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## SOP APPENDIX



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01

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**Document Title:**

## RAW MATERIAL SPECIFICATION, NEUTRAL PROTEASE NB, GMP GRADE

### 1.0 Requirements:

TEST	METHOD	REQUIREMENT
<b>Identity</b>	Visual Inspection	Container labeling and Certificate of Analysis must specify: "Neutral Protease NB, GMP Grade" and must have same lot number.
<b>Vendor</b>	Visual Inspection	Distributor: SERVA Manufacturer: Nordmark, Cat. #30303
<b>Review of Vendor's Certificate of Analysis</b>	Visual Inspection	The following criteria must be met: Color: Beige to brown powder Constitution: Lyophilisate Container: Vial SDS-page, main bands: Complies to reference Water: ≤ 15% Neutral protease activity: ≥ 0.50 U/mg lyophilisate Neutral protease activity: ≥ 100 U/vial Total viable aerobic bacteria & fungi: ≤ 10/vial Clostridia: Must comply Abnormal toxicity: Must comply Bacterial Endotoxins: ≤ 100.0 EU/mg lyophilisate The Certificate of Analysis must be signed and dated.

### 2.0 Storage

+ 2°C to + 8°C

### 3.0 Formulation:

NA