



BD Industrial Microbiology

Hospital Pharmacy

For full confidence in your aseptic drugs preparation



BD: advancing the world of health

BD Expertise & Global Strength

BD is a leading global medical technology company that develops, manufactures and provides solutions to enhance the quality and speed of diagnosing infectious diseases and cancers, and to advance research discovery in the production of new drugs and vaccines.



Nearly

65,000

associates



Serving

190+

countries



Founded in

1897

a legacy of
health impact



Quality Assurance at all levels

- ➔ BD controls and integrates all the processes involved in microbiological media production.
- ➔ BD manages and monitors every challenging step required to deliver the highest quality products available.
- ➔ BD Media production line equipment 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.



Regulatory compliance

- ➔ Required to follow Good Manufacturing Practices (GMP) principles, hospital pharmacies are subject to special requirements to minimize the risks of microbial contamination and to ensure the safety of pharmaceutical administration to patients.
- ➔ Our ISO 13485 quality system standard 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 in accordance with BD's policies.

BD solutions for Compounding Sterile preparations

Our goal is your goal: eliminate the risk of microbial contamination for the health and safety of your patients.

As a major partner of the pharmaceutical industry, we understand the specific requirements and processes for compounding and dispensing sterile preparations that meet the highest quality standards.

Our Microbiology Media Solutions for compounding sterile preparations are designed to **meet the hospital's unique requirements** for sterility, process validations, specified organism testing and environmental monitoring.



Sterility Tests and process validation

The complete line of BD Prepared Sterility Test Media provides one source for all your sterility testing and process validation needs.

BD Standard Bottles



- ➔ Products conform to USP¹, EP², and JP³ performance specifications for Sterility Tests and CLSI⁴ requirements for recovery, where applicable
- ➔ Sterility Assurance Level (SAL) of 10⁻⁶ on all standard bottles
- ➔ All BD FTM bottles are made with a proprietary formulation that yields a crystal clear, light-yellow FTM and complies with pharmacopeia requirements
- ➔ Multiple configurations of bottles, caps and fill volumes
- ➔ Color-coded caps and/or labeling offer easy identification
- ➔ Transparent labels allow a clear view of media and cultures and resist alcohol or chlorine treatment

BD EtO (Ethylene Oxide) Gassed Multi Packed Bottles

Bottles combine the benefits of the BD Standard Bottles with the following additional features.



- ➔ Bottles are sterile outside and do not require sterilization before transferring into controlled environments
- ➔ Bottle are packed in a polypropylene box, wrapped with Stericlin[®] bag(s), and an outer transport box
- ➔ 24 bottles per box allow easy transfer into controlled environments
- ➔ Polypropylene boxes design keeps shedding of particles to a minimum

BD Sterile Pack Double-Wrapped Bottles

Bottles combine the benefits of the BD Standard Bottles with the following additional features.



- ➔ Terminally sterilized inside autoclavable double-bags for a bottle exterior free from microbial contamination
- ➔ Double-wrapping ensures area under the cap remains sterile, and reduces the risk of false positive results
- ➔ Sterility Assurance Level of 10⁻⁶
- ➔ Validated for use in isolators

1 United States Pharmacopeia Convention, Inc. The United States Pharmacopeia 42/The National Formulary 37. Rockville, MD: United States Pharmacopeial Convention, 2019.

2 European Directorate for the Quality of Medicine. European Pharmacopeia, 9th Edition. Strasburg Cedex 1, France: European Directorate for the Quality of Medicine, 2019.

3 The Ministry of Health, Labour and Welfare. Japanese Pharmacopeia, Seventeenth Edition. Tokyo, Japan: The Ministry of Health, Labour and Welfare, 2016

4 Clinical and Laboratory Standards Institute. M22-A3 - Quality control for commercially prepared microbiological culture media; Approved Standard – Third Edition. 2004. Clinical and Laboratory Standards Institute, Wayne, PA.

