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SOP APPENDIX



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Document Title:

RAW MATERIAL SPECIFICATION, GRADIENT STOCK SOLUTION

1.0 Requirements:

TEST	METHOD	REQUIREMENT
Identity	Visual Inspection	Container label and Certificate of Analysis must specify: "Gradient Stock Solution" and must have same lot number.
Vendor	Visual Inspection	Mediatech, Inc., Cat. No. 99-674, or other qualified vendor
Review of Vendor's Certificate of Analysis	Visual Inspection	All requirements on the Certificate of Analysis must be met. Osmolality: 430 – 460 mOsm/kg H ₂ O @ 22 – 25°C Density: 1.110 – 1.116 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 to slightly yellow liquid The Certificate of Analysis must be signed and dated.

2.0 Packaging, Labeling & Storage

- Sterile 1 L bottles
- Gradient Stock 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(+)-Raffinose 5 H ₂ O	17.83500000
L-Histidine	4.65600000
NaOH	4.60000000
Lactobionic Acid	35.83000000
KOH	0.39300000
CaCl ₂ 2 H ₂ O	0.07400000
MgSO ₄ 7 H ₂ O	1.23300000
NaH ₂ PO ₄ H ₂ O	3.45000000
PentaStarch*	20.00000000
Optiprep	250.00000000

*Viastarch manufactured by Fresenius Kabi, distributed by Preservation Solutions, Catalog No. E9703075