

**OCTREOTIDE ACETATE  
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 1019.3 (free peptide)

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Sequence: H-D-Phe-Cys-Phe-D-Trp-Lys-Thr-Cys-Thr(ol), supplied as acetate salt

Last update: 30 AUG 2007

Available registration documents (CTD format): EU and US DMF

Please note that regional minor differences in analytical procedures and acceptance criteria might occur.

| TEST                      | ACCEPTANCE CRITERIA   | ANALYTICAL PROCEDURE |
|---------------------------|---|----------------------|
| <b>CHARACTERS</b>         |   |                      |
| Appearance                | White to off-white<br>amorphous powder  | Visual inspection    |
| Solubility                | Soluble in water and 1%<br>acetic acid at a concentration<br>of $\geq 1$ mg/mL to give a clear,<br>colorless solution | Ph.Eur.              |
| <b>IDENTIFICATION</b>     |   |                      |
| Identification, MS        | Monoisotopic mass<br>$1018.4 \pm 1$   | Ph.Eur.              |
| Amino acid analysis       | Thr: 0.9 to 1.1<br>Cys: 1.3 to 2.1<br>Phe: 1.8 to 2.2<br>Lys: 0.9 to 1.1<br>Trp: 0.3 to 1.0<br>Thr(ol): 0.9 to 1.1    | Ph.Eur.              |
| Identification, HPLC      | Co-elutes with reference<br>standard  | In-house             |
| <b>PURITY</b>             |   |                      |
| Peptide purity, HPLC:     | $\geq 98\%$   | In-house             |
| Related substances, HPLC: |   | In-house             |
| Total amount              | $\leq 2\%$  |                      |
| Any individual impurity   | $\leq 0.5\%$  |                      |

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|--|---|----------------------|
| <b>ASSAY</b>   |   |                      |
| Mass balance   | 95 to 105%                                    | Calculation          |
| <b>OTHER TESTS</b>   |   |                      |
| Acetic acid  | 7.6 to 12.8%<br>(corrected for water content) | In-house             |
| Water  | ≤ 10%   | USP/Ph.Eur.          |
| Specific optical rotation<br>[ $\alpha$ ] <sub>D</sub> <sup>20</sup> (c = 0.5, 1% acetic acid) | -17 to -21<br>(corrected for peptide content) | Ph.Eur.              |
| Trifluoroacetic acid   | ≤ 0.25%                                       | In-house             |
| Inorganic fluoride   | ≤ 0.1%  | In-house             |
| pH of solution<br>(10 mg/mL in water)  | 5 to 7  | USP                  |
| <b>RESIDUAL SOLVENTS</b>   |   |                      |
| Any individual residual solvent  | ≤ 0.1%  | In-house             |
| <b>MICROBIOLOGICAL TESTS</b>   |   |                      |
| Total viable aerobic count   | ≤ 300 CFU/g                                   | In-house             |
| Bacterial endotoxins   | ≤ 1 IU/mg                                     | USP/Ph.Eur.          |