

Certificate of Analysis

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Code:	082-33	DSM Code:	5030838
Product:	Pefachrome® uPA 8294		
Lot:	41827801	Manufacturing date:	04/2014
Analysis No.:	7441827801	Retest date:	04/2017
Filling	25 mg/vial (+ 40 mg mannitol)		
Chemical formula	C ₁₉ H ₂₆ N ₆ O ₆ · 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. 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 butanol : acetic acid : water [6:2:2]	corresponds to reference chromatogram	corresponds
Identity by FT-IR	corresponds to reference spectrum	corresponds
Solubility in water (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:



Registered as

DSM Nutritional Products Ltd Branch Pentapharm

P.O. Box, CH-4002 Basel, Switzerland

 Phone: +41 61 706 4848, Fax: +41 61 706 4800, <http://www.pentapharm.com>

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