Ensure the quality release of your preparations

Catalog #	Description	Fill Volume	Pack size
BD BBL™ Tryptic Soy Broth (TSB)			
A general purpose medium used in qualitative procedures for the detection, isolation, and cultivation of fastidious and non fastidious microorganisms and used in sterility testing and process validation.			
257247	infusion bottle, 125 ml, flip tear off seal stopper, standard packaging	100 ml	25
257213	infusion bottle, 125 ml, flip tear off seal stopper, double wrapped bottles	100 ml	10
257307	infusion bottle, 125 ml, flip tear off seal stopper, ETO double wrapped box	100 ml	44
299416	sirup bottle, 125 ml, screw cap with integrated stopper, standard packaging	100 ml	10
257294	wide mouth bottle, 245 ml, twist-off, double wrapped bottles	100 ml	10
257543	sirup bottle, 125 ml, screw cap with septum and hole, ETO double wrapped box	100 ml	20
299113	infusion bottle, 660 ml, screw cap with integrated stopper, standard packaging	500 ml	10
257547	sirup bottle, 660 ml, screw cap/septum, ETO double wrapped box	500 ml	8
257203	hemostat bag, 5000 ml, luerlock	5000 ml	2
BD BBL™ Fluid Thioglycollate Medium (FTM)			
Used for the sterility testing of biologics and for enrichment and cultivation of anaerobes, aerobes, and microaerophiles. The headspace of all Fluid Thioglycollate Media is gassed with a stream of nitrogen to maintain anaerobiosis.			
257246	infusion bottle, 125 ml, flip tear off seal stopper, standard packaging	100 ml	25
257217	infusion bottle, 125 ml, flip tear off seal stopper, double wrapped bottles	100 ml	10
257097	infusion bottle, 125 ml, flip tear off seal stopper, ETO double wrapped box	100 ml	44
299417	sirup bottle, 125 ml, screw cap with integrated stopper, standard packaging	100 ml	10
257293	wide mouth bottle, 245 ml, twist-off, double wrapped bottles	100 ml	10
257544	sirup bottle, 125 ml, screw cap with septum and hole, ETO double wrapped box	100 ml	20
299112	infusion bottle, 660 ml, screw cap with integrated stopper, standard packaging	500 ml	10
257548	sirup bottle, 660 ml, screw cap/septum, ETO double wrapped box	500 ml	8
BD™ Fluid A			
Used for diluting or rinsing when performing sterility testing. This fluid aids in the complete rinsing of the membrane filter apparatus and is not toxic to microorganisms.			
257332	infusion bottle, 125 ml, flip tear off seal stopper,	100 ml	25
257549	sirup bottle, 125 ml, screw cap with septum and hole, ETO double wrapped box	100 ml	20
254979	infusion bottle, 500 ml, flip tear off seal stopper, standard packaging	300 ml	10
257263	infusion bottle, 500 ml, crimp cap, stopper, double wrapped bottles	300 ml	10
BD™ Fluid D			
Diluting and rinsing fluid for sterility tests of pharmaceutical products according to the membrane filtration method. Fluid D is Fluid A supplemented with 0.1% Tween®.			
290831	serum bottle, 100 ml, flip tear off seal stopper, standard packaging	100 ml	10
257241	infusion bottle, 500 ml, flip tear off seal stopper, standard packaging	300 ml	10
257601	infusion bottle, 500 ml, flip tear off seal stopper, double wrapped bottles	300 ml	10





Environmental Monitoring

BD specially designed BD BBL™ IC-XT Plated Media for use in monitoring controlled environments.

- Available in various dish format: RODAC™, 90 mm and 150 mm
- Triple wrapped IC-XT packaging
- IC-XT Pack resistant to vaporized hydrogen peroxide
- Complete validation packages available
- Media with 2 - 25°C flexible storage conditions*
- All products with dehydration sachet inside bag for keeping the optimal appearance of the plates
- Gamma irradiated; SAL 10⁻⁵



BD 90 mm plated media provide optimal performance for MiniCapt™ air sampling procedures

