

Thermo Scientific[™] Culture Media in BioProcess Containers

For simple and safe validation

Where validation meets innovation

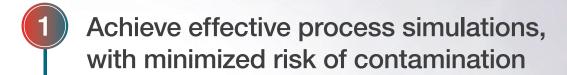
Media fills play a critical role in the validation of aseptic manufacturing processes.

To ensure a positive outcome, it is essential to use a sterile growth medium as the placebo in place of your final product.

Stay in total control of this demanding process using compliant, validated Thermo Scientific[™] Culture Media, ready-to-use in a range of convenient, plug-and-play Thermo Scientific[™] BioProcess Containers (BPCs).



Complete confidence is as easy as 1, 2, 3, 4...



 Innovative BPC design and connector options for easy process integration

2 Minimize preparation time

- Standard, ready-to-use format
- No water for injection
- No component weighing
- No mixing
- No filter blockages
- No vessel cleaning

3 Satisfy regulatory compliance

- Pharmacopoeial-compliant Tryptone Soya Broth
- Animal Derived Component Free (ADCF) vegetable peptone-based formulations available
- No Mycoplasma contamination
- Qualified microbial recovery performance
- Comprehensive validation package for media, BPC, components and filling process

4 Maximize efficiency and security

- No need for prep, autoclaving or transporting around the lab
- No time-consuming heating or filter changing

Media fills made easy



Achieve effective process simulation, with minimized risk of contamination

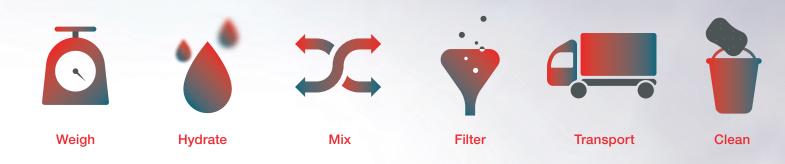
Ready-prepared Thermo Scientific[™] Cold Filterable Tryptone Soya Broth or Cold Filterable Vegetable Peptone Broth, supplied in BioProcess Containers, allows you to:

- Evaluate the aseptic assembly and operation of critical, sterile equipment
- · Qualify the operator
- Demonstrate that the environmental controls meet basic, sterile aseptic processing requirements

Efficient process simulations ensure the effectiveness of the filling process and minimize production downtime.

The innovative bag and connector design allow you to plug-and-play, efficiently replicating your filling processes while eliminating the risk of contamination.





2 Minimize preparation time

Contaminated media may lead to false-positive results, leading to delays in reinstating production and additional costs.

Utilizing our experience as leaders in the manufacture of both dehydrated culture media and BioProcess Containers, together with our liquid filling capabilities, we combine our cold filterable dehydrated media with water for injection (WFI) to provide you with an optimal placebo.

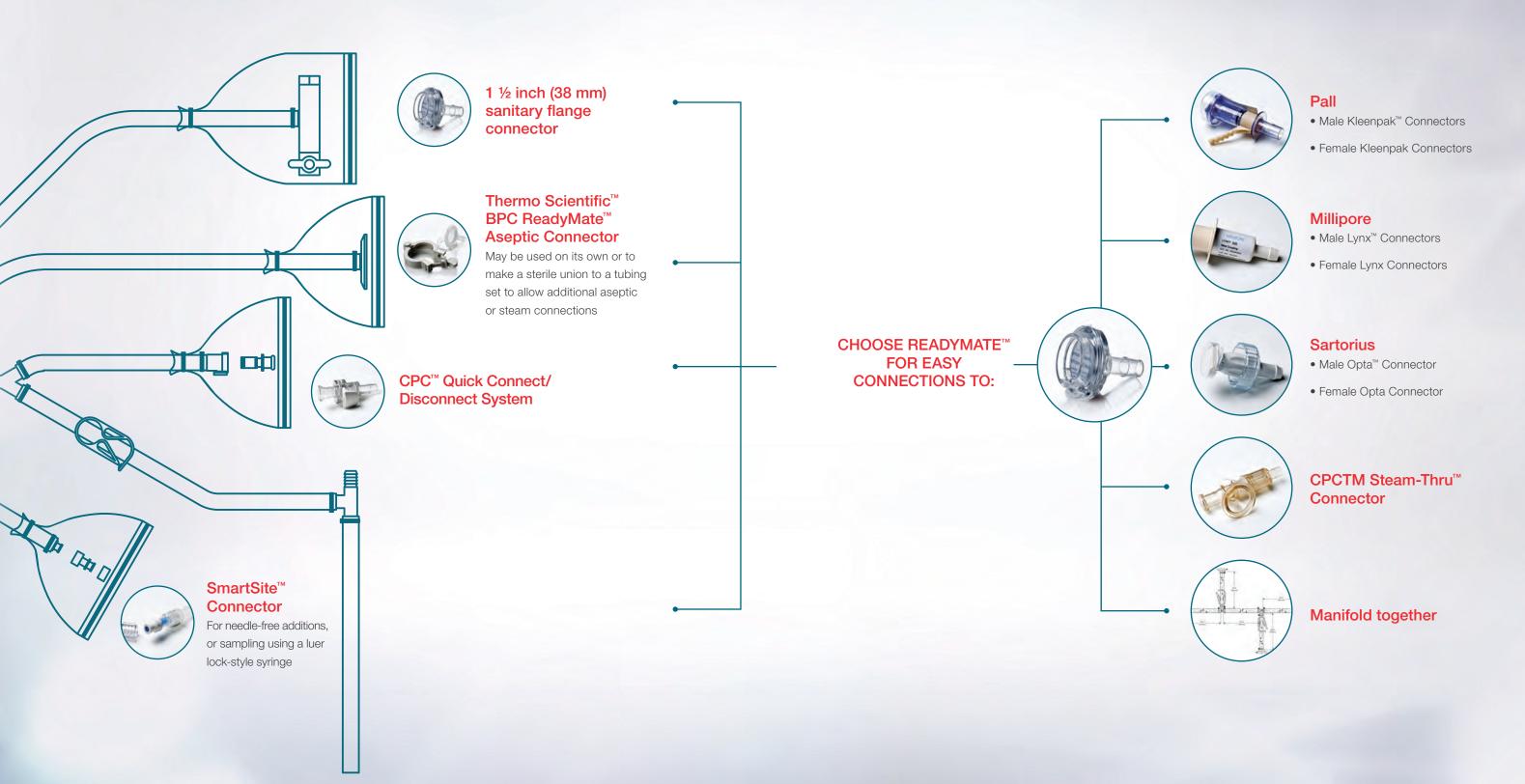
The ready-to-use media saves time and reduces labor costs by eliminating:

