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## SOP APPENDIX



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**Document Title:**

## RAW MATERIAL SPECIFICATION, STOCK POLYSUCROSE SOLUTION, STERILE

### 1.0 Requirements:

TEST	METHOD	REQUIREMENT
<b>Identity</b>	Visual Inspection	Container labeling and Certificate of Analysis must both specify: "Stock Polysucrose Solution, sterile," "Catalog No. 99-662-CVS" and same lot number.
<b>Vendor</b>	Visual Inspection	Manufacturer & Distributor: Mediatech
<b>Review of Certificate of Analysis</b>	Visual Inspection	The following criteria must be met: pH <span style="float: right;">7.3 ± 0.2 @ 20 – 25°C</span> Osmolality <span style="float: right;">330 – 530 mOsm/kg H<sub>2</sub>O</span> Endotoxin <span style="float: right;">≤ 2.0 EU/mL</span> Mycoplasma <span style="float: right;">Tested Negative</span> Sterility <span style="float: right;">Pass</span> Density <span style="float: right;">1.132 ± 0.002 g/mL @ 20 – 25°C</span> USP Safety Test <span style="float: right;">Pass</span> Appearance: <span style="float: right;">Clear, almost colorless solution</span>

### 2.0 Storage

2 – 30°C

### 3.0 Formulation:

NA