Catalog #	Description	Pack size
IC-XT Sterile Plates		
Validated Sterility Assurance Level 10 ⁻⁵		
90 mm Petri Dish		
257632	Trypticase™ Soy Agar, heavy fill	100
257729	Trypticase™ Soy Agar with Lecithin and Polysorbate 80, heavy fill	100
257731	Sanitizer Neutralizing Agar, heavy fill	100
257662	Sabouraud Dextrose Agar with Lecithin and Polysorbate 80, heavy fill	100
150 mm Petri Dish		
257636	Trypticase™ Soy Agar with Lecithin and Polysorbate 80	30
Contact Plates		
257637	Trypticase™ Soy Agar with Lecithin and Polysorbate 80	100
257617	Sanitizer Neutralizing Agar	100
257630	Sabouraud Dextrose Agar with Lecithin and Polysorbate 80	100

* Exception for SDA LP80&Chloramphenicol products which have a storage temperature of 2-8°C

Air Sampling

Monitoring of airborne microorganisms is integral to ensuring the sterility of final pharmaceutical products compounded in hospital pharmacies. There are two principal means of monitoring the microbiological quality of the air: passive monitoring and active sampling.

Passive Air Monitoring

To detect underlying trends in airborne contamination and provide indication of controlled environment sterility, qualitative analysis of airborne microorganisms is gathered using plated media for passive air sampling procedures over specified time.

- ➔ Heavy fill volume plated media optimized for air monitoring procedures
- ➔ Available in 90 mm and 150 mm plate styles
- ➔ Triple wrapped IC-XT packaging
- ➔ Sterility Assurance Level (SAL) of 10^{-5} for BD BBL™ IC-XT Prepared Plated Media

Active Air Monitoring

Active air monitoring utilizes kinetic sampling of air in a controlled environment. The sampling is measured continuously and calculates the number of viable organisms per cubic meter of air.



The MiniCapt™ Microbial Sampler enables an operator to actively sample biocontamination throughout controlled environments.

Performance

- ➔ **Autoclavable BioCapt Impactor Head: easy to sanitize sample control module**
- ➔ **Optional compressed gas kit for compressed gas sampling**
- ➔ 100 l/min, 50 l/min, and 25 l/min flow rates: sample volume is controlled quickly enough to avoid physical and chemical degradation of the collection medium
- ➔ Slit design of BioCapt Impactor Head: laminar flow and optimal recovery of microorganisms
- ➔ Customizable sampling intervals
- ➔ HEPA filtered outlet air reduces contamination risk to the controlled environments
- ➔ Optional isolator kit for remote sampling

Compliance

- ➔ High physical and biological collection efficiency calculated per ISO 14698-1/Annex B
- ➔ ISO 14698-1: Biocontamination Control of Cleanrooms and Associated Controlled Environments
- ➔ Compliant with cGMP data integrity, GAMP 5, and compendial requirements



BD™ Sterile Pack Swabs:

Save time and reduce contamination risk

BD™ Sterile Pack Swabs are ideal for the stringent sterility requirements of surface sampling in controlled room and isolators.

Sterile and Easy-To-Use Surface Sampling

- ➔ Specifically designed for hard-to-reach places including equipment recesses, nooks and crevices
- ➔ Simple sampling and transport with an easy-to-use swab fixed to the screw cap
- ➔ ATP-free, Dacron™ swab
- ➔ Polypropylene tube is pre-filled with a 10ml rinse solution
- ➔ Gamma irradiated
- ➔ Sterility Assurance Level (SAL) of 10^{-6}
- ➔ Packaged 50 to a box, with 10 single wrapped swabs in each double wrapped pouch
- ➔ One year shelf-life at room temperature
- ➔ Storage temperature range: 5 - 25°C



Catalog #	Description	Pack unit
220518	BD™ Sterile Pack Swabs	200

BD Dehydrated & Prepared Media:

Non Sterile Product Testing

BD Dehydrated and Prepared Culture Media offer solutions for specified organism testing and process validations, and support a wide range of microorganisms.

