

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

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**SOP
ATTACHMENT**



Document No. 3106, B01	Revision Number 00	Effective Date 07 July 2008	Supersedes Date N/A	Page 1 of 1
Document Title: PURIFIED HUMAN PANCREATIC ISLETS, CIT DIGESTION SOLUTION				

Manufacturing Site: _____ Date: _____

1. **Materials:**

Material	Source	Lot #	Expiration Date	Quantity Required	Quantity Used
Phase I Solution	Mediatech, 99-678-CM			1 L Bottle	Bottle
Heparin Sodium Injection USP	_____ Units/mL			10,000 units (_____ mL)	mL

2. **Procedure**

- 2.1 In a BSC place a 1 L bottle of Phase I Solution.
- 2.2 Add Heparin to the bottle to obtain a final concentration of 10 Units/mL (10,000 Units total).
- 2.3 Cap the bottle and mix by gentle inversion 5 times.
- 2.4 Label the bottle with:
 - "CIT Digestion 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
- 2.5 Store the bottle(s) of solution at 2°C to 8°C before use.

Total Volume Prepared: _____ mL

Prepared by: _____ **Date:** _____

Reviewed by: _____ **Date:** _____

Islets Lot Number: _____