

**DESMOPRESSIN EU  
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 1069

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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: 12 SEP 2007

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

Please note that regional minor differences in analytical procedures and acceptance criteria might occur.

TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
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**CHARACTERS**

Appearance	A white powder	Visual inspection
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**IDENTIFICATION**

Identification, HPLC	Retention time and size of main peak correspond to that of reference	In-house
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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.
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<b>PURITY</b>		
Related substances, HPLC:		In-house
[Asp <sup>5</sup> ]desmopressin	≤ 0.4%	
[Glu <sup>4</sup> ]desmopressin	≤ 0.4%	
[Gly <sup>9</sup> OH]desmopressin	≤ 0.4%	
[L-Arg <sup>8</sup> ]desmopressin	≤ 0.4%	
[Gln <sup>4</sup> (Acm)]desmopressin and [Asn <sup>5</sup> (Acm)]desmopressin	≤ 0.4%	
[Gly <sup>9</sup> N(CH <sub>3</sub> ) <sub>2</sub> ]desmopressin	≤ 0.4%	
Any other individual impurity	≤ 0.3%	
Total amount	≤ 1.5%	
<b>ASSAY</b>		
Mass balance	95.0 to 105.0%	Calculation
<b>OTHER TESTS</b>		
Acetic acid	3.0 to 8.0%	Ph.Eur.
Water	≤ 6.0%	USP/Ph.Eur.
Specific optical rotation	-82 to -72	USP/Ph.Eur.
<b>RESIDUAL SOLVENTS</b>		
Ethanol	≤ 0.5%	In-house

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TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
<b>MICROBIOLOGICAL TESTS</b>		
Total viable aerobic count	< 100 CFU/g	USP/Ph.Eur.
Bacterial endotoxins	< 500 IU/mg	USP/Ph.Eur.