



Becton Dickinson and Company
 BD Diagnostic Systems
 PO Box 999
 Sparks MD 21152-0999 US

Certificate of Analysis

Product Name : BOTTLE BACTO PEPTONE 500G
Catalog Number : 211677 **Manufacture Date** : 2008/07/15
Batch Number : 8198113
Expiration Date : 2013/06/10

01. Dehydrated Appearance: Tan, free-flowing, homogeneous powder.
02. Solubility: 1, 2 and 10% solutions, soluble in distilled or deionized water.
03. Solution Appearance 1%: Light amber, clear.
04. Solution Appearance 2%: Light to medium amber, clear.
05. Solution Appearance 10%: Medium to dark amber, clear to very slightly opalescent, may have a very slight precipitate.
06. Certificate of Suitability issued by the European Directorate for the Quality of Medicines (EDQM): CEP 2000-175
07. Cultural Response: This lot was tested and found satisfactory for fermentable carbohydrate (negative) and production of indole, acetylmethylcarbinol and hydrogen sulfide (all positive). In addition, the following growth response was obtained:

| TEST ORGANISMS | ATCC® | RECOVERY |
|-----------------------|-------|----------|
| Escherichia coli | 25922 | good |
| Staphylococcus aureus | 25923 | good |

08. Residual Solvents (CPMP/ICH/283/95): Typical Analysis for Peptone indicates that there is less than 5000 ppm of 1-butanol. No other solvents were detected during analysis.

The test methods for characteristics listed below are:
 Nitrogen (Kjeldahl)
 Amino Nitrogen (Modified Sorenson)

| Characteristic | Unit | Value | LowLimit | HighLimit |
|-------------------|------|---------|----------|-----------|
| pH at 25°C : | | 7.1 | 6.8 | 7.2 |
| Loss on Drying : | % | 3.0 | 0.0 | 5.0 |
| Ash : | % | 3.3 | 0.0 | 6.2 |
| Bulk Lot Number : | | 8080887 | | |
| Nitrogen : | % | 15.9 | 14.2 | 17.4 |
| Amino Nitrogen : | % | 3.6 | 2.5 | 4.0 |

| Animal Source | Country of Origin | Tissue Category | | |
|---------------|-------------------|-----------------|-----|-----|
| | | BIC | SIC | ABC |
| Porcine | USA | III | III | B |
| Bovine | USA | III | IV | C |
| Bovine | USA | I | IV | C |
| Bovine | USA | IV | IV | C |



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| | | | | |
|--------|-----|----|----|-----|
| Bovine | USA | IV | IV | NDF |
|--------|-----|----|----|-----|

The Batch Number on this certificate is synonymous with the Lot Number shown on the product label.

BD Diagnostic Systems (BDDS) is an ISO 13485:2003 and ISO 9001:2000 Registered facility. BDDS products are manufactured in facilities registered with the United States Food and Drug Administration (FDA), and are regulated by the FDA's Quality System Regulations (QSRs). This product met BDDS stringent quality standards at time of batch/lot release. Any test results reported on this certificate were obtained at time of release.

BD Diagnostic Systems' Certificates of Analysis (COA) typically are set up to contain animal origin information for finished products manufactured using materials of animal origin. The animal origin information may be contained in the animal source table and/or in one or more of the additional paragraphs found on the COA. This information is a compilation of animal origin data from the individual lots of raw materials used to manufacture the batch of BD Diagnostic Systems (BDDS) finished product for which the COA was created.

At the time the BDDS Certificate of Analysis is created and sent to the Internet website address at <http://www.bd.com/regdocs/>, the animal origin information as provided to BDDS by its suppliers is pulled into the certificate as it is created by the BDDS automated certificate system.

At times, suppliers notify BDDS of new and/or additional information they have received from their raw material suppliers that modifies the animal origin information for lots previously provided to BDDS. When this situation occurs, BDDS updates the animal origin information in the automated certificate system, recreates the affected finished product COAs for batches within expiration date, and sends them to the Internet website where they replace the prior certificate and are immediately available to customers.

Customers enrolled in BD Diagnostic Systems' Automated Change Notification Program will be notified of the changes described above.

For complete details refer to "BD Position Statement - BD Diagnostic-Diagnostic Systems, COA Animal Origin Information Position Statement", located on the Internet website address at <http://www.bd.com/regdocs/>.



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John Gerlich
Vice President,
Quality Management and
Regulatory Compliance
Signature Date: 2008/08/18