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live healthy lives

# Harmonized Microbiological Examination of Nonsterile Products with BD™ Culture Media

Your Assurance in Meeting Regulatory Requirements

## USP / EP / JP Compliance

In 2006, the United States Pharmacopeial Convention published a revised Chapter 61, and introduced a new Chapter 62, that cover the Microbiological Examination of Nonsterile Products.<sup>(1)</sup> These chapters are harmonized with the *European Pharmacopeia*<sup>(2)</sup> and the *Japanese Pharmacopeia*<sup>(3)</sup>. The chapters will become effective in January 2009 (EP) and May 2009 (USP).

BD has reviewed and revised, where applicable, the formulations and performance testing for the media that are specified in these new chapters. The labeling of these products are being changed accordingly to read: Meets USP/EP/JP performance specifications, where applicable. We stand ready to assist you with the transition to these new testing requirements. You can use these media now, secure that you are meeting today's requirements for the USP, EP and JP as well as those of the harmonized requirements of the future.



**Note:** Even if products with modified testing and labeling, as applicable, are already available in BD, these modifications are not captured in the current version of the BD Difco & BBL Manual but will be in the next version coming soon.

## Quality Assurance

Rigid quality control provides thorough testing of raw materials and dehydrated culture media. Mixing ingredients is an exacting and delicate task, similar to creating a perfect painting. At BD, we meet these challenges daily.

At BD, we make all our own plastic dishes, safe-guarding our product lines and ensuring continual high quality. The machinery used in the production of BD Media is designed to provide consistently high-quality products. The experience of dedicated line operators, laboratory and research technologists and other professionals goes into each container of BD Media.

Our ISO 9000 quality systems and cGMP manufacturing practices ensure consistent delivery of the highest quality media available. We are proud of our facilities and our products, and welcome our customers to audit our facilities.



<sup>(1)</sup> United States Pharmacopeial Convention, Inc. 2006. The United States Pharmacopeia 29/The National Formulary 24, 2006. The United States Pharmacopeial Convention, Rockville, MD.

<sup>(2)</sup> European Pharmacopeia, 5th Edition. European Directorate for the Quality of Medicine, Council of Europe, 226 Avenue de Colmar BP907-, F-67029 Strasbourg Cedex 1, France.

<sup>(3)</sup> Japanese Pharmacopeia, Fifteenth Edition.

## Below are the media required for compliance with the new EP/USP chapters

These media meet today's requirements for the EP, USP, and JP as well as the harmonized requirements of the future.

**EP 2.6.12 / USP <61> - microbiological examination of non-sterile products: microbial enumeration tests**

**EP 2.6.13 / USP <62> - microbiological examination of non-sterile products: tests for specified micro-organisms**

| CAT NO. | DESCRIPTION | TYPE | FILL VOLUME | PACK SIZE |
|---------|-------------|------|-------------|-----------|
|---------|-------------|------|-------------|-----------|

### Test for *Escherichia coli*

|                 |                 |                                             |              |          |
|-----------------|-----------------|---------------------------------------------|--------------|----------|
| MacConkey Broth |                 |                                             |              |          |
| 254957          | MacConkey Broth | Bottle; Syrup 125 ml; Srew Cap; Durham Tube | 100 ml       | 25 each  |
| 220100          |                 | Dehydrated                                  | 500 g        | 1 each   |
| MacConkey Agar  |                 |                                             |              |          |
| 215197          | MacConkey Agar  | Plate                                       | 100 mm style | 20 each  |
| 297064          |                 | Plate                                       | 100 mm style | 100 each |
| 212123          |                 | Dehydrated                                  | 500 g        | 1 each   |
| 212122          |                 | Dehydrated                                  | 2 kg         | 1 each   |
| 275300          |                 | Dehydrated                                  | 10 kg        | 1 each   |
| 211387          |                 | Dehydrated                                  | 500 g        | 1 each   |
| 211390          |                 | Dehydrated                                  | 500 g        | 1 each   |
| 211391          |                 | Dehydrated                                  | 5 lb         | 1 each   |

