

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

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## SOP ATTACHMENT



<b>Document No.</b> 3106, B12	<b>Revision No.</b> 00	<b>Effective Date</b> 07 July 2008	<b>Supersedes Date</b> N/A	Page 1 of 1
<b>Document Title:</b>  <b>PURIFIED HUMAN PANCREATIC ISLETS, CIT WASH SOLUTION</b>				

Manufacturing Site: \_\_\_\_\_ Date: \_\_\_\_\_

1. **Materials:**

Material	Source	Lot #	Expiration Date	Quantity Required	Quantity Used
<b>Cold Storage/Purification Stock Solution</b>	Mediatech, Product No. 99-677-CM			765 to 774 mL	mL
<b>PentaStarch, 10% Solution</b>	Mediatech, Product No. 99-723-CM			200 mL	mL
<b>Albumin Human USP, 25% Solution</b>				25 mL	mL
<b>Heparin Sodium Injection USP</b>	_____ Units/mL			10,000 units (_____ mL)	mL
<b>Insulin Human Injection USP, Recombinant,</b>				200 units	units

2. **Procedure**

- 2.1 In a BSC place a sterile 1 L bottle.
- 2.2 Add 765 to 774 mL of Cold Storage/Purification Solution to the bottle. (Volume will be adjusted based on volume of Heparin added so that the total volume is 1 liter.)
- 2.3 Add 200 mL of 10% PentaStarch Solution to the bottle.
- 2.4 Add 25 mL of Albumin Human USP, 25% Solution to the bottle.
- 2.5 Add Heparin to the bottle to obtain a final concentration of 10 Units/mL (10,000 Units total).
- 2.6 Add 200 units of Insulin Human Injection USP, Recombinant, to the bottle.
- 2.7 Cap the bottle and mix by gentle inversion at least 5 times.
- 2.8 Label the bottle with:
  - "CIT Wash 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
- 2.9 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: \_\_\_\_\_