

Manufacture Date :2016/08/02

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3

of



Product Name

Catalog Number Batch Number

homogeneous

indicated.

necessary.

Characteristic

pH at 25°C :

Animal source

Bovine

Porcine

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

: 211825

New Zealand

USA

: 6235902 **Expiration Date** : 2021/06/30 01. Dehydrated Medium Appearance: Light beige, free-flowing, 02. Solubility: 3% solution, soluble in distilled or deionized water 03. Solution Appearance: Light amber, clear 04. Medium was tested per European (EP), Japan (JP), and United States Pharmacopeia (USP) Growth Promotion requirements. Tubes were inoculated with < 100 CFUs. Tubes were incubated aerobically for 3 days and up to 5 days for (\*) organisms and gave cultural responses as TEMPERATURE TEST ORGANISMS ATCC® RECOVERY INCUBATION Up to 5 days \*Asperigillus brasiliensis 16404 growth 20-25°C 6633 growth 30-35°C,20-25°C Up to 3 days Bacillus subtilis \*Candida albicans 10231 growth 20-25°C Up to 5 days Escherichia coli 30-35°C Up to 3 days 8739 growth Pseudomonas aeruginosa 9027 growth 30-35°C Up to 3 days 14028 growth Salmonella typhimurium 30-35°C Up to 3 days Staphylococcus aureus 6538 growth 30-35°C Up to 3 days 05. Cultural Response: Medium was prepared per label instructions. Tubes were inoculated with the test organisms and incubated at the temperatures specified for 18-48 hours, or up to 72 hours if TEST ORGANISMS ATCC® TEMPERATURE RECOVERY Neisseria meningitidis 30-35°C 13090 fair to good Staphylococcus epidermidis 12228 30-35°C good 30-35°C Streptococcus pneumoniae 6305 qood 30-35°C 19615 Streptococcus pyogenes good 06. Residual Solvents (CPMP/ICH/283/95): Typical Analysis for Tryptic Soy Broth indicates that there is less than 5000 ppm of Acetone. No other solvents were detected during analysis. Lower Upper Unit Limit Limit Value Loss on Drying : Ŷ 2 0 5 7.1 7.5 7.4 Bulk Lot Number : 6209640 Country of **Tissue Category** Origin BIC SIC ABC

IV

III

: Bottle Bacto TSB Casein Med 500G

MLK

IΒ

τv

III



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

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| Product Name    | : Bottle Bacto 1 | TSB Casein Med 500G          |
|-----------------|------------------|------------------------------|
| Catalog Number  | : 211825         | Manufacture Date :2016/08/02 |
| Batch Number    | : 6235902        |                              |
| Expiration Date | : 2021/06/30     |                              |

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

BD Diagnostics - Diagnostic Systems products are manufactured in ISO 9001:2008 Registered facilities. In addition, BD Diagnostics - Diagnostic Systems facilities are registered with the United States Food and Drug Administration (FDA), are regulated by the FDA's Quality System Regulations (QSRs), and are also ISO 13485:2003 Registered. 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. This material is not for human or animal consumption.

BD Diagnostics - Diagnostic Systems' Certificates of Analysis (COA) typically contain animal origin information when products are manufactured using materials of animal origin. This information may be contained in the animal source table and/or in one or more of the additional paragraphs found on the COA. Following Quality Control release, the COA is created and published at http://www.bd.com/regdocs. For each batch of finished product that contains animal origin raw materials, the COA shows the animal origin data from the individual lots of animal origin raw materials used, as provided by the raw material suppliers.

At times, suppliers notify BD Diagnostics - Diagnostic Systems 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 BD. See "COA Animal Origin Information Position Statement" located at http://www.bd.com/regdocs under "Position Statements" for the impact that retrospective information has on COAs and on customers enrolled in the BDDS and BDAB Automated Change Notification Program.

For complete details on animal origin information, refer to "BD Position Statement - BD Diagnostic-Diagnostic Systems, COA Animal Origin Information Position Statement", at http://www.bd.com/regdocs under "Position Statements".

Manufacturer is Becton Dickinson and Company, 7 Loveton Circle, Sparks, MD 21152 USA. To determine location of manufacturing for this product, please see www.bd.com/ds/technicalCenter/regulatory.asp.



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Product Name: Bottle Bacto TSB Casein Med 500GCatalog Number: 211825Manufacture Date : 2016/08/02Batch Number: 6235902Expiration Date: 2021/06/30

Charlette Danserfilter

Charlotte Dannenfelser BD Life Sciences - Diagnostic Systems Quality Director, Microbiology Signature Date:2016/09/19