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: 28 SEP 2020

Available registration documents (CTD format): US DMF

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Appearance	A white powder	Visual inspection
Identification,		
Monoisotopic mass, MS	1068.4 ± 0.5	USP
HPLC	Retention time of main peak corresponds to the retention time of the reference to give a single peak in the composite solution of sample and reference.	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[1]		In-house
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
Residual solvents, Ethanol	≤ 0.5%	In-house

[1] Detailed impurity specification not provided

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

Last update: 28 SEP 2020

Available registration documents (CTD format): US DMF

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Microbiological control		
Microbial enumeration tests:		USP
TAMC	≤ 100 CFU/g	
TYMC	≤ 100 CFU/g	
Bacterial endotoxins	< 500 EU/mg	USP