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SOP APPENDIX



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Document Title:

RAW MATERIAL SPECIFICATION, ISLET GRADIENT 1.096, STERILE

1.0 Requirements:

TEST	METHOD	REQUIREMENT
Identity	Visual Inspection	Container labeling and Certificate of Analysis must both specify: "Islet Gradient 1.037, sterile," "Catalog No. 99-691-CIS" and same lot number.
Vendor	Visual Inspection	Manufacturer & Distributor: Mediatech
Review of Certificate of Analysis	Visual Inspection	The following criteria must be met: Density 1.096 ± 0.002 g/mL @ 20 – 25°C pH 7.3 ± 0.2 @ 20 – 25°C Osmolality 330 – 530 mOsm/kg H ₂ O Endotoxin ≤ 2.0 EU/mL Mycoplasma Tested Negative Sterility Pass USP Safety Test Pass Appearance: Clear, almost colorless solution

2.0 Storage

2 – 30°C

3.0 Formulation:

NA