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SOP APPENDIX



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Document Title:

RAW MATERIAL SPECIFICATION, RPMI 1640 WITH L-GLUTAMINE

1.0 Requirements:

TEST	METHOD	REQUIREMENT
Identity	Visual Inspection	Container label and Certificate of Analysis must specify: "RPMI 1640 with L-Glutamine," and must have same lot number.
Vendor	Visual Inspection	Mediatech, Inc., Cat. No. 99-595, or other qualified vendor.
Review of Vendor's Certificate of Analysis	Visual Inspection	All requirements on the Certificate of Analysis must be met. pH: 7.2 ± 0.2 Osmolality: 276 ± 20 mOsm/kg H ₂ O Endotoxin: ≤ 0.25 EU/mL Sterility : Pass Mycoplasma: Tested Negative USP Safety Test <88>: Pass The Certificate of Analysis must be signed and dated.

2.0 Storage

2°C to 8°C

3.0 Formulation:

Chemical	Concentration (g/L)	Chemical	Concentration (g/L)
Ca(NO ₃) ₂ 4 H ₂ O	0.10000000	L-Phenylalanine	0.01500000
MgSO ₄ , anhydrous	0.04880000	L-Proline	0.02000000
NaH ₂ PO ₄ H ₂ O	0.00011110	L-Serine	0.03000000
Na ₂ HPO ₄ , anhydrous	0.80070000	L-Threonine	0.02000000
Dextrose	2.00000000	L-Tryptophan	0.00500000
KCl	0.40000000	L-Valine	0.02000000
NaCl	6.00000000	L-Tyrosine 2Na 2 H ₂ O	0.02883000
L-Arginine	0.20000000	Biotin	0.00020000
L-Asparagine H ₂ O	0.05682000	Folic Acid	0.00100000
L-Aspartic Acid	0.02000000	Riboflavin	0.00020000
L-Cystine 2HCl	0.06520000	D-Ca-Pantothenate	0.00025000
L-Glutamic Acid	0.02000000	Choline Chloride	0.00300000
L-Glutamine	0.30000000	i-Inositol	0.03500000
Glycine	0.01000000	Nicotinamide	0.00100000
L-Histidine	0.01500000	PABA	0.00100000
Hydroxy-L-Proline	0.02000000	Pyridoxine HCl	0.00100000
L-Isoleucine	0.05000000	Thiamine HCl	0.00100000
L-Leucine	0.05000000	Vitamin B ₁₂	0.00000500
L-Lysine HCl	0.04000000	NaHCO ₃	2.00000000
L-Methionine	0.01500000		