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


The NIH CIT Consortium


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SOP ATTACHMENT

Document Title:

PURIFIED HUMAN PANCREATIC ISLETS, CIT WASH SOLUTION

Manufacturing Site: ____________________________ Date: ____________________________

1. Materials:

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

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: ____________________________