

Purified Human Pancreatic Islets, CIT Purification Solution – A Standard Operating Procedure of the NIH Clinical Islet Transplantation Consortium

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SOP ATTACHMENT



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Document Title:

PURIFIED HUMAN PANCREATIC ISLETS, CIT PURIFICATION SOLUTION

Manufacturing Site: _____ Date: _____

1. Materials:

Material	Source	Lot #	Expiration Date	Quantity Required	Quantity Used
Cold Storage/Purification Stock Solution	Mediatech, Product No. 99-677-CM			790 to 799 mL	mL
PentaStarch, 10% Solution	Mediatech, Product No. 99-723-CM			200 mL	mL
Heparin Sodium Injection USP	_____ Units/mL			10,000 units (_____ mL)	mL

2. Procedure

- 2.1 In a BSC place a sterile 1 L bottle.
- 2.2 Add 790 to 799 mL of Cold Storage/Purification Stock Solution to the bottle. (Volume will be adjusted based on volume of Heparin added so that total volume is 1 liter.)
- 2.3 Add 200 mL of PentaStarch, 10% Solution to the bottle.
- 2.4 Add Heparin to the bottle to obtain a final concentration of 10 Units/mL (10,000 Units total).
- 2.5 Cap the bottle and mix by gentle inversion at least 5 times.
- 2.6 Label the bottle with:
 - "CIT Purification Solution"
 - Islets Lot Number
 - "Store at 2°C to 8°C"
 - Date Prepared
 - Expiration Date (the end of the day after preparation)
 - Initials of the person who prepared the solution
- 2.7 Store the bottle of solution at 2°C to 8°C before use.

Total volume prepared: _____ mL

Prepared by: _____ Date: _____

Reviewed by: _____ Date: _____

Islets Lot Number: _____