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SOP APPENDIX



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Document Title:

RAW MATERIAL SPECIFICATION, CIZYME THERMOLYSIN

1.0 Requirements:

TEST	METHOD	REQUIREMENT
Identity	Visual Inspection	Container labeling and Certificate of Analysis must specify: "Cizyme Thermolysin" and must have same lot number.
Vendor	Visual Inspection	Manufacturer: VitaCyte LLC, Cat. #002-1000
Review of Vendor's Certificate of Analysis	Visual Inspection	The following criteria must be met: Appearance: White lyophilized cake Neutral protease activity: $> 2.3 \times 10^6$ Units Endotoxins: < 50 EU/mg protein The Certificate of Analysis must be signed and dated.

2.0 Storage

$< -20^{\circ}\text{C}$

3.0 Formulation:

NA