

**DESMOPRESSIN US  
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): US DMF

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

TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
<b>CHARACTERS</b>		
Appearance	A white powder	Visual inspection
<b>IDENTIFICATION</b>		
Identification, HPLC	Retention time of main peak corresponds to the retention time of reference sample	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	Ph.Eur.
<b>PURITY</b>		
Related substances, HPLC:		In-house
Any individual impurity	≤ 0.5%	
Total amount	≤ 1.5%	
<b>ASSAY</b>		
Mass balance	95.0 to 105.0%	Calculation

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