

Certificate of Analysis

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Code:	381-01	DSM Code:	5038403
Product:	Pefabloc® TH (αNAPAP)		
Lot:	42074801	Manufacturing date:	04/2017
Analysis No.:	7442074801	Retest date:	04/2022
Chemical formula	$C_{27}H_{31}N_5O_4S \cdot AcOH$		
Identity	N-α-(2-naphthylsulfonylglycyl)-4-amidino-(D,L)-phenylalanine piperidide acetate salt		
Molecular weight	581.7		
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.		

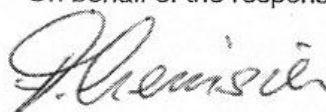
Tests, Parameters:	Specification:	Results:
Purity by RP-HPLC	≥ 90 rel. area-%	99 rel. area-%
Identity by MS-ESI [M+H]	522.2 ± 1.0	522.2
Thin-layer chromatography butanol : acetic acid : water [6:2:2]	corresponds to reference chromatogram	corresponds
Additional tests:	Expectation:	Report finding:
- Appearance	white to slightly yellowish powder	corresponds
- Solubility in water (c = 1.5 mg/ml)	soluble	corresponds
- Melting temperature	report finding	225 °C
- Ki-value [nmol/l vs. thrombin]	report value	1.5 nmol/l
- Carbon (theory 59.9 %)	report value	56.9 %
- Hydrogen (theory 6.1 %)	report value	5.9 %
- Nitrogen (theory 12.0 %)	report value	11.6 %
- Sulfur (theory 5.5 %)	report value	4.8 %

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

Basle/Switzerland: 10.11.2017 / frc

Michael Eberhardt / QA

On behalf of the responsible department:



Registered as

DSM Nutritional Products Ltd Branch Pentapharm

Dornacherstrasse 112, CH-4147 Aesch BL, Switzerland

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

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