

Analytical Data Sheet

| | |
|---------------------------------|---|
| Lot number | 1000020351 not for drug use |
| Product | Atosiban (1-8) lactam |
| Product number | 4081127.2001 |
| Molecular formula (net) | C ₄₁ H ₆₁ N ₉ O ₁₁ S ₂ |
| Molecular mass (average) | 920.1 |

| Tests | Results |
|---|------------------|
| Components | |
| Appearance | |
| Color | slightly yellow |
| Physical form | lyophilizate |
| Visible impurities | none |
| Appearance of solution | |
| Clarity | clear |
| Color of solution | colorless |
| Visible impurities | none |
| Solvent and concentration | 1 mg/ml in water |
| Identification (ESI-MS) | |
| Monoisotopic mass | 919.4 u |
| Purity and related impurities (HPLC) | |
| Purity | 98.6% |
| Total impurities | 1.4% |
| Assay (elemental analysis) | |
| Assay (EA, as is) | 89.4% |
| Water content (Karl Fischer coulometric) | |
| Water content | 3.9% |
| Mass balance | |
| Mass balance (EA) | 99.2% |

This Analytical Data Sheet is based on reviewed analytical data and is valid without handwritten signatures.

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BACHEM

Lot number

1000020351

Product

Atosiban (1-8) lactam

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