

**DESMOPRESSIN EU  
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 1069 (as free base)

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Sequence: SCH<sub>2</sub>CH<sub>2</sub>CO-Tyr-Phe-Gln-Asn-Cys-Pro-D-Arg-Gly-NH<sub>2</sub> Acetate salt

Last update: 15 MAR 2010

Available registration documents (CTD format): CEP/COS certificate

TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
<b>CHARACTERISTICS</b>		
Appearance	A white powder	Visual inspection
<b>IDENTIFICATION</b>		
HPLC	Retention time and size of main peak correspond to that 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	Ph. Eur.
<b>PURITY</b>		
Peptide related impurities, HPLC:		In-house
A [Asp <sup>5</sup> ]desmopressin	≤ 0.4%	
B [Glu <sup>4</sup> ]desmopressin	≤ 0.4%	
C [Gly <sup>9</sup> OH]desmopressin	≤ 0.4%	
D [L-Arg <sup>8</sup> ]desmopressin	≤ 0.4%	
E [Gln <sup>4</sup> (Acm)]desmopressin and		
F [Asn <sup>5</sup> (Acm)]desmopressin	≤ 0.4%	
G [Gly <sup>9</sup> N(CH <sub>3</sub> ) <sub>2</sub> ]desmopressin	≤ 0.4%	
Any unspecified impurity	≤ 0.3%	
Sum of impurities	≤ 1.5%	

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<b>ASSAY</b>		
Peptide content, HPLC	95.0 to 105.0% of desmopressin calculated with reference to the anhydrous, acetic acid/acetate free substance	In-house
<b>OTHER TESTS</b>		
Acetic acid content	3.0 to 8.0%	Ph. Eur.
Water content	≤ 6.0% w/w	Ph. Eur.
Specific optical rotation	589 nm: -82 to -72	Ph. Eur.
<b>RESIDUAL SOLVENTS</b>		
Ethanol	≤ 0.5%	In-house
<b>MICROBIOLOGICAL TESTS</b>		
Microbial enumeration tests; TAMC	< 100 CFU/g	Ph. Eur.
TYMC	< 100 CFU/g	
Bacterial endotoxins	< 500 IU/mg	Ph. Eur.