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SOP ATTACHMENT



Document No. 3106, B07	Revision Number 01	Effective Date 25 October 2010	Supersedes Date 07 July 2008	Page 1 of 2
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Document Title:

PURIFIED HUMAN PANCREATIC ISLETS, CIT CULTURE MEDIA WITH LISOFYLLINE

Manufacturing Site: _____ Date: _____

1. **Materials:**

Material	Source	Lot #	Expiration Date	Quantity Required	Quantity Used
CMRL 1066, Supplemented				500 mL	mL
Albumin Human USP, 25% Solution				10 mL	mL
Heparin Sodium Injection USP	_____ Units/mL			5,000 units (_____ mL)	mL
Lisofylline, 60 mg/mL	Cell Therapeutics Formula #0109-00			240 µL	µL
Hydrochloric Acid, 1 N				0.2 mL	mL
Sterile Water for Injection				20 mL	mL
IGF-1, 1 mg/vial	Cell Sciences Cat. #CM001			50 µL	µL

2. **Procedure**

- 2.1 In a BSC place a 500 mL bottle of CMRL 1066, Supplemented.
- 2.2 Add 10 mL of Albumin Human USP, 25% Solution, to the bottle.
- 2.3 Add 5,000 Units of Heparin to the bottle.
- 2.4 Add 240 µL of 60 mg/mL Lisofylline.
- 2.5 Separately, add 0.2 mL of 1 N Hydrochloric Acid to 20 mL of Sterile Water for Injection to make 10 mM HCl solution. Reconstitute one 1 mg vial of IGF-1 with 1.0 mL of the 10 mM HCl solution. Add 50 µL of the IGF-1 solution to the beaker or flask. Aliquot the remaining IGF-1 solution into 19 small sterile vials and store below -20°C. Cap the bottle and label it with:
 - “CIT IGF-1 Solution, 50 µL, ”
 - Islets Lot Number (for traceability of preparation record)
 - “Store below -20°C”
 - Date Prepared
 - Expiration Date (3 months after preparation)
 - Initials of the person who prepared the solution

Islets Lot Number: _____

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Document Title:
**PURIFIED HUMAN PANCREATIC ISLETS,
CIT CULTURE MEDIA WITH LISOFYLLINE**

- 2.6 Cap the bottle and mix by gentle inversion at least five times.
- 2.7 Cap the bottle and label it with:
- “CIT Culture Media with Lisofylline”
 - 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
- 2.8 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: _____