

## Certificate of Analysis

TrypLE (TM) Select 10X

**Catalog Number:** 

A12177 1827205

Lot Number:

15 to 30C

Storage Instructions:

Storage Temperature:

Protect from light

Expiration Date:

2018-09

Caution: For manufacturing, processing, or repacking.

EST	SPECIFICATION	RESULT	UNITS
Activity Assay	>=0.2	0.22	rPu/mL
<sup>1</sup> Endotoxin Testing, as (1X)	<=1.0	<0.030	EU/mL
<sup>2</sup> In-Vitro Bioassay	Acceptable	Acceptable	
<sup>3</sup> Osmolality	>=270 to <=320	287	mOsm/kg
<sup>4</sup> pH	>=6.9 to <=7.4	7.1	
<sup>5</sup> Sterility Testing	Negative	Negative	

See SDS.

Product of Denmark.

TrypLE (TM) Select is animal origin free, derived from microbial fermentation. There are no animal derived components utilized in the formulation.

Quality Systems Department

Date: 16-Sep-2016



## Certificate of Analysis

(Continued)

## **REFERENCES:**

- 1 Current United States Pharmacopeia, <85> Bacterial Endotoxins Test.
- 2 Life Technologies Specifications, Ref.: GIBCO Catalog. Cell Line Used: A549 (Human Lung Carcinoma, ATCC No. CCL-185). An in-vitro bioassay is performed to verify the ability of final product trypsin preparations to remove adherent cell lines from the substratum. Cell removal times, viability, reattachment, and morphology of the tested cell line has been demonstrated to be within established guidelines for the product relative to a previously tested and accepted reference control trypsin solution.
- 3 Life Technologies Specifications.
- 4 Life Technologies Specifications.
- 5 Current Edition of USP, Life Technologies Modified.