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## SOP APPENDIX



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Page 1 of 1

**Document Title:**

## RAW MATERIAL SPECIFICATION, VIASpan (BELZER UW) COLD STORAGE SOLUTION

### 1.0 Requirements:

TEST	METHOD	REQUIREMENT
<b>Identity</b>	Visual Inspection	Container label and Certificate of Analysis must specify: "ViaSpan" or "Belzer UW" or "UW" Cold Storage Solution, and must have same lot number.
<b>Vendor</b>	Visual Inspection	Qualified Supplier
<b>Review of Vendor's Certificate of Analysis</b>	Visual Inspection	<p>All requirement on the Certificate of Analysis must be met.</p> <p>Appearance: Clear, straw-yellow solution, with no obvious particulate matter</p> <p>pH: 6.8 – 8.0</p> <p>Molecular Mass Distribution: 100000 – 300000</p> <p>High Fraction (10%): ≤ 2000000</p> <p>Low Fraction (10%): ≥ 25000</p> <p>Assay, Pentafraction: 45.0 – 57.5 mg/mL</p> <p>Assay, Lactobionic Acid: 32.25 – 41.20 mg/mL</p> <p>Assay, Raffinose Pentahydrate: 16.05 – 20.50 mg/mL</p> <p>Assay, Allopurinol: 0.122 – 0.156 mg/mL</p> <p>Assay, Glutathione: 0.830 – 1.060 mg/mL</p> <p>Assay, Adenosine: 1.21 – 1.54 mg/mL</p> <p>Sterility: No Growth</p> <p>Bacterial Endotoxins: ≤ 0.5 EU/mL</p> <p>The Certificate of Analysis must be signed and dated.</p>

### 2.0 Storage

- 2°C to 8°C
- Avoid excessive heat
- Do not use if frozen, discolored, or if particulate matter, precipitates or contamination is evident.

### 3.0 Formulation:

Chemical	Concentration (g/L)
Hydroxyethyl Starch (Pentafraction)	50.00
Lactobionic Acid	35.83
KH <sub>2</sub> PO <sub>4</sub>	3.40
MgSO <sub>4</sub> 7 H <sub>2</sub> O	1.23
Raffinose Pentahydrate	17.83
Adenosine	1.34
Allopurinol	0.136
Glutathione	0.922
Potassium Hydroxide	5.61
NaOH and/or HCl	Adjust pH to 7.4
Sterile Water for Injection	q.s. to 1 L