

## **Certificate of Analysis**

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Code:

DPG444-25

DSM Code:

5030838

Product:

Diapharma CS UK

41827801

Manufacturing date:

04/2014

Lot: Analysis No.:

7441827801

Retest date:

09/2018

Filling

25 mg/vial (+ 40 mg mannitol)

Chemical formula

 $C_{19}H_{26}N_8O_6\cdot HCI$ 

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 to reference spectrum

corresponds

Identity by FT-IR

soluble

corresponds

Solubility in water

(c = 10 mmol/L)

≥ 95 rel. area-%

corresponds

96 rel. area-%

Purity by RP-HPLC

463.3

MS-ESI [M+H]

463.2 ± 1.0 ≥ 90 %

corresponds

Digestible by trypsin
"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: 20.03.2017 / frc

Frédéric Crevoisier / QA

Genicie

On behalf of the responsible department:

Manufactured for Diapharma Group, Inc. 8948 Beckett Road, West Chester, OH 45069 USA

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