## Chemische Werke Hommel GmbH & Co. KG

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## **Specification**

Concerning Product:			
Article number	165450179CURL		
Trade name / designation / denomination	Neotam (97-102%), USP		
CAS number	165450-17-9		
Other names / synonyms	•(3R)-3-(3,3-dimethylbutylamino)-4-[[(2R)-1-methoxy-1-oxo-3-phenylpropan-2-yl]amino]-4-oxobutanoic acid; •L-Phenylalanine, N-(3,3-dimethylbutyl)-L-α-aspartyl-, 2-methyl ester;		
EC number	605-408-8		
Molecular weight [g / mol]	378.4626		
Formula	$C_{20}H_{30}N_2O_5$		

Parameter	Specification	Unit
Organoleptic test		
Appearance	white to off-white Powder	
Physical parameter		
Loss on drying	≤ 5,0	%
pH value	(5g/l solution) 5,0 - 7,0	
Specific Optical Rotation	(20°C,D)[•dm <sup>2</sup> /kg] -40,043,4	٥
Solubility	Ethanol & Ethyl Acetate @ 25° C: ≤ 1,26	% (w/w)
Solubility	in H <sub>2</sub> O @ 60° C: ≤ 4,75	% (w/w)
Identity		•
Assay	97,0 - 102,0	% [w/w]
Infrared absorbtion spectrometry	Conforms with standard	•
Melting Point (identity)	81 – 84	°C
Impurities		
Residue on ignition	≤ 0,2	%

Impurity	N-[N-(3,3-Dimethylbutyl)-Aspartyl]- L-Phenylatanine ≤ 1,5	%		
Related substances	≤ 2,0	% [w/w]		
Residual Solvents				
Residual solvents	neg.			
Elemental Impurities				
Lead (Pb)	≤ 1	ppm		
Microbiological data				
Aerobic microorganisms	≤ 250	CFU/g		
Coliform bacteria	≤ 10	MPN/g		
Salmonella	neg.			
Staphylococcus Aureus	neg.			
Yeast and Mould	≤ 100	CFU/g		

## **Supplemental information:**

Shelf life: 2 years

**Storage conditions:** Keep in tightly closed original sealed packing in a cool, clean and dry place, away from direct sunlight and water.

Complies with monographie: USP, GB 29944-2013

Regional origin: CN

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Waltrop, 09. Feb. 2022

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