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SOP APPENDIX



Document No. SOP 3102, A03	Revision No. 01	Effective Date 15 April 2009	Supersedes Date 07 July 2008	Page 1 of 2
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Document Title:

RAW MATERIAL SPECIFICATION, CMRL 1066 TRANSPLANT MEDIA, CONTAINS HEPES AND WITHOUT SODIUM BICARBONATE

1.0 Requirements:

TEST	METHOD	REQUIREMENT
Identity	Visual Inspection	Container label and Certificate of Analysis must specify: "CMRL 1066 Transplant Media," and "Contains HEPES and without Sodium Bicarbonate," and must have same lot number.
Vendor	Visual Inspection	Mediatech, Inc., Cat. No. 98-291, or other qualified vendor.
Review of Vendor's Certificate of Analysis	Visual Inspection	All requirement on the Certificate of Analysis must be met. pH: 7.3 ± 0.1 @ 20 to 25°C Osmolality: 300 ± 20 mOsm/kg H ₂ O Endotoxin: ≤ 0.5 EU/mL @ FW Sterility : Pass Mycoplasma: 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)
CaCl ₂ , anhydrous	0.20000000	Biotin	0.00001000
MgSO ₄ , anhydrous	0.09970000	Folic Acid	0.00001000
Na Acetate, anhydrous	0.05000000	Riboflavin	0.00001000
NaH ₂ PO ₄ H ₂ O	0.14000000	Coccarboxylase	0.00100000
Dextrose	1.00000000	Li ₃ Coenzyme A 2 H ₂ O	0.00250000
KCl	0.40000000	Cozymase	0.00700000
NaCl	6.80000000	Na ₂ FAD	0.00100000
Na Gluconate H ₂ O	0.00420000	Na TPN	0.00100000
L-Alanine	0.02500000	Na ₃ UTP X H ₂ O	0.00100000
L-Arginine HCl	0.07000000	Ascorbic Acid	0.05000000
L-Aspartic Acid	0.03000000	D-Ca-Pantothenate	0.00001000
L-Cysteine HCl H ₂ O	0.26000000	Choline Chloride	0.00050000
L-Cystine 2 HCl	0.02600000	i-Inositol	0.00005000
L-Glutamic Acid	0.07500000	Nicotinic Acid	0.00002500
Glycine	0.05000000	Nicotinamide	0.00002500
L-Histidine HCl H ₂ O	0.02000000	PABA	0.00005000

Document No. SOP 3102, A03	Revision No. 01	Effective Date 15 April 2009	Supersedes Date 07 July 2008	Page 2 of 2
Document Title: RAW MATERIAL SPECIFICATION, CMRL 1066 WITHOUT SODIUM BICARBONATE, WITH L-GLUTAMINE				

Chemical	Concentration (g/L)	Chemical	Concentration (g/L)
Hydroxy-L-Proline	0.01000000	Pyridoxine HCl	0.00005000
L-Isoleucine	0.02000000	Thiamine HCl	0.00001000
L-Leucine	0.06000000	Glutathione (reduced)	0.01000000
L-Lysine HCl	0.07000000	Thymidine	0.01000000
L-Methionine	0.01500000	2D-Adenosine	0.01000000
L-Phenylalanine	0.02500000	2D-Cytidine HCl	0.01000000
L-Proline	0.04000000	2D-Guanosine	0.01000000
L-Serine	0.02500000	5-Methyl-2'-Deoxycytidine	0.00010000
L-Threonine	0.03000000	Cholesterol	0.00020000
L-Tryptophan	0.01000000	Tween 80	0.00500000
L-Valine	0.02500000	HEPES	5.95000000
L-Tyrosine 2 Na 2 H ₂ O	0.05800000	L-Alanyl-L-Glutamine	0.42380000