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**SOP
APPENDIX**



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Document Title:

**RAW MATERIAL SPECIFICATION,
HEPES BUFFER, 1 M SOLUTION, STERILE**

1.0 Requirements:

TEST	METHOD	REQUIREMENT
Identity	Visual Inspection	Container label and Certificate of Analysis must specify: "HEPES Buffer, 1 M Solution, Sterile," and must have same lot number.
Vendor	Visual Inspection	Mediatech, Inc., Part #25-060, or other qualified vendor.
Review of Vendor's Certificate of Analysis	Visual Inspection	All requirement on the Certificate of Analysis must be met. pH: 7.2 ± 0.2 @ 20 to 25°C Osmolality: Test & Report Endotoxin: ≤ 0.25 EU/mL @ 1:100 Mycoplasma: Tested Negative Sterility: Pass Cell Growth: Tested The Certificate of Analysis must be signed and dated.

2.0 Storage

15°C to 30°C

3.0 Formulation:

Components	Concentration (g/L)
HEPES	238.3
Water	q.s. to 1 L