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Supported by grants from the National Institute of Allergy and Infectious Diseases and the National Institute for Diabetes and Digestive and Kidney Diseases.

- At Emory University, U01AI089317.
- At Northwestern University, U01AI089316.
- At the University of Alberta, Edmonton: U01AI065191.
- At the University of California, San Francisco, U01DK085531.
- At the University of Illinois, Chicago, 5U01DK070431-10.
- At the University of Iowa, U01DK070431.
- At the University of Miami, U01DK070460.
- At the University of Minnesota, U01AI065193.
- At the University of Pennsylvania, U01DK070430.
- At Uppsala University, U01AI065192.

In addition, the study was supported by the following GCRC and CTSA awards:

- At Emory University: UL1TR000454.
- At Northwestern University: 5UL1RR025741 and 8UL1TR000150.
- At the University of California, San Francisco, UL1TR000004.
- At the University of Illinois, Chicago, UL1TR000050.
- At the University of Miami: 1UL1TR000460.
- At the University of Minnesota: 5M01-RR000400 and UL1TR000114.
- At the University of Pennsylvania: UL1TR000003.

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To cite this article

Raw Material Specification, Liberase MTF, C/T GMP Grade – Standard Operating Procedure of the NIH Clinical Islet Transplantation Consortium

CellR4 2016; 4 (3): e2012

DAIT, NIAID, NIH

SOP APPENDIX



Document No. SOP 3102, A40	Revision No. 00	Effective Date 25 October 2010	Supersedes Date NA	Page 1 of 1
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Document Title:

RAW MATERIAL SPECIFICATION, LIBERASE MTF C/T GMP GRADE

1.0 Requirements:

TEST	METHOD	REQUIREMENT																																				
Identity	Visual Inspection	Container labeling and Certificate of Analysis must both specify: "Liberase MTF C/T GMP Grade," "Catalog No. 05339880001" and same lot number.																																				
Vendor	Visual Inspection	Manufacturer & Distributor: Roche Diagnostics																																				
Product	Visual Inspection	Contents: 2 bottles of Collagenase 2000 MTF MPB (05349907) 3 bottles of Thermolysin MTF MPB (05349915)																																				
Review of Certificate of Analysis	Visual Inspection	<p>The following criteria must be met:</p> <p><u>Collagenase 2000 MTF MPB (05349907)</u></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;">Appearance:</td> <td>White lyophilized cake</td> </tr> <tr> <td>Protein Mass/Bottle:</td> <td>430 – 644 mg protein</td> </tr> <tr> <td>Collagenase I Content:</td> <td>258 – 386 mg</td> </tr> <tr> <td>Collagenase II Content:</td> <td>172 – 258 mg</td> </tr> <tr> <td>Collagenase Ib, c part of Collagenase I:</td> <td>≤ 10% (area)</td> </tr> <tr> <td>HPLC Purity</td> <td></td> </tr> <tr> <td> Total Peak Areas (Col I + Col II):</td> <td>≥ 85%</td> </tr> <tr> <td>Activity (Wünsch) Calculate:</td> <td>2172 – 3617 U/vial</td> </tr> <tr> <td>Ratio Collagenase II/Total Collagenase:</td> <td>0.3 – 0.5</td> </tr> <tr> <td>Endotoxins:</td> <td>≤ 10 EU/mg protein</td> </tr> <tr> <td>Bioburden:</td> <td>≤ 10 CFU/bottle</td> </tr> </table> <p><u>Thermolysin MTF MPB (0534991)</u></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;">Appearance:</td> <td>White lyophilized cake</td> </tr> <tr> <td>Protein Mass/Bottle:</td> <td>12.0 – 18.0 mg protein</td> </tr> <tr> <td>Activity Neutral Protease calculated:</td> <td>130,500 – 234,000 U/vial</td> </tr> <tr> <td>HPLC Purity</td> <td></td> </tr> <tr> <td> Total peak area Thermolysin:</td> <td>≥ 85%</td> </tr> <tr> <td>Endotoxins:</td> <td>≤ 50 EU/mg protein</td> </tr> <tr> <td>Bioburden:</td> <td>≤ 10 CFU/bottle</td> </tr> </table>	Appearance:	White lyophilized cake	Protein Mass/Bottle:	430 – 644 mg protein	Collagenase I Content:	258 – 386 mg	Collagenase II Content:	172 – 258 mg	Collagenase Ib, c part of Collagenase I:	≤ 10% (area)	HPLC Purity		Total Peak Areas (Col I + Col II):	≥ 85%	Activity (Wünsch) Calculate:	2172 – 3617 U/vial	Ratio Collagenase II/Total Collagenase:	0.3 – 0.5	Endotoxins:	≤ 10 EU/mg protein	Bioburden:	≤ 10 CFU/bottle	Appearance:	White lyophilized cake	Protein Mass/Bottle:	12.0 – 18.0 mg protein	Activity Neutral Protease calculated:	130,500 – 234,000 U/vial	HPLC Purity		Total peak area Thermolysin:	≥ 85%	Endotoxins:	≤ 50 EU/mg protein	Bioburden:	≤ 10 CFU/bottle
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2.0 Storage

≤ 20°C

3.0 Formulation:

NA