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Supported by grants from the National Institute of Allergy and Infectious Diseases and the National Institute for Diabetes and Digestive and Kidney Diseases.

- At Emory University, U01AI089317.
- At Northwestern University, U01AI089316.
- At the University of Alberta, Edmonton: U01AI065191.
- At the University of California, San Francisco, U01DK085531.
- At the University of Illinois, Chicago, 5U01DK070431-10.
- At the University of Iowa, U01DK070431.
- At the University of Miami, U01DK070460.
- At the University of Minnesota, U01AI065193.
- At the University of Pennsylvania, U01DK070430.
- At Uppsala University, U01AI065192.

In addition, the study was supported by the following GCRC and CTSA awards:

- At Emory University: UL1TR000454.
- At Northwestern University: 5UL1RR025741 and 8UL1TR000150.
- At the University of California, San Francisco, UL1TR000004.
- At the University of Illinois, Chicago, UL1TR000050.
- At the University of Miami: 1UL1TR000460.
- At the University of Minnesota: 5M01-RR000400 and UL1TR000114.
- At the University of Pennsylvania: UL1TR000003.

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To cite this article

Raw Material Specification, Hanks' Balanced Salt Solution, Sterile – Standard Operating Procedure of the NIH Clinical Islet Transplantation Consortium

CellR4 2016; 4 (3): e1904

DAIT, NIAID, NIH

SOP APPENDIX



Document No.
SOP 3102, A04

Revision No.
00

Effective Date
07 July 08

Supersedes Date
NA

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Document Title:

RAW MATERIAL SPECIFICATION, HANKS' BALANCED SALT SOLUTION, STERILE

1.0 Requirements:

TEST	METHOD	REQUIREMENT
Identity	Visual Inspection	Container label and Certificate of Analysis must specify: "Hanks' Balanced Salt Solution, Sterile," and must have same lot number.
Vendor	Visual Inspection	Mediatech, Inc., or other qualified vendor
Review of Vendor's Certificate of Analysis	Visual Inspection	All requirement on the Certificate of Analysis must be met. pH: $7.3 \pm 0.1 @ 20 \text{ to } 25^\circ\text{C}$ Osmolality: $280 \pm 20 \text{ mOsm/kg H}_2\text{O} @ 20 \text{ to } 25^\circ\text{C}$ Endotoxin: $\leq 0.5 \text{ EU/mL}$ Mycoplasma: Negative Sterility: Negative Toxicity (USP 26): Negative The Certificate of Analysis must be signed and dated.

2.0 Storage

2°C to 8°C

3.0 Formulation:

Chemical	Concentration (g/L)	Chemical	Concentration (g/L)
CaCl ₂ anhydrous	0.140	NaCl	8.00
KH ₂ PO ₄ anhydrous	0.0600	MgCl ₂ 6 H ₂ O	0.100
NaH ₂ PO ₄ H ₂ O	0.000111	MgSO ₄ 7 H ₂ O	0.100
Na ₂ HPO ₄ anhydrous	0.0480	L-Glutamine	0.300
Dextrose	1.00	NaHCO ₃	0.350
KCl	0.400		