FELYPRESSIN
DRUG SUBSTANCE SPECIFICATION

PolyPeptide GROUP

Molecular weight: 1039

Sequence: H-Cys-Phe-Phe-Gln-Asn-Cys-Pro-Lys-Gly-NH_2 Acetate salt

Last update: 09 JUN 2018

Available registration documents (CTD format): CEP certificate, CEP-dossier

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Appearance	White or almost white powder or flakes	Visual inspection
Identity, HPLC	Felypressin co-elutes with reference	Ph.Eur.
Identity, Amino acid analysis	Asp 0.9 to 1.1 Glu 0.9 to 1.1 Pro 0.9 to 1.1 Gly 0.9 to 1.1 Cys 1.8 to 2.2 Phe 1.8 to 2.2 Lys 0.9 to 1.1	Ph.Eur.
Specific optical rotation	-35 to -29	Ph.Eur.
Purity, HPLC		Ph.Eur.
Specified impurities		
A. [Cys^1(Acm),Cys^6(Acm)]-felypressin	≤ 0.5 %	
C. Dimer(1,6´;6,1´)	≤ 0.5 %	
D. Dimer(1,1´;6,6´)	≤ 0.5 %	
E. [Ac-Cys^1]felypressin	≤ 0.5 %	
Unspecified impurities	≤ 0.1 %	
Sum of impurities	≤ 3.0 %	
Assay, HPLC Felypressin content calculated with reference to the anhydrous, acetic acid free substance	95.0 -102.0 %	Ph.Eur.
Acetic acid content, HPLC	9.0 -13.0 %	Ph.Eur.
Water content, Karl Fischer	≤ 7.0 %	Ph. Eur.

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TEST	**ACCEPTANCE CRITERION**	**ANALYTICAL PROCEDURE**
Trifluoroacetic acid content, IC	< 100 ppm	In-house
Phosphorous content, IC	≤ 0.1%	In-house
Residual Solvents, GC		In-house
Ethanol	≤ 5000 ppm	
Methanol	≤ 1000 ppm	
TAMC	≤ 100 CFU/g	Ph.Eur.
TYMC	≤ 100 CFU/g	Ph.Eur.
Bacterial endotoxins	< 100 IU/mg	Ph.Eur.