



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 (1X) SOLUTION

0.05% Trypsin - 0.53 mM EDTA in HBSS, w/o Calcium & Magnesium

Sterile Filtered 0.2µ

Catalog Number: E1503

PRDOUCT FORMULATION

E1503

Trypsin-EDTA (1X) Solution in HBSS

0.05% Trypsin - 0.53 mM EDTA, w/o Ca & Mg

<u>Components</u>	<u>mg/Liter</u>
<u>INORGANIC SALTS</u>	
Potassium Chloride (KCl)	400.0000
Potassium Phosphate Monobasic (KH ₂ PO ₄)	60.00000
Sodium Chloride (NaCl)	8000.000
Sodium Phosphate Monobasic, Anhydrous (NaH ₂ PO ₄)	47.70000
<u>OTHER COMPONENTS</u>	
Trypsin 1:250	500.0000
EDTA, Disodium Dihydrate	200.0000
D-Glucose, Anhydrous (C ₆ H ₁₂ O ₆)	1000.000
Phenol Red, Sodium Salt (C ₁₉ H ₁₃ NaO ₅ S)	10.00000

ASSAY:

Appearance

pH

Osmolality

Sterility per 9 CFR 113.26

Fungal

Bacterial

Mycoplasma per 9 CFR 113.28

Bovine Extraneous Virus per 9 CFR 113.47/53

Bovine Viral Diarrhea (BVD or BVDD)

Reovirus (REO)

Rabies Virus (Rabies)

Bluetongue Virus (BTV)

Bovine Adenovirus (BAV or BAdV)

Bovine Parvovirus (BPV)

Bovine Respiratory Syncytial Virus (BRSV)

SPECIFICATION:

Clear, Reddish Solution

7.0 - 7.4

260 - 360 mOsm/KgH₂O

NEGATIVE

NEGATIVE

NEGATIVE

NEGATIVE

NEGATIVE

NEGATIVE

NEGATIVE

NEGATIVE

NEGATIVE

NEGATIVE

Not for Human or Animal Consumption.

For Further Manufacturing Use Only.



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ASSAY:

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

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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: [4 Years from Date of Manufacturing]

Approved by:



6/27/2019

Quality and Compliance Manager

Date

Customer Representative

Date

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