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**DAIT, NIAID, NIH**

**SOP  
ATTACHMENT**



<b>Document No.</b> 3106, B08	<b>Revision Number</b> 00	<b>Effective Date</b> 07 July 2008	<b>Supersedes Date</b> N/A	<b>Page 1 of 2</b>
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**Document Title:**

**PURIFIED HUMAN PANCREATIC ISLETS,  
CIT TRANSPLANT WASH MEDIA  
WITH LISOFYLLINE OR EXENATIDE**

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

This lot will be made with:      Lisofylline                      or                      Exenatide                      (Circle One)

1.      Materials:

<b>Material</b>	<b>Source</b>	<b>Lot #</b>	<b>Expiration Date</b>	<b>Quantity Required</b>	<b>Quantity Used</b>
<b>CMRL 1066 Transplant Media, Contains HEPES and without Sodium Bicarbonate</b>	Mediatech 98-291-L			500 mL	mL
<b>Albumin Human USP, 25% Solution</b>				50 mL	mL
<b>Heparin Sodium Injection USP</b>	_____ Units/mL			5,000 units (_____ mL)	mL
<b>Lisofylline, 60 mg/mL</b>	Cell Therapeutics Formula #0109-00			260 µL	µL
<b>Exenatide, 250 µg/mL</b>	Amylin Pharmaceuticals NDC # 66780-210-07			190 µL	µL

2.      Procedure

- 2.1      In a BSC place a 500 mL bottle of CMRL 1066 Transplant Media, contains HEPES and without Sodium Bicarbonate.
- 2.2      Add 50 mL of Albumin Human Serum, 25% Solution to the bottle.
- 2.3      Add Heparin to the bottle to obtain a final concentration of 10 Units/mL (5,000 Units total).
- 2.4      Add 260 µL of 60 mg/mL Lisofylline or 190 µL of 250 µg/mL Exenatide. Cross out, initial and date the one **not** used.
- 2.5      Cap the bottle and mix by gentle inversion at least five times.

Islets Lot Number: \_\_\_\_\_

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<b>Document Title:</b>				
<b>PURIFIED HUMAN PANCREATIC ISLETS, CIT TRANSPLANT WASH MEDIA WITH LISOFYLLINE OR EXENATIDE</b>				

- 2.6 Cap the bottle and label it with:
- "CIT Transplant Wash Media with Lisofylline"
  - or
  - "CIT Transplant Wash Media with Exenatide"
  - 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: \_\_\_\_\_