### Test for Bile-tolerant Gram-negative Bacteria

|                                            |                              |                                                      |               |         |
|--------------------------------------------|------------------------------|------------------------------------------------------|---------------|---------|
| Violet Red Bile Glucose Agar               |                              |                                                      |               |         |
| 254486                                     | Violet Red Bile Glucose Agar | Plate                                                | 100 mm style  | 20 each |
| 257042                                     |                              | Plate                                                | Contact style | 33 each |
| 218661                                     |                              | Dehydrated                                           | 500g          | 1 each  |
| Mossel Enterobacteriaceae Enrichment Broth |                              |                                                      |               |         |
| 254959                                     | EE Broth Mossel              | Bottle; Syrup 125 ml; Screw Cap                      | 100 ml        | 25 each |
| 257135                                     |                              | Bottle; Jar Glass 212 ml; Twist Off Cap; Durham Tube | 100 ml        | 10 each |
| 256620                                     |                              | Dehydrated                                           | 500 g         | 1 each  |
| 297005                                     |                              | Dehydrated                                           | 500 g         | 1 each  |

### Test for *Salmonella* spp.

|                                                   |               |                       |              |          |
|---------------------------------------------------|---------------|-----------------------|--------------|----------|
| Rappaport Vassiliadis Salmonella Enrichment Broth |               |                       |              |          |
| 215199                                            | RVS Soy Broth | K Tube; 102 x 16.5 mm | 10 ml        | 10 each  |
| 214943                                            |               | Dehydrated            | 500 g        | 1 each   |
| Xylose-Lysine-Deoxycholate Agar                   |               |                       |              |          |
| 254055                                            | XLD Agar      | Plate                 | 100 mm style | 20 each  |
| 254090                                            |               | Plate                 | 100 mm style | 120 each |
| 278850                                            |               | Dehydrated            | 500 g        | 1 each   |
| 278820                                            |               | Dehydrated            | 2 kg         | 1 each   |
| 278830                                            |               | Dehydrated            | 10 kg        | 1 each   |

**EP 2.6.12 / USP <61> - microbiological examination of non-sterile products: microbial enumeration tests**  
**EP 2.6.13 / USP <62> - microbiological examination of non-sterile products: tests for specified micro-organisms**

| CAT NO. | DESCRIPTION | TYPE | FILL VOLUME | PACK SIZE |
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|---------|-------------|------|-------------|-----------|

