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SOP APPENDIX



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Document Title:

RAW MATERIAL SPECIFICATION, TRIMMING SOLUTION

1.0 Requirements:

TEST	METHOD	REQUIREMENT
Identity	Visual Inspection	Container label and Certificate of Analysis must specify: "Trimming Solution" and must have same lot number.
Vendor	Visual Inspection	Mediatech, Inc., Cat. No. 99-676, or other qualified vendor.
Review of Vendor's Certificate of Analysis	Visual Inspection	All requirements on the Certificate of Analysis must be met. Osmolality: 303 – 318 mOsm/kg H ₂ O @ 22 – 25°C Density: 1.016 – 1.032 g/cm ³ @ 22 – 25°C pH: 7.2 – 7.5 @ 22 – 25°C Endotoxin: ≤ 2.0 EU/mL @ 37°C ± 0.5 °C Sterility: Pass USP Safety Test <88>: Pass Mycoplasma Test: Negative Appearance: Clear, colorless liquid The Certificate of Analysis must be signed and dated.

2.0 Packaging, Labeling & Storage

- Sterile 1 L bottles
- Trimming Solution, for investigational use, not for injection
- 2°C to 8°C; do not store in strong light

3.0 Formulation:

Components	Concentration
Sterile Purified Water USP	q.s. to 1 L
D-Mannitol	9.11000000 g/L
L-Histidine	4.65600000 g/L
Sodium Gluconate	19.62900000 g/L
KOH	1.12200000 g/L
CaCl ₂ 2 H ₂ O	0.03700000 g/L
MgSO ₄ 7 H ₂ O	1.23300000 g/L
Nicotinamide	0.61100000 g/L
Sodium Pyruvate	0.55000000 g/L
KH ₂ PO ₄	2.72200000 g/L