



## Certificate of Analysis

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|                    |   |                     |         |
|--------------------|---|---------------------|---------|
| Code:              | <b>082-33</b>   | DSM Code:           | 5030838 |
| Product:           | Pefachrome® uPA 8294 Corresponds to DPG444-25   |                     |         |
| Lot:               | <b>41827801</b>   | Manufacturing date: | 04/2014 |
| Analysis No.:      | <b>7441827801</b>   | Retest date:        | 04/2017 |
| Filling            | 25 mg/vial (+ 40 mg mannitol)   |                     |         |
| Chemical formula   | C <sub>19</sub> H <sub>26</sub> N <sub>6</sub> O <sub>6</sub> · HCl   |                     |         |
| Identity           | Pyroglu-Gly-Arg-pNA · HCl   |                     |         |
| Molecular weight   | 498.9 g/mol   |                     |         |
| Storage conditions | In a closed container, protected from moisture, in the dark, +2 to +8°C.<br>Shipment of product does not require cooling during the time of transportation. |                     |         |

| Tests, Parameters:   | Specification:                        | Results:       |
|--|---------------------------------------|----------------|
| Appearance   | white to slightly yellow lyophilisate | corresponds    |
| Thin-layer chromatography<br>butanol : acetic acid : water [6:2:2] | corresponds to reference chromatogram | corresponds    |
| Identity by FT-IR  | corresponds to reference spectrum     | corresponds    |
| Solubility in water<br>(c = 10 mmol/L)                             | soluble                               | corresponds    |
| Purity by RP-HPLC  | ≥ 95 rel. area-%                      | 95 rel. area-% |
| MS-ESI [M+H]   | 463.2 ± 1.0                           | 463.3          |
| Digestible by trypsin  | ≥ 90 %                                | corresponds    |
| "Free" p-nitro-aniline   | ≤ 0.5 %                               | 0.1 %          |

This lot was analysed and released by our authorized Quality Assurance Department and was found to meet the specifications as given above.

Basle/Switzerland: 08.05.2014 / inm

Frédéric Crevoisier / QA

On behalf of the responsible department:

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