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## SOP APPENDIX



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01

**Effective Date**  
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**Supersedes Date**  
07 July 2008

Page 1 of 1

**Document Title:**

## RAW MATERIAL SPECIFICATION, COLLAGENASE NB 1, GMP GRADE

### 1.0 Requirements:

TEST	METHOD	REQUIREMENT																														
<b>Identity</b>	Visual Inspection	Container labeling and Certificate of Analysis must specify: "Collagenase NB 1, GMP Grade" and must have same lot number.																														
<b>Vendor</b>	Visual Inspection	Distributor: SERVA Manufacturer: Nordmark, Cat. #17452																														
<b>Review of Vendor's Certificate of Analysis</b>	Visual Inspection	<p>The following criteria must be met:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;">Color:</td> <td>White to almost white powder</td> </tr> <tr> <td>Constitution:</td> <td>Lyophilisate</td> </tr> <tr> <td>Container:</td> <td>Vial</td> </tr> <tr> <td>SDS-page, main bands:</td> <td>Complies to reference</td> </tr> <tr> <td>Water:</td> <td>≤ 15%</td> </tr> <tr> <td>PZ (Wünsch) @ 25°C:</td> <td>≥ 3.0 U/mg lyophilisate</td> </tr> <tr> <td>PZ (Wünsch) @ 25°C:</td> <td>≥ 2,000 U/vial</td> </tr> <tr> <td>Neutral protease Activity:</td> <td>≤ 0.050 U/mg lyophilisate</td> </tr> <tr> <td>Trypsin-like activity:</td> <td>≤ 0.50 U/mg</td> </tr> <tr> <td>Total viable aerobic bacteria &amp; fungi:</td> <td>≤ 10/vial</td> </tr> <tr> <td>Clostridia:</td> <td>Must comply</td> </tr> <tr> <td>Abnormal toxicity:</td> <td>Must comply</td> </tr> <tr> <td>Bacterial Endotoxins:</td> <td>≤ 10.0 EU/mg lyophilisate</td> </tr> <tr> <td>Date Manufactured:</td> <td>Present</td> </tr> <tr> <td>Expiration Date:</td> <td>Present</td> </tr> </table> <p>The Certificate of Analysis must be signed and dated.</p>	Color:	White to almost white powder	Constitution:	Lyophilisate	Container:	Vial	SDS-page, main bands:	Complies to reference	Water:	≤ 15%	PZ (Wünsch) @ 25°C:	≥ 3.0 U/mg lyophilisate	PZ (Wünsch) @ 25°C:	≥ 2,000 U/vial	Neutral protease Activity:	≤ 0.050 U/mg lyophilisate	Trypsin-like activity:	≤ 0.50 U/mg	Total viable aerobic bacteria & fungi:	≤ 10/vial	Clostridia:	Must comply	Abnormal toxicity:	Must comply	Bacterial Endotoxins:	≤ 10.0 EU/mg lyophilisate	Date Manufactured:	Present	Expiration Date:	Present
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Date Manufactured:	Present																															
Expiration Date:	Present																															

### 2.0 Storage

+ 2°C to + 8°C

### 3.0 Formulation:

NA