



Thermo Scientific Oxoid
Culture Media in BPCs

minimize your media fill trials burden maximize production

Effective media fill trials are an essential part of any aseptic filling process. Oxoid ready-to-use culture media in bioprocess containers ensures you are in full control.

Thermo
SCIENTIFIC

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 liquid.

To ensure that you are in total control of this demanding process, use compliant, validated, Oxoid Culture Media in bioprocess containers (BPCs).

It's now supplied, ready to use, in a range of convenient, plug-and-play BPCs.



LYNX® S2S
Male Coupling
CAT. NO. SSCMHB2A
LOT NO. 101215A
READ INSTRUCTIONS



Use Oxoid Media and our four-point plan to:

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

- Innovative bag design and connector options for easy process integration
- Just plug and play

② Minimize preparation time

- Standard, ready-to-use, off-the-shelf product range
- No mixing, no sterilization, long shelf life at ambient storage

③ Satisfy regulatory compliance

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

④ Save time, reduce labour costs

- No filter blockages
- No mixing required
- No sterilization
- No WFI (water for injection) required
- No vessel cleaning

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

Media fill trials are critical events. Current regulations indicate that the media fill should evaluate the aseptic assembly and operation of the critical (sterile) equipment, qualify the operator, and demonstrate that the environmental controls are adequate to meet the basic requirements necessary to produce a sterile drug by aseptic processing. The media fill does not validate the ability of the filter to sterilize growth media.

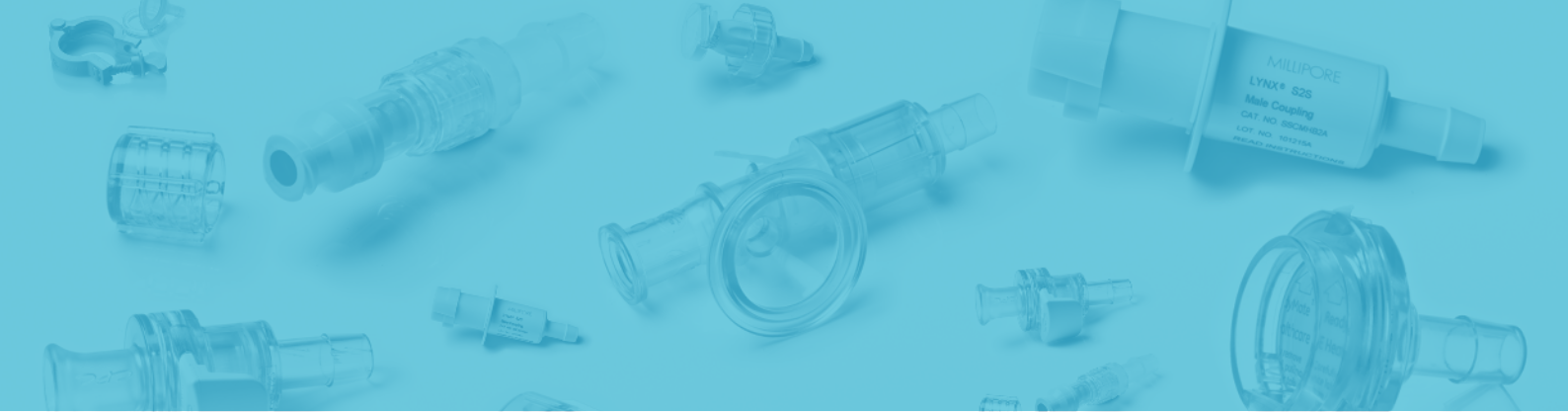
Using ready-prepared Thermo Scientific Oxoid Cold Filterable Tryptone Soya Broth or Cold Filterable Vegetable Peptone Broth, supplied in Thermo Scientific Hyclone Bioprocess Containers, allows you to do just this.

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

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



We make media fills easy.



② Minimize preparation time

Here's how to make life easy for the media fill simulation operators.

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

Utilizing Thermo Fisher Scientific's 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, with guaranteed performance capabilities.

The result is ready-to-use liquid media, available off the shelf. No mixing, no sterilization, just long shelf life, quality media that can be stored at ambient temperature.



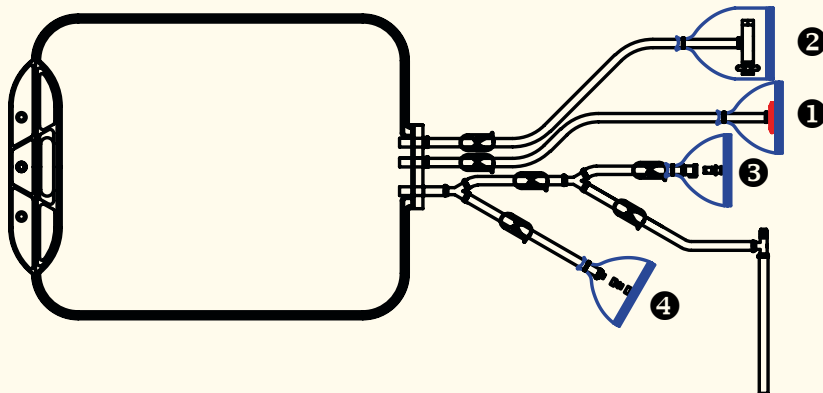
It's pure and simple.

Convenient Connections

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



1-inch sanitary flange connector ②



CHOOSE
READYMATE
FOR EASY
CONNECTIONS
TO

CPC quick connect/disconnect system ③



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





- A** PALL
 - Male Kleenpak™ Connectors
 - Female Kleenpak™ Connectors



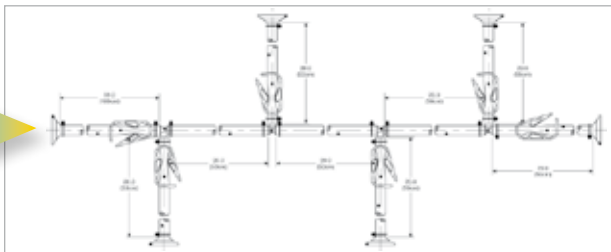
- B** MILLIPORE
 - Male Lynx™ Connectors
 - Female Lynx™ Connectors



- C** SARTORIUS
 - Male Opta™ Connectors
 - Female Opta™ Connectors



- D** CPC™ STEAM-THRU™ CONNECTOR



- E** MANIFOLD TOGETHER

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 in the UK, specifically for media fill trials.

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

The media are gamma irradiated using a qualified cycle to ensure conformance to bioburden and mycoplasma specifications. Full details are available on request.

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.



It's reassurance you can trust.



④ Save time and labour 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.

Our ready-to-use, cold-filterable media is produced and tested to guarantee quantified, minimum throughput in relation to most 0.2 micron filter medium.

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 litre 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.

These stock products come with all of the quality assurance/traceability certification and validation studies you would expect from Thermo Fisher Scientific.

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



We make efficient, worry-free media fill trials a reality.

Ordering Information

1-litre 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: <ul style="list-style-type: none"> i) LUER lock female ¼" ii) SmartSite, needle-free valve additional sampling port 		
10- and 20-litre 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: <ul style="list-style-type: none"> i) SmartSite, needle-free valve additional sampling port ii) Quick connect, ¼" body (MPC) iii) 1½" triclamp iv) ReadyMate aseptic connector 		



Tubing Sets and 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:

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 through	BP0070A
ReadyMate to 2x ReadyMate “Y piece”	BP0080A
ReadyMate to 5x ReadyMate manifold	BP0090A

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