

Version : 01

Update : 08/31/2022

CERTIFICATE OF ANALYSIS

Product Information

Product Name	Benz-Neburase™ GMP, tag free
Cat. No.	Z03708
Lot No.	T2205016
Size	Specified on product label
Storage Buffer	20 mM Tris-HCl, 2 mM MgCl ₂ , 20 mM NaCl, 50% Glycerol, pH 8.0.
Storage	Store at -20 °C for up to 24 months or at 4 °C for 2 weeks from the date of manufacture. Avoid repeated freeze-thaw cycles. Do not store below -20 °C!
Expiry Date:	05/28/2024

Quality Control

Test Items	Specifications	Results
Appearance	Clear, colorless liquid	Passed
Specific Activity	$\geq 1.1 \times 10^6$ U/mg	1.3×10^6 U/mg
Enzyme Activity	≥ 250 U/ μ l	867 U/ μ l
Purity	$\geq 95\%$ as analyzed by SDS-PAGE $\geq 99\%$ as analyzed by SEC-HPLC	Passed
Endotoxin Level	< 0.01 EU/ μ g	Passed
Protease Activity	Non-detectable	Passed
Residual HCP	≤ 20 ng/mg	Passed
Bioburden	< 1 CFU/ml	Passed
Mycoplasma	Negative	Passed

Date: 09/15/2022

Approved by:



Quality Department

For research and manufacturing use. Direct human use, including taking orally and injection and clinical use are forbidden.