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RAW MATERIAL SPECIFICATION, PENTASTARCH, 10% SOLUTION

1.0 Requirements:

TEST	METHOD	REQUIREMENT
Identity	Visual Inspection	Container label and Certificate of Analysis must specify: "PentaStarch, 10% Solution" and must have same lot number.
Vendor	Visual Inspection	Mediatech, Inc., Cat. No. 99-723, or other qualified vendor.
Review of Vendor's Certificate of Analysis	Visual Inspection	All requirements on the Certificate of Analysis must be met. Osmolality: 345 – 365 mOsm/kg H_2O @ 22 – 25ºC Density: 1.056 – 1.064 g/cm^3 @ 22 – 25ºC pH: 7.2 – 7.5 @ 22 – 25ºC Endotoxin: ≤ 2.0 EU/mL @ 37ºC ± 0.5 ºC Sterility: Pass USP Safety Test <88>: Pass Mycoplasma Test: Negative Appearance: Clear, colorless to slightly yellow liquid The Certificate of Analysis must be signed and dated.

2.0 Packaging, Labeling & Storage

- Sterile 1 L bottles
- PentaStarch, 10% Solution, for investigational use, not for injection
- 2ºC to 8ºC, do not store in strong light

3.0 Formulation:

Components	Concentration (g/L)
Sterile Purified Water USP	q.s. to 1 L
D(+)–Raffinose 5 H_2O	17.83500000
L-Histidine	4.65600000
NaOH	4.60000000
Lactobionic Acid	35.83000000
KOH	0.39300000
$CaCl_2$ 2 H_2O	0.07400000
$MgSO_4$ 7 H_2O	1.23300000
NaH_2PO_4 H_2O	3.45000000
PentaStarch*	100.00000000

*Viastarch manufactured by Fresenius Kabi, distributed by Preservation Solutions, Catalog No. E9703075

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