- Filter blockages
- Mixing
- Sterilization
- Vessel cleaning

The result is high-quality liquid media with a 12-month shelf life from date of manufacture.

It's pure and simple

Convenient connections



5

It's reassurance you can trust

3

Satisfy regulatory requirements

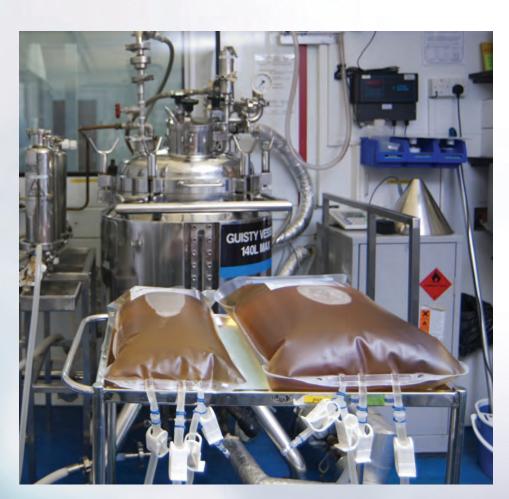
Our gamma-irradiated, Cold Filterable Tryptone Soya Broth (TSB) and ADCF Vegetable Peptone Broth were formulated in our research and development laboratories, specifically for media fill trials.

Selected to maximize recovery and growth of microbial contaminants, ingredients used in our media are sourced for regulatory compliance, traceability and performance.

The media are gamma-irradiated using a qualified cycle to ensure conformance to bioburden and Mycoplasma specifications.

Performance of our cold filterable TSB is tested according to the pharmacopeia requirements for the microbiological control and monitoring of aseptic processing environments.

Where an animal-derived component-free (ADCF) product is required, our vegetable peptone broth is a performance conformant alternative to Tryptone Soya Broth.













4

Maximize efficiency and security

Media fill trials must simulate accurately the filling production processes. Standard tryptone soya broths may cause filter blockages that can lead to interruptions in the process simulation.

Preparation, autoclaving and transporting of bulk media around the facility and time-consuming cleaning are now things of the past.

Our gamma-irradiated, cold-filterable media in 1-, 10- and 20-liter BioProcess Containers are convenient and easy to use. They provide optimum filterability, with no need to heat the medium or change filters during the simulation, so that you save even more valuable time.

A comprehensive validation package covers our media, the BPC and its components, and the filling process.



Ordering information

1-liter options

Medium	Format	Order Code
Cold Filterable Tryptone Soya Broth	1L BPC	BP1065A
Cold Filterable Vegetable Peptone Broth	1L BPC	BP0104A

The above products are supplied with these connectors as standard:

i) LUER lock female 1/4"

ii) SmartSite™, needle-free valve additional sampling port

10- and 20-liter options

Medium	Format	Order Code
Cold Filterable Tryptone Soya Broth	10L BPC	BP1065C
	20L BPC	BP1065E
Cold Filterable Vegetable Peptone Broth	10L BPC	BP0104C
	20L BPC	BP0104E

The above products are supplied with these connectors as standard:

i) SmartSite™, needle-free valve additional sampling port

ii) Quick connect, 1/4" body (MPC)

iii) 1½" triclamp

iv) ReadyMate™ aseptic connector

ReadyMate aseptic connectors may be used on their own, or to make a sterile union to a tubing set, to allow additional aseptic or steam connections.

The following tubing sets are available separately:

Tubing Sets and Manifold Options

Product	Format
ReadyMate to male Lynx™	BP0010A
ReadyMate to female Lynx [™]	BP0020A
ReadyMate to male KPC	BP0030A
ReadyMate to female KPC	BP0040A
ReadyMate to male Opta [™]	BP0050A
ReadyMate to female Opta	BP0060A
ReadyMate to Steam-Thru™	BP0070A
ReadyMate to 2x ReadyMate™ "Y piece"	BP0080A
ReadyMate to 5x ReadyMate™ manifold	BP0090A



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