

## Specification

## 1.12488.1000 N-Acetyl-DL-tryptophan EMPROVE® EXPERT Ph Eur,BP

substance)  dentity (IR-spectrum)  Appearance  white to almost white, crystalline powder or colorless crystals  Appearance of solution (10 g/l; sodium nydroxide solution 1 mol/l)  Clear and not more intense in color than reference solution Y7 or GY7  Clopt. rotation (100 g/l, sodium hydroxide 1 mol/)  Fe (Iron)  Residual solvents (ICH Q3C)  Related substances (HPLC)  largest single impurity)  Related substances (HPLC)  Sum of all impurities)  Sulfated ash (600 °C)  Loss on Drying (105 °C)  Sacterial endotoxins  white to almost white to almost white, crystalline powder or colorless crystals  clear and not more intense in color than reference solution Y7 or GY7  -0.1 to +0.1  °  Loss on Drying (105 °C)  Sulfated substances (HPLC)	S	pecification	
Appearance  white to almost white, crystalline powder or colorless crystals  Appearance of solution (10 g/l; sodium or color c	Assay (alkalimetric, calculated on dried substance)	99.0 - 101.0	%
white, crystalline powder or colorless crystals  Appearance of solution (10 g/l; sodium mydroxide solution 1 mol/l)  Clear and not more intense in color than reference solution Y <sub>7</sub> or GY <sub>7</sub> Cpt. rotation (100 g/l, sodium hydroxide 1 mol/ -0.1 to +0.1 °)  Fe (Iron) ≤ 10 ppm  NH₄ (Ammonium) ≤ 200 ppm  Residual solvents (ICH Q3C) excluded by manufacturing process  Related substances (HPLC) ≤ 0.25 %  Related substances (HPLC) ≤ 0.5 %  Sulfated ash (600 °C) ≤ 0.1 %  Loss on Drying (105 °C) ≤ 0.5 %  Bacterial endotoxins ≤ 50 I.U./g	Identity (IR-spectrum)	passes test	
more intense in color than reference solution $Y_7$ or $GY_7$ .  Opt. rotation (100 g/l, sodium hydroxide 1 mol/)  Fe (Iron) $\leq 10$ ppm  NH4 (Ammonium) $\leq 200$ ppm  Residual solvents (ICH Q3C) excluded by manufacturing process  Related substances (HPLC) $\leq 0.25$ %  Related substances (HPLC) $\leq 0.5$ %  Sulfated ash (600 °C) $\leq 0.1$ %  Loss on Drying (105 °C) $\leq 0.5$ %  Bacterial endotoxins	Appearance	white, crystalline powder or	
Fe (Iron) ≤ 10 ppm  NH₄ (Ammonium) ≤ 200 ppm  Residual solvents (ICH Q3C) excluded by manufacturing process  Related substances (HPLC) ≤ 0.25 %  Iargest single impurity)  Related substances (HPLC) ≤ 0.5 %  Sum of all impurities)  Sulfated ash (600 °C) ≤ 0.1 %  Loss on Drying (105 °C) ≤ 0.5 %  Bacterial endotoxins ≤ 50 I.U./g	Appearance of solution (10 g/l; sodium hydroxide solution 1 mol/l)	more intense in color than reference solution	
NH₄ (Ammonium) ≤ 200 ppm  Residual solvents (ICH Q3C) excluded by manufacturing process  Related substances (HPLC) ≤ 0.25 %  Related substances (HPLC) ≤ 0.5 %  Sum of all impurities)  Sulfated ash (600 °C) ≤ 0.1 %  Loss on Drying (105 °C) ≤ 0.5 %  Bacterial endotoxins ≤ 50 I.U./g	Opt. rotation (100 g/l, sodium hydroxide 1 mol/ l)	-0.1 to +0.1	•
Residual solvents (ICH Q3C)  excluded by manufacturing process  Related substances (HPLC)  largest single impurity)  Related substances (HPLC)  Sum of all impurities)  Sulfated ash (600 °C)  Loss on Drying (105 °C)  Bacterial endotoxins  excluded by manufacturing process  %  5 0.25  %  1.U./g	Fe (Iron)	≤ 10	ppm
manufacturing process  Related substances (HPLC) ≤ 0.25 %  Iargest single impurity)  Related substances (HPLC) ≤ 0.5 %  Sum of all impurities)  Sulfated ash (600 °C) ≤ 0.1 %  Loss on Drying (105 °C) ≤ 0.5 %  Bacterial endotoxins ≤ 50 I.U./g	NH <sub>4</sub> (Ammonium)	≤ 200	ppm
largest single impurity)  Related substances (HPLC) $\leq 0.5$ %  Sum of all impurities)  Sulfated ash (600 °C) $\leq 0.1$ %  Loss on Drying (105 °C) $\leq 0.5$ %  Bacterial endotoxins $\leq 50$ I.U./g	Residual solvents (ICH Q3C)	manufacturing	
Sum of all impurities)         Sulfated ash (600 °C)       ≤ 0.1       %         Loss on Drying (105 °C)       ≤ 0.5       %         Bacterial endotoxins       ≤ 50       I.U./g	Related substances (HPLC) (largest single impurity)	≤ 0.25	%
Loss on Drying (105 °C) $\leq$ 0.5 %  Bacterial endotoxins $\leq$ 50 I.U./g	Related substances (HPLC) (Sum of all impurities)	≤ 0.5	%
Sacterial endotoxins ≤ 50 I.U./g	Sulfated ash (600 °C)	≤ 0.1	%
	Loss on Drying (105 °C)	≤ 0.5	%
Fotal aerobic microbial count (TAMC) ≤ 10 <sup>2</sup> CFU/g	Bacterial endotoxins	≤ 50	I.U./g
	Total aerobic microbial count (TAMC)	≤ 10²	CFU/g
Fotal combined yeasts/moulds count (TYMC) ≤ 10¹ CFU/g	Total combined yeasts/moulds count (TYMC)	≤ 10¹	CFU/g

Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental Impurities). Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (\*). Corresponds to Ph. Eur., BP

Dr. Michael Memmel

Responsible laboratory manager quality control

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