**Microbial Enumeration Tests**

|                             |                          |                                                                  |        |         |
|-----------------------------|--------------------------|------------------------------------------------------------------|--------|---------|
| Soybean-Casein Digest Broth |                          |                                                                  |        |         |
| 254967                      | BD Trypticase™ Soy Broth | Bottle; Jar Glass 380 ml; Twist Off Cap                          | 100 ml | 10 each |
| 257107                      |                          | Bottle; Vial 30 ml; Srew Cap                                     | 20 ml  | 50 each |
| 257109                      |                          | Bottle; Vial 30 ml; Srew Cap                                     | 9 ml   | 50 each |
| 257158                      |                          | Bottle; Syrup 90 ml; Screw Cap/Septum                            | 50 ml  | 25 each |
| 257159                      |                          | Bottle; Syrup 150 ml; Screw Cap/Septum                           | 100 ml | 25 each |
| 257160                      |                          | Bottle; Infusion 500 ml; Septum                                  | 500 ml | 10 each |
| 257228                      |                          | Bottle; Syrup 125 ml; Screw Cap                                  | 100 ml | 25 each |
| 257242                      |                          | Bottle; Infusion 250 ml; Septum                                  | 90 ml  | 10 each |
| 257247                      |                          | Bottle; Infusion 125 ml; Septum                                  | 100 ml | 25 each |
| 257248                      |                          | Bottle; Jar Glass 212 ml; Twist Off Cap                          | 100 ml | 10 each |
| 257276                      |                          | Bottle; Syrup 150 ml; Screw Cap                                  | 100 ml | 25 each |
| 257316                      |                          | Bottle; Jar Glass 212 ml; Twist Off Cap                          | 100 ml | 25 each |
| 257411                      |                          | Bottle; Infusion 250 ml; Septum                                  | 200 ml | 10 each |
| 257412                      |                          | Bottle; Infusion 500 ml; Septum                                  | 300 ml | 10 each |
| 257413                      |                          | Bottle; Infusion 1000 ml; Septum                                 | 500 ml | 4 each  |
| 257414                      |                          | Bottle; Infusion 1000 ml; Septum                                 | 600 ml | 4 each  |
| 257423                      |                          | Bottle; Infusion 100 ml; Septum                                  | 13 ml  | 25 each |
| 257424                      |                          | Bottle; Jar Glass 150 ml; Twist Off Cap                          | 100 ml | 25 each |
| 257202                      |                          | Bag                                                              | 10l    | 1 each  |
| 257185                      |                          | Bag                                                              | 3l     | 3 each  |
| 257203                      |                          | Bag                                                              | 5l     | 5 each  |
| 257211                      |                          | Bottle; 100 ml; Srew Cap/Septum; ETO; double wrapped             | 50 ml  | 48 each |
| 257307                      |                          | Bottle; Infusion 125 ml; Septum; ETO; double wrapped             | 100 ml | 44 each |
| 257371                      |                          | Bottle; Infusion 125 ml; Septum w/pour ring; ETO; double wrapped | 100 ml | 44 each |
| 257425                      |                          | Bottle; Infusion 30 ml; Septum; ETO; double wrapped              | 12 ml  | 60 each |
| 257197                      |                          | Bottle; Syrup 1000 ml; Screw Cap; double wrapped                 | 800 ml | 4 each  |
| 257215                      |                          | Bottle; Jar Glass 380 ml; Twist Off Cap; double wrapped          | 250 ml | 10 each |
| 257265                      |                          | Bottle; Infusion 125 ml; Septum; double wrapped                  | 100 ml | 10 each |
| 257213                      |                          | Bottle; Infusion 125 ml; Septum w/pour ring; double wrapped      | 100 ml | 10 each |
| 257291                      |                          | Bottle; Infusion 1000 ml; Septum w/pour ring; double wrapped     | 800 ml | 4 each  |
| 211768                      |                          | Dehydrated                                                       | 500 g  | 1 each  |
| 211771                      |                          | Dehydrated                                                       | 5 lb   | 1 each  |
| 211772                      |                          | Dehydrated                                                       | 25 lb  | 1 each  |
| 211824                      |                          | Dehydrated                                                       | 100 g  | 1 each  |
| 211825                      |                          | Dehydrated                                                       | 500 g  | 1 each  |
| 211822                      |                          | Dehydrated                                                       | 2 kg   | 1 each  |
| 211823                      |                          | Dehydrated                                                       | 10 kg  | 1 each  |

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**Microbial Enumeration Tests cntd**

|                            |                         |                                        |               |          |
|----------------------------|-------------------------|----------------------------------------|---------------|----------|
| Soybean-Casein Digest Agar |                         |                                        |               |          |
| 254051                     | BD Trypticase™ Soy Agar | Plate                                  | 100 mm style  | 20 each  |
| 254086                     |                         | Plate                                  | 100 mm style  | 120 each |
| 257080                     |                         | Plate, BD™ Isolator Pack               | 100 mm style  | 10 each  |
| 257081                     |                         | Plate, BD™ Isolator Pack               | 100 mm style  | 100 each |
| 257055                     |                         | Plate, BD™ Sterile Pack                | Contact style | 10 each  |
| 257051                     |                         | Plate, BD™ Sterile Pack                | 100 mm style  | 10 each  |
| 254955                     |                         | Plate, BD™ Sterile Pack                | 100 mm style  | 100 each |
| 254954                     |                         | Plate, BD™ Sterile Pack                | 100 mm style  | 10 each  |
| 254956                     |                         | Plate, BD™ Sterile Pack                | 100 mm style  | 100 each |
| 256665                     |                         | Bottle; Syrup 250 ml; Screw Cap        | 100 ml        | 10 each  |
| 257105                     |                         | Bottle; Flat 300 ml; Screw Cap         | 250 ml        | 12 each  |
| 257106                     |                         | Bottle; Syrup 500 ml; Srew Cap         | 500 ml        | 10 each  |
| 257240                     |                         | Bottle; Lab 500 ml; Septum w/pour ring | 400 ml        | 4 each   |
| 211043                     |                         | Dehydrated                             | 500 g         | 1 each   |
| 211046                     |                         | Dehydrated                             | 5 lb          | 1 each   |
| 211047                     |                         | Dehydrated                             | 25 lb         | 1 each   |
| 236940                     |                         | Dehydrated                             | 100 g         | 1 each   |
| 236950                     |                         | Dehydrated                             | 500 g         | 1 each   |
| 236920                     |                         | Dehydrated                             | 2 kg          | 1 each   |
| 236930                     |                         | Dehydrated                             | 10 kg         | 1 each   |
| Potato Dextrose Agar       |                         |                                        |               |          |
| 254108                     | Potato Dextrose Agar    | Plate                                  | 100 mm style  | 20 each  |
| 299906                     |                         | Bottle; Screw Cap/Septum               | 500 ml        | 10 each  |
| 213300                     |                         | Dehydrated                             | 100 g         | 1 each   |
| 213400                     |                         | Dehydrated                             | 500 g         | 1 each   |

