

Certificate of Analysis

Xeno-Free Medium for CAR-T (Sterile, W/o Phenol Red, With Stable Glutamine)

Cat No.: N109-500 / N109-1000
Production Date: 6th January, 2025
Storage: 2-8 °C

Lot No.: N10925010601
Expiry Date: 5th July, 2026
Page: 1 / 1

Physical and Chemical Analysis

	Specifications	Results
Appearance	Colorless, clear	Colorless, clear
pH ^[1]	6.8-8.0	7.56
Osmolality ^[2]	280-350 mOsm/kg	322 mOsm/kg
Endotoxin ^[3]	≤1 EU/ml	≤0.25 EU/ml

Sterility Testing

	Specifications	Results
Sterility ^[4]	Negative	Pass
Mycoplasma ^[5]	Negative	Pass

Cell Culture Test

	Specifications	Results
Cell Culture Test	Pass	Pass

References

- [1] Potentiometric Determination; Current Edition EP
- [2] Freeze-Point Depression; Current Edition EP
- [3] Gel-clot technique; Current Edition EP
- [4] Direct Inoculation; Current Edition EP
- [5] Culture + Indicator Cell Assay

These signatures indicate the material mentioned above has met specifications and has been reviewed by the quality unit.

Quality Statement : This product is manufactured, tested and released in accordance with GMP guidelines.

This product complies with ISO 13485.

Signature: 
Position: Approver
Issue date: 13th January, 2025