

FELYPRESSIN
DRUG SUBSTANCE SPECIFICATION



Molecular weight: 1039

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Sequence: H-Cys-Phe-Phe-Gln-Asn-Cys-Pro-Lys-Gly-NH₂ Acetate salt

Last update: 12 SEP 2007

Available registration documents (CTD format): Contact PolyPeptide Laboratories
Please note that regional minor differences in analytical procedures and acceptance criteria might occur.

TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
CHARACTERS		
Appearance	White or almost white powder or flakes	Visual inspection
IDENTIFICATION		
Identification, HPLC	Retention time conforms to that of reference	Ph.Eur.
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.
PURITY		
Peptide purity	≥ 97.0%	Ph.Eur.
Related substances, HPLC:		Ph.Eur.
[Cys ¹ (Acm),Cys ⁶ (Acm)]-Felypressin	≤ 0.5%	
[Asp ⁵]Felypressin	≤ 0.3%	
Dimer(1,6';6,1')	≤ 0.5%	
Dimer(1,1';6,6')	≤ 0.5%	
[Ac-Cys ¹]Felypressin	≤ 0.5%	
Any other individual impurity	≤ 0.1%	
Total amount	≤ 3.0%	

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TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
ASSAY		
Mass balance	95.0 to 102.0%	Calculation
OTHER TESTS		
Water	≤ 7.0%	USP
Specific optical rotation	-35 to -29	USP/Ph.Eur.
Acetic acid	≤ 9.0 to 13.0%	Ph.Eur.
Trifluoroacetic acid	< Trifluoroacetic acid	In-house
RESIDUAL SOLVENTS		
Ethanol	≤ 5000 ppm	In-house
Methanol	≤ 3000 ppm	In-house
MICROBIOLOGICAL TESTS		
Total viable aerobic count	≤ 100 CFU/g	Ph.Eur.
Bacterial endotoxins	≤ 100 IU/mg	Ph.Eur.