

**DESMOPRESSIN US
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 1069 (as free base)

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Sequence: SCH₂CH₂CO-Tyr-Phe-Gln-Asn-Cys-Pro-D-Arg-Gly-NH₂ Acetate salt

Last update: 15 MAR 2010

Available registration documents (CTD format): US DMF

TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
CHARACTERISTICS		
Appearance	A white powder	Visual inspection
IDENTIFICATION		
Monoisotopic mass, MS MS/MS	1069.4 ± 0.5 Product ions at m/z of about 641, 742, and 995 are present	USP
HPLC	Retention time of main peak corresponds to the retention time of reference	In-house
Amino acid analysis	Asp: 0.95 to 1.05 Glu: 0.95 to 1.05 Pro: 0.95 to 1.05 Gly: 0.95 to 1.05 Cys: 0.95 to 1.05 Tyr: 0.95 to 1.05 Phe: 0.95 to 1.05 Arg: 0.95 to 1.05 Not more than traces of other amino acids are present	USP

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TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
PURITY		
Peptide related impurities, HPLC:		In-house
[Asp ⁵]desmopressin	≤ 0.4%	
[Glu ⁴]desmopressin	≤ 0.4%	
[Gly ⁹ OH]desmopressin	≤ 0.4%	
[L-Arg ⁸]desmopressin	≤ 0.4%	
[Gln ⁴ (Acm)]desmopressin and [Asn ⁵ (Acm)]desmopressin	≤ 0.4%	
[Gly ⁹ N(CH ₃) ₂]desmopressin	≤ 0.4%	
Any unspecified impurity	≤ 0.3%	
Sum of impurities	< 1.5%	
ASSAY		
Peptide content, HPLC	95.0 to 105.0% of desmopressin calculated with reference to the anhydrous, acetic acid/acetate free substance	In-house
OTHER TESTS		
Acetic acid content	3.0 to 8.0%	USP
Water content	≤ 6.0% w/w	USP
Specific optical rotation	589 nm: -82 to -72 calculated with reference to the anhydrous, acetic acid/acetate free substance	USP

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TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
RESIDUAL SOLVENTS		
Ethanol	≤ 0.5%	In-house
MICROBIOLOGICAL TESTS		
Microbial enumeration tests;		
TAMC	≤ 100 CFU/g	USP
TYMC	≤ 100 CFU/g	
Bacterial endotoxins	< 500 EU/mg	USP