

**FELYPRESSIN**  
**DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 1039

Page 1 of 2

Sequence: H-Cys-Phe-Phe-Gln-Asn-Cys-Pro-Lys-Gly-NH<sub>2</sub> Acetate salt

Last update: 12 AUG 2020

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

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Appearance	White or almost white powder or flakes	Visual inspection
Identification, HPLC	Felypressin co-elutes with reference	Ph.Eur.
Identification, 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.
<b>Purity, HPLC</b>		Ph.Eur.
Specified impurities <sup>1</sup>		
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.
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	

<sup>1</sup> Detailed impurity specification not provided

**FELYPRESSIN**  
**DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 1039

Page 2 of 2

Sequence: H-Cys-Phe-Phe-Gln-Asn-Cys-Pro-Lys-Gly-NH<sub>2</sub> Acetate salt

Last update: 12 AUG 2020

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

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Total aerobic microbial count (TAMC)	≤ 100 CFU/g	Ph.Eur.
Total yeast and mould count (TYMC)	≤ 100 CFU/g	Ph.Eur.
Bacterial endotoxins	< 100 IU/mg	Ph.Eur.