**Buffers and Solutions**

|                                                  |                                                  |                                             |        |         |
|--------------------------------------------------|--------------------------------------------------|---------------------------------------------|--------|---------|
| Phosphate Buffer pH 7.2                          |                                                  |                                             |        |         |
| 257385                                           | Phosphate Buffer pH 7.2 (Stock Solution)         | Bottle; Infusion 100 ml; Septum w/pour ring | 100 ml | 25 each |
| Buffered Sodium Chloride-Peptone Solution pH 7.0 |                                                  |                                             |        |         |
| 257086                                           | Buffered Sodium Chloride-Peptone Solution pH 7.0 | Bottle; Infusion 100 ml; Septum w/pour ring | 100 ml | 25 each |
| 257087                                           |                                                  | Bottle; Infusion 500 ml; Septum w/pour ring | 500 ml | 10 each |

**EP 2.6.12 / USP <61> - microbiological examination of non-sterile products: microbial enumeration tests**  
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|---------|-------------|------|-------------|-----------|
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**Test for *Pseudomonas aeruginosa***

|                |                                 |            |              |         |
|----------------|---------------------------------|------------|--------------|---------|
| Cetrimide Agar |                                 |            |              |         |
| 254419         | BD Pseudosel™ Agar<br>Cetrimide | Plate      | 100 mm style | 20 each |
| 285420         | Cetrimide Agar Base             | Dehydrated | 500 g        | 1 each  |

**Test for *Staphylococcus aureus***

|                    |                    |            |              |          |
|--------------------|--------------------|------------|--------------|----------|
| Mannitol Salt Agar |                    |            |              |          |
| 254027             | Mannitol Salt Agar | Plate      | 100 mm style | 20 each  |
| 254079             |                    | Plate      | 100 mm style | 120 each |
| 211407             |                    | Dehydrated | 500 g        | 1 each   |
| 211410             |                    | Dehydrated | 5 lb         | 1 each   |
| 293689             |                    | Dehydrated | 25 lb        | 1 each   |

**Test for Clostridia**

|                                  |                                  |                         |              |         |
|----------------------------------|----------------------------------|-------------------------|--------------|---------|
| Reinforced Medium for Clostridia |                                  |                         |              |         |
| 215192                           | Reinforced Medium for Clostridia | Bottle; Srew Cap/Septum | 100 ml       | 10 each |
| 218081                           |                                  | Dehydrated              | 500 g        | 1 each  |
| Columbia Agar                    |                                  |                         |              |         |
| 215191                           | Columbia Agar w/o blood          | Plate                   | 100 mm style | 20 each |
| 211124                           |                                  | Dehydrated              | 500 g        | 1 each  |
| 211125                           |                                  | Dehydrated              | 5 lb         | 1 each  |
| 211126                           |                                  | Dehydrated              | 25 lb        | 1 each  |

