



Certificate of Analysis

Dulbecco's Modified Eagle Medium (1X), liquid

+ 1 g/L D-Glucose
+ L-Glutamine
+ 110 mg/L Sodium Pyruvate

Catalog Number: 11885
Lot Number: 1620364

Storage Temperature: 2 to 8C
Storage Instructions: Protect from light
Expiration Date: 2015-09

For human ex vivo tissue and cell culture processing applications. CAUTION: When used as a medical device, Federal Law restricts this device to sale by or on the order of a physician.

Sterile filtered (0.1 um)

TEST	SPECIFICATION	RESULT	UNITS
¹ Endotoxin Testing	Tested	<0.06	EU/mL
² Osmolality	>=310 to <=340	320	mOsm/kg
³ pH	>=7.0 to <=7.4	7.3	
⁴ Sp2 Toxicity Assay	Acceptable	Acceptable	
⁵ Sterility Testing	Negative	Negative	

GIBCO brand, Life Technologies cell culture liquid products are prepared by an aseptic process for which each step has been validated to ensure that all products meet the industry standard sterility assurance level of 10^{-3} ; i.e. product that demonstrates a contamination level of no more than 1 of 1,000 units during the manufacturing process. The highest level of sterility assurance (equal to or greater than 10^{-6}) cannot be achieved without terminal sterilization which is harmful to the performance of cell culture products.

The manufacturing facility is in compliance with 21CFR part 820 Quality Systems Regulation and is certified to ISO 13485 and ISO 9001.

Quality Systems Department

Date: 22-Sep-2014

REFERENCES:

- 1 Current United States Pharmacopeia, <85> Bacterial Endotoxins Test.
- 2 Life Technologies Specifications.
- 3 Life Technologies Specifications.
- 4 Life Technologies Specifications, Ref.: GIBCO Catalog. Cell Line Used: Sp2/O-Ag14 (ATCC No. CRL-1581). Test samples were evaluated for nutritional support of target cells utilizing the murine myeloma cell line Sp2/O-Ag14 (Sp2). Comparable growth rates of Sp2 cells in samples of complete test medium were obtained relative to parallel cultures grown in reference control medium.
- 5 Current edition of USP.