DESMOPRESSIN EU
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: 27 AUG 2021

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

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Appearance	A white powder	Visual inspection
Identity, HPLC	Retention time and size of main peak correspond to that of reference	In-house
Amino acid analysis	Asp 0.90 to 1.10 Glu 0.90 to 1.10 Pro 0.90 to 1.10 Gly 0.90 to 1.10 Cy 0.90 to 1.05 Tyr 0.90 to 1.05 Phe 0.90 to 1.10 Arg 0.90 to 1.10 Not more than traces of other amino acids are present	Ph. Eur.
Specific optical rotation	589 nm: -82 to -72	Ph. Eur.
Peptide related impurities, HPLC[1]		In-house
Any unspecified impurity	≤ 0.3%	
Sum of impurities	≤ 1.5%	
Acetic acid content	3.0 to 8.0%	Ph. Eur.
Water content	≤ 6.0% w/w	Ph. Eur.

[1] Detailed impurity specification not provided.

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TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Peptide content, HPLC	95.0 to 105.0% of Desmopressin calculated with reference to the anhydrous, acetic acid/acetate free substance	In-house
Residual solvents, GC		
Ethanol	≤ 0.5%	In-house
Microbiological control		
Microbial enumeration tests		Ph. Eur.
TAMC	< 100 CFU/g	
TYMC	< 100 CFU/g	
Bacterial endotoxins	< 500 IU/mg	Ph. Eur.