 0.4%	
[Glu^4]desmopressin	≤ 0.4%	
[Gly^9OH]desmopressin	≤ 0.4%	
[L-Arg^8]desmopressin	≤ 0.4%	
[Gln^4(Acm)]desmopressin and + [Asn^5(Acm)]desmopressin	≤ 0.4%	
[$Gly^9N(CH_3)_2$]desmopressin	≤ 0.4%	
Any unspecified impurity	≤ 0.3%	
Sum of impurities	< 1.5%	
Acetic acid content, HPLC	3.0 - 8.0%	USP
Water content, Karl Fischer titration	≤ 6.0% w/w	USP

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TEST	**ACCEPTANCE CRITERION**	**ANALYTICAL PROCEDURE**
Residual solvents, Ethanol, GC	≤ 0.5%	In-house
Microbial enumeration tests:		USP
TAMC	≤ 100 CFU/g	
TYMC	≤ 100 CFU/g	
Bacterial endotoxins	< 500 EU/mg	USP