



ISO 13485:2016 Certified | GMP Certified

2235 Cornell Ave. Montgomery, IL 60538 | (800) 246 - 4088 | CustomerService@Biologos.com | Biologos.com

SPECIFICATION SHEET

PRODUCT: Trypsin - EDTA Solution (10X) in HBSS Solution
Without Calcium and Magnesium
Sterile Filtered 0.2µ

Catalog Number: E1510

PRODUCT FORMULATION

E1510

Trypsin - EDTA Solution (10X) in HBSS Solution
w/o Calcium & Magnesium
Sterile Filtered 0.2µ

Table with 2 columns: Component Name and mg/Liter. Rows include Inorganic Salts (KCl, KH2PO4, NaCl, NaHCO3, Na2HPO4) and Other Components (Trypsin, EDTA, D-Glucose, Phenol Red).

ASSAY:

Appearance
pH
Sterility per 9 CFR 113.26

SPECIFICATION:

Clear, Reddish Solution
7.0-7.4

Table with 2 columns: Assay Name and Result. Rows include Bacterial, Fungal, Mycoplasma, Bovine Extraneous Virus (BVD, Reovirus, Rabies).

Not for Human or Animal Consumption.
For Further Manufacturing Use Only.



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ASSAY:

Bovine Extraneous Virus per 9 CFR 113.47/53

Bluetongue Virus (BTV)

Bovine Adenovirus (BAV or BAdV)

Bovine Parvovirus (BPV)

Bovine Respiratory Syncytial Virus (BRSV)

Porcine Extraneous Virus per 9 CFR 113.47/53

Porcine Adenovirus (PAdV)

Porcine Parvovirus (PPV)

Transmissible Gastroenteritis Virus (TGE/TGEV)

Porcine Hemagglutinating Encephalomyelitis Virus (PHEV)

Hemadsorbing Agents per 9 CFR 113.46/53

Cytopathic Agents per 9 CFR 113.46/53

Seneca Virus A (SVA) per CVB Notice 18-05

SPECIFICATION:

NEGATIVE

NEGATIVE

NEGATIVE

NEGATIVE

NEGATIVE

NEGATIVE

NEGATIVE

NEGATIVE

NEGATIVE

NEGATIVE

NEGATIVE

NOTE: Full 9 CFR 113.46/53 Vero Cell Testing, 9 CFR 113.28 Mycoplasma, 9 CFR 113.47/53 Bovine & Porcine Adventitious Virus, & Seneca Valley A Viral testing was completed on the Trypsin raw material powder used in the product formulation. pH & 9 CFR 113.26 Sterility Testing was performed on the final 10X liquid product.

Storage: -5°C to -20°C

Minimum Recommended Expiration Date: [5 years from date of manufacturing]

Approved by:

1/8/2019

Quality and Compliance Manager

Date

Customer Representative

Date

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