

Certificate of Analysis

Date of Testing: 2024-11-04 16:30:02

Date of Next Testing: 2028-11-03 16:30:02

Product Name: **Tris(hydroxymethyl)aminomethane**

CAS Number: 77-86-1

Specifications & Purity: PharmPure™, ≥99.9%(T)

Lot #: K2401540

SKU #: **T110598**

Version: **1**

Analysis #: **426080**

Storage Temperature: Argon charged

Parameter	Limit Values	Result
Loss on drying(EP)	0-0.5 (%)	0.12 %
Melting point	168-172 (°C)	171.03000 °C
Ignition Residue(Ash)	0-0.1 (%)	0.00 %
Water by Karl Fischer	0-0.2 (%)	0.02 %
Iron(Fe)(ICP)	0-1 (ppm)	0.00 ppm
Purity (Titration by H2SO4)	99.7-100.3 (%)	99.98 %
Heavy metal (as Pb)	0-2 (ppm)	0.00 ppm
PH(5% in water)	10-11.5	10.84
UV Absorbance 280nm(40%,H2O)	0-0.4	0.09
UV Absorbance 290nm(40%,H2O)	0-0.4	0.09
UV Absorbance 260nm(40%,H2O)	0-0.4	0.11
Loss on Drying(USP)	≤1 (%)	0.51800 %
Chloride (Cl-)	≤100 (ppm)	1.24 ppm
Endotoxin Level	<1 (EU/mg)	0.02600 EU/mg
Total Count Aerobic, Yeast, plus Mold	≤100 (cfu/g)	10.25400 cfu/g
Appearance (T110598)	White to Off-White Solid, Powder, or Crystals	White to Off-White Solid, Powder, or Crystals
Identity Test B (USP)	Pass	Pass
Identity Test C (USP)	Pass	Pass
Infrared spectrum	Conforms to Structure	Conforms to Structure
Related substances	Pass	Pass
Solubility in H2O , clear colorless , 200g plus 300ml of water	pass	Pass
Solubility in 2.5 g plus 50 ml of CO2-Free H2O (EP),colorless ,clear	Pass	Pass



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Parameter	Limit Values	Result
Identity Test A (USP)	Pass	Pass
DNAse, Exonuclease Detection	None Detected	none detected
NICKase, Endonuclease Detection	none Detected	none detected
RNAse Detection	None Detected	none detected
Protease Detection	None Detected	none detected
Cell Culture Test	pass	Pass

A handwritten signature in black ink that reads "John Su".

John Su
QA & QC Manager