

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 AUG 2021

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. |
| Purity, HPLC | | Ph.Eur. |
| Specified impurities ¹ | | |
| 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 | |

¹ Detailed impurity specification not provided

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|--------------------------------------|-----------------------------|-----------------------------|
| 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. |