**Thermo Scientific**
Culture Media in Bioprocess Containers

# Safe & simple validation

Thermo SCIENTIFIC

# 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.

Supplied, ready-to-use, in a range of convenient, plug-and-play bioprocess containers (BPCs).

## Complete confidence in 1, 2, 3

**1 Achieve effective process simulations, with minimized risk of contamination**

- 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

# Media fills made easy


## 1 Achieve effective process simulation, with minimized risk of contamination

Using ready-prepared Thermo Scientific™ Cold Filterable Tryptone Soya Broth or Cold Filterable Vegetable Peptone Broth, supplied in Thermo Scientific™ 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

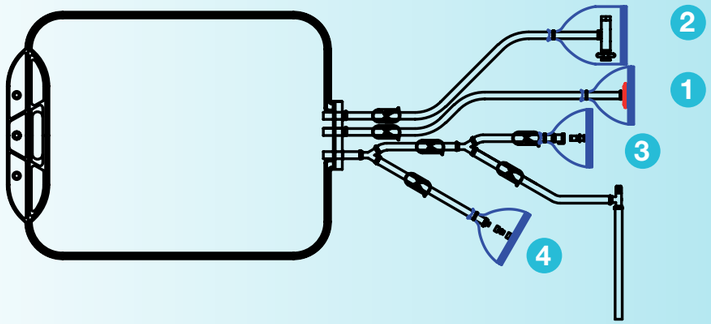
The result is high-quality liquid media with a 12-month shelf life from date of manufacture.

**It's pure & simple**

# Convenient connections

**1 ReadyMate™ aseptic connector**
may be used on its own or to make a sterile union to a tubing set to allow additional aseptic or steam connections

**2 1½-inch sanitary flange connector**




CHOOSE READYMATE™ FOR EASY CONNECTIONS TO

**3 CPC™ quick connect/disconnect system**

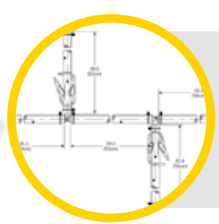
**4 SmartSite™ connector**
for needle-free additions, or sampling using a luer lock-style syringe

**Pall**
- Male Kleenpak™ Connectors
- Female Kleenpak™ Connectors

**Millipore**
- Male Lynx™ Connectors
- Female Lynx™ Connectors

**Sartorius**
- Male Opta™ Connector
- Female Opta™ Connector

**CPC™ Steam-Thru™ Connector**



**Manifold together**

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 specifications for the growth of control microorganisms laid down by the European, British, US and Japanese Pharmacopoeias.

Where an ADCF product is required, our vegetable peptone broth is a performance conformant alternative to Tryptone Soya Broth.

## 4 Save time & labor costs

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 filterabilty, 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 ¼”
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, ¼” body (MPC)
iii) 1½” triclamp
iv) ReadyMate™ aseptic connector

## Tubing Sets & Manifold Options

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:

| Product | Order Code |
|---|---|
| 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 |

**thermoscientific.com/BPCs**



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