

Certificate of Analysis

Quality

N-Acetyl-L-Tyrosine EP 9, oral quality

Lot No. 391160030 **Page** 1 of 1

Retest Date October 2020

Manufacturing Date October 2016

Parameter	Specification	Result
Appearance	white or almost white crystalline powder or colourless crystals	passes
Identification	Infrared Absorption	passes
Test on turbidity	≤ Ref.Susp.I	passes
Test on colour	≤ B ₉	passes
Specific optical rotation (α^{20}_D)	+ 46° to + 49°	47.6 °
Related substances	HPLC	
Impurity A (tyrosine)	≤ 0.8 %	0.3%
Unspecified impurities	≤ 0.10 %	< 0.10%
Total impurities	≤ 1.0 %	< 1.0 %
Chlorides	≤ 200 ppm	passes
Sulfates	≤ 200 ppm	passes
Ammonium	≤ 200 ppm	passes
Iron	≤ 20 ppm	passes
Loss on drying	≤ 0.5 %	0.01%
Residue on ignition	≤ 0.1 %	passes
Assay	98.5 to 101.0 %	100.0%
Total viable aerobic count	≤ 1000 CFU/g	passes
Moulds and yeasts	≤ 100 CFU/g	passes
<i>Escherichia coli</i>	in 1 g not detectable	passes
Salmonella	in 1 g not detectable	passes
<i>Pseudomonas aeruginosa</i>	in 1 g not detectable	passes
<i>Staphylococcus aureus</i>	in 1 g not detectable	passes

Poppenhäger
 Qualified Person

Dr. Bös
 Head of Quality Control