Ensure the quality testing requirement

- ➔ Meets USP⁵/EP⁶/JP⁷ performance specifications for sterility testing and the harmonized chapters for "Microbiological Examination of Non-sterile Products", where applicable
- ➔ Available in various formats and packaging sizes to meet your unique needs



Catalog #	Description	Fill Volume	Pack size
Test for Bile-tolerant Gram-negative Bacteria			
Violet Red Bile Glucose Agar			
254486	Plate	90 mm style	20 each
218661	Dehydrated	500 g	1 each
Mossel Enterobacteriaceae Enrichment Broth			
254959	Bottle; Syrup 125 ml; Screw Cap	100 ml	25 each
256620	Dehydrated	500 g	1 each
Test for Escherichia coli			
MacConkey Broth			
257653	Bottle; Syrup 150 ml; Screw Cap	100 ml	10 each
220100	Dehydrated	500 g	1 each
MacConkey Agar			
215197	Plate	90 mm style	20 each
211387	Dehydrated	500 g	1 each
Test for Pseudomonas aeruginosa			
Cetrimide Agar			
254419	Plate	90 mm style	20 each
285420	Dehydrated	500 g	1 each
Test for Staphylococcus aureus			
Mannitol Salt Agar			
254027	Plate	90 mm style	20 each
285420	Dehydrated	500 g	1 each

5 United States Pharmacopeia Convention, Inc. The United States Pharmacopeia 42/The National Formulary 37. Rockville, MD: United States Pharmacopeial Convention, 2019.

6 European Directorate for the Quality of Medicine. European Pharmacopeia, 9th Edition. Strasburg Cedex 1, France: European Directorate for the Quality of Medicine, 2019.

7 The Ministry of Health, Labour and Welfare. Japanese Pharmacopeia, Seventeenth Edition. Tokyo, Japan: The Ministry of Health, Labour and Welfare, 2016



BD Dehydrated & Prepared Media: Specified Organism Testing



Catalog #	Description	Fill Volume	Pack size
Test for Salmonella spp.			
Rappaport Vassiliadis Salmonella Enrichment Broth			
215199	K Tube; 102 x 16.5 mm	10 ml	10 each
214943	Dehydrated XLD	500 g	1 each
Xylose-Lysine-Deoxycholate Agar			
254090	Plate	90 mm style	120 each
278850	Dehydrated	500 g	1 each
Test for Clostridia			
Reinforced Medium for Clostridia			
215192	Bottle; Syrup 150 ml; Screw Cap	100 ml	10 each
218081	Dehydrated	500 g	1 each
Columbia Agar			
215191	Plate	90 mm style	20 each
211124	Dehydrated	500 g	1 each
Test for Candida albicans			
Sabouraud Dextrose Broth			
215193	Bottle, 125 ml; Srew Cap/Septum	100 ml	10 each
238230	Dehydrated	500 g	1 each
Sabouraud Dextrose Agar			
254039	Plate	90 mm style	20 each
210950	Dehydrated	500 g	1 each
Microbial Enumeration Tests			
Soybean-Casein Digest Broth			
211825	Dehydrated	500 g	1 each
Soybean-Casein Digest Agar			
254051	Plate	90 mm style	20 each
236950	Dehydrated	500 g	1 each
Potato Dextrose Agar			
254108	Plate	90 mm style	20 each
213400	Dehydrated	500 g	1 each
Buffers and Solutions			
Phosphate Buffer pH 7.2			
257385	Bottle; Infusion 100 ml; Septum	100 ml	25 each
Buffered Sodium Chloride-Peptone Solution pH 7.0			
257086	Bottle; Infusion 100 ml; Septum	100 ml	25 each
257087	Bottle; Infusion 500 ml; Septum	500 ml	10 each

BD support: exceeding your expectations



Commitment to highest quality standards

As one of the world's leading manufacturers of quality media, BD has refined research, manufacturing and quality control processes to achieve the highest standards for BD microbiological media products. The ISO standards and guidelines of the world's leading regulatory agencies are embedded in our Quality System.



Online Access to Regulatory Documentation

- ➔ Material Safety Data Sheets (MSDS)
- ➔ Certificates of Analysis (CoA)
- ➔ Animal Origin Position Statement
- ➔ On-line access 24/7 from <http://regdocs.bd.com/regdocs/regDocsHomePage.do>



Automated Change Notification Program

- ➔ The Automated Change Notification system uses a sophisticated database to notify product changes by email to customers enrolled in the program
- ➔ Free of charge service

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