**Test for *Candida albicans***

|                          |                          |                                        |               |          |
|--------------------------|--------------------------|----------------------------------------|---------------|----------|
| Sabouraud Dextrose Broth |                          |                                        |               |          |
| 215193                   | Sabouraud Dextrose Broth | Bottle; Srew Cap/Septum                | 100 ml        | 10 each  |
| 238230                   |                          | Dehydrated                             | 500 g         | 1 each   |
| 238210                   |                          | Dehydrated                             | 2 kg          | 1 each   |
| Sabouraud Dextrose Aga   |                          |                                        |               |          |
| 254039                   | Sabouraud Dextrose Agar  | Plate                                  | 100 mm style  | 20 each  |
| 254083                   |                          | Plate                                  | 100 mm style  | 120 each |
| 257050                   |                          | Plate, BD™ Sterile Pack                | 100 mm style  | 10 each  |
| 257059                   |                          | Plate, BD™ Sterile Pack                | Contact style | 10 each  |
| 257296                   |                          | Plate, BD™ Sterile Pack                | 100 mm style  | 100 each |
| 257104                   |                          | Bottle; Flat 300 ml; Screw Cap         | 250 ml        | 12 each  |
| 257153                   |                          | Bottle; Syrup 150 ml; Screw Cap/Septum | 100 ml        | 25 each  |
| 257261                   |                          | Bottle; Lab 500 ml; Septum w/pour ring | 400 ml        | 4 each   |
| 211584                   |                          | Dehydrated                             | 500 g         | 1 each   |
| 211585                   |                          | Dehydrated                             | 5 lb          | 1 each   |
| 210940                   |                          | Dehydrated                             | 100 g         | 1 each   |
| 210950                   |                          | Dehydrated                             | 500 g         | 1 each   |
| 211661                   |                          | Dehydrated                             | 2 kg          | 1 each   |
| 210930                   |                          | Dehydrated                             | 10 kg         | 1 each   |

European Media Manufacturing Plant in Heidelberg



Production Entrance Heidelberg Plant



Heidelberg Production

## Local BD Offices

### Austria

Am Concorde Park E1/7  
2320 Schwechat  
Tel: +43 1 70 63 66 00

### Belgium

Erembodegem-Dorp 86  
9320 Erembodegem  
Tel +32 53 72 02 11

### Denmark

Park Allé 290  
2605 Brøndby  
Tel: +45 43 43 45 66

### Eastern Europe/ Middle East, Africa

Tullastrasse 8-12  
69126 Heide lberg  
Tel: +49 6221 305 184

### Finland

Pronssitie 1  
00440 Helsinki  
Tel: +358 9 8870 780

### France

11 rue Aristide Bergès  
38800 Le Pont de Claix  
Tel: +33 4 76 68 36 36

### Germany

Tullastrasse 8-12  
69126 Heide lberg  
Tel: +49 6221 305 0

### Greece

5 Amfitheas Avenue  
17122 Nea Smyrni  
Athens  
Tel: +30 210 940 77 41

### Italy

Via delle Azalee 19  
20090 Buccinasco (MI)  
Tel: +39 02 48 24 01

### Netherlands

Europalaan 16  
2408 AT Alphen a.d. Rijn  
Tel: +31 20 582 94 16

### Spain

Camino de Valdeoliva s/n San Agustin  
de Guadalix  
28750 Madrid  
Tel: +34 91 848 81 00

### Sweden

Arstaangsvagen 25  
Box 47204  
100 74 Stockholm  
Tel: +46 8 775 5100

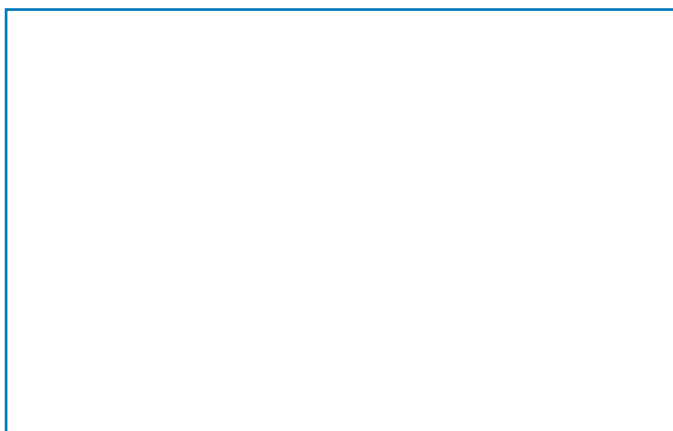
### Switzerland

Becton Dickinson AG  
Gewerbezentrum Im Letten  
Binningerstr. 94  
4123 Allschwil  
Tel: +41 61 485 22 22

### U.K.

The Danby Bldg  
Edmund Halley Rd.  
Oxford Science Park  
Oxford OX4 4DQ  
Tel: +44 1 865 748844

## Your local distributor:



### BD

Tullastr. 8-12  
69126 Heide lberg  
Germany  
Tel. +49-6221 3050  
Fax +49-6221 305216  
[www.bd.com](http://www.bd.com)