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SOP APPENDIX



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Document Title:

RAW MATERIAL SPECIFICATION PHASE I SOLUTION

1.0 Requirements:

TEST	METHOD	REQUIREMENT
Identity	Visual Inspection	Container label and Certificate of Analysis must specify: "Phase I Solution" and must have same lot number.
Vendor	Visual Inspection	Mediatech, Inc., Cat. No. 99-678, or other qualified vendor.
Review of Vendor's Certificate of Analysis	Visual Inspection	All requirements on the Certificate of Analysis must be met. Osmolality: 275 – 290 mOsm/kg H ₂ O @ 22 – 25°C Density: 1.005 – 1.009 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
- Phase I Solution, for investigational use, not for injection
- 2°C to 8°C, do not store in strong light

3.0 Formulation:

Components	Concentration (g/L)
Sterile Purified Water USP	q.s. to 1 L
D-Mannitol	5.46600000 g/L
NaOH	0.60000000 g/L
NaCl	6.13600000 g/L
KOH	0.32500000 g/L
CaCl ₂ 2 H ₂ O	0.11000000 g/L
MgSO ₄ 7 H ₂ O	0.19700000 g/L
NaH ₂ PO ₄ H ₂ O	3.45000000 g/L