

Certificate of Analysis

Product Name

rAAV5

Vector information

ssAAV-CMV-EGFP-WPRE-SV40pA

Batch Number

PTB006-GTPD-DS230816-01

Specification

50µl/Vial

Production date

2023-08-16

Storage Condition

Store at -80°C

Expiration Date

2024-08-15

Storage Buffer

Virus formulated in 10mM Tris buffer supplemented with 100mM sodium citrate

and 0.001% poloxamer 188 (pH8.0)

The product is functionally tested for optimum performance using the following tests:

Titer Determination

The titer was determined by the quantitative PCR (qPCR) method. Viral DNA was extracted from viral particles.

The EGFP sequence of AAV was used as a target to quantify the amount of viral genome.

Specification: >10¹³ vg/ml

Result: 6.38x10¹³ vg/ml

Virus Purity

Viral purity was determined by SDS-PAGE followed by silver staining.

Specification: Report

Result: 88.70%

Full Capsid Ratio

The full capsid ratio was determined by the AUC method.

Specification: Report

Result: 69.75%

Sterility Test

Bacteria and fungi were detected by rapid sterility test. The virus sample was inoculated into a culture medium 5 days and detected by BD BACTEC FX40 to detect bacterial and fungal growth.

Specification: Negative

Result: Pass

Mycoplasma Test

Through a DNA extraction kit, the mycoplasma DNA in the sample was purified, and the sample was amplified and detected by the qPCR method. Whether there was mycoplasma contamination in the sample was determined by

Specification: Negative

Result: Pass

Endotoxin

Endotoxin was determined by LAL

Specification: <10 EU/ml

Result: 6.2EU/ml



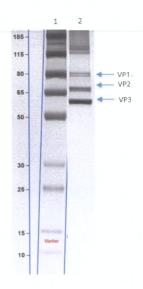


Figure 1. SDS-PAGE picture (lane1: marker, lane2: sample)

Note: Stray bands between 115KD and 185 KD are also included in the purity calculation

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Reporter	Kothy. Wu	Reviewer	1000	Auditor	到原面》	013.59-27
Date	2023-09-26	Date	2023-07-27	Date		