Media fills needn’t be a trial

OXOID

Oxoid Cold Filterable Tryptone Soya Broth in BioProcess

The Media Fills Headache

Media fill trials are stressful regulatory requirements that involve production line downtime and financial consequences for your business.

Thankfully, they are not daily events. But this infrequency brings its own problems – staff may be unfamiliar with the media preparation procedures and accidental contamination of the media may occur defeating the whole process and giving false results. In extreme circumstances lines may then be shut down as a result of a problem introduced at media fill stage, when a real processing problem may not exist.

The Oxoid Solution

Ready-made, quality assured media from Oxoid will help to alleviate the stress of media fills and let you undertake the process swiftly and efficiently.

Our Cold Filterable Tryptone Soya Broth (TSB), made with WFI (Water for Injection) quality water and complete with quality certification for every batch, is now available in up to 100 litre containers that you just plug into your processing lines.

So, no lengthy media preparation, no time consuming QC, no worries about staff competencies, just less stressful media fills to get your production lines running as efficiently as possible.

• Quality Ingredients

Made using Oxoid Cold Filterable Tryptone Soya Broth (TSB) medium – a highly nutritious, general purpose medium that can support the growth of a wide range of bacteria, yeasts and fungi when incubated under appropriate conditions[1] – and WFI (Water for Injection) quality water.

• Packed Ready to Use

The ready-to-use media is supplied in single-use, flexible, high density polythene bags – called BioProcess Containers (BPCs) – that are engineered specifically for pharmaceutical applications.

• Sterile

The Cold Filterable TSB medium has been given a sterilising dose of gamma irradiation validated to be lethal for all yeasts, moulds and bacteria including bacterial spores and mycoplasma. The

Container systems that simply plug into your processing lines

WFI quality water is produced using a fully validated system and is filter sterilised into the BPCs.

• Volumes

Cold Filterable TSB BPCs are available in 10, 20, 50 and 100 litre volumes.

• Compliant

The formulation of Oxoid Cold Filterable TSB medium conforms to that stated for media fill trials in the European[2], the US[3] and the Japanese[4] Pharmacopoeia. The WFI quality water meets current USP production and test requirements.

BPCs are constructed of superior medical grade plastics that meet USP Class VI requirements.

• Filtration

Each component of Cold Filterable TSB has been specially screened and selected to ensure easy filtration. A V_{cap} value for each batch has been determined with three different filter types.

• Intended Use

Oxoid Cold Filterable TSB is intended for use in process simulations in the pharmaceutical industry, either as a liquid placebo, or as a growth medium for a solid placebo, added downstream of processing.

After carrying out the media fill, the medium is incubated under appropriate conditions for the recovery of any bacteria, yeasts and moulds.

• Incubation and Observation

Incubation of media fill units is usually carried out for 14 days at either 20-25ºC or 30-35ºC. If both temperatures are used, units should be incubated for not less than 7 days at each temperature[5]. Visual inspection of the units should be carried out on a daily or every second day basis.

Micro-organisms from any contaminated units should be sub-cultured, purified and identified to species level. Refer to the appropriate regulatory body for full guidelines[2,3,4].

Technical Information

Medium Formulation	Grams per litre
Pancreatic digest of casein	17.0
Papaic digest of soybean meal	3.0
Sodium chloride	5.0
Di-potassium hydrogen phosphate	2.5
Glucose	2.5

Final pH 7.3 ± 0.2 at 25ºC

Water

WFI Quality Water meets current USP production and test requirements for WFI.

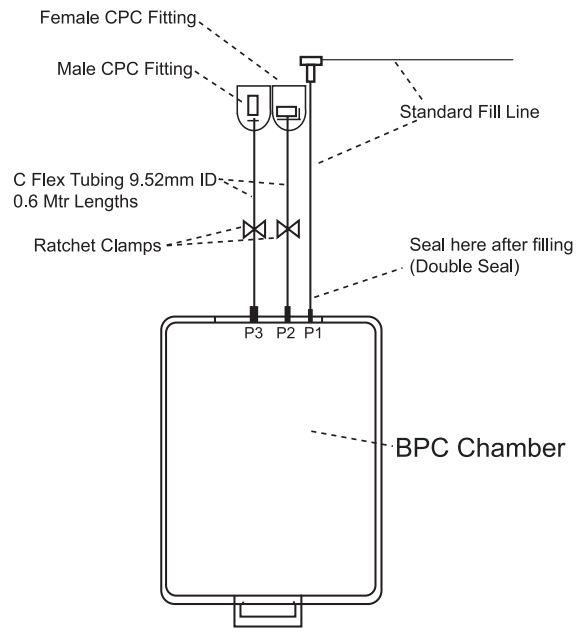
Product Appearance

The liquid media is a straw coloured solution.

BioProcess Containers

BPCs are constructed of superior medical grade plastics that meet USP Class VI requirements. BPCs are made of CX5-14, a film that is free of animal derived components. Connection is made through a Male or Female connector which is attached to the BPC with C-Flex® tubing. BPCs are packed in cardboard outers for easy storage.

BPC Designs



10 & 20 Ltr Schematic for the Standard Fill BPC

Precautions

Cold Filterable TSB is for laboratory use only. Do not use beyond the stated expiry date, or if the product shows any sign of deterioration.

Storage and Stability

Cold Filterable TSB must be stored at 2-8ºC. When stored as directed the unopened product will remain stable until the expiry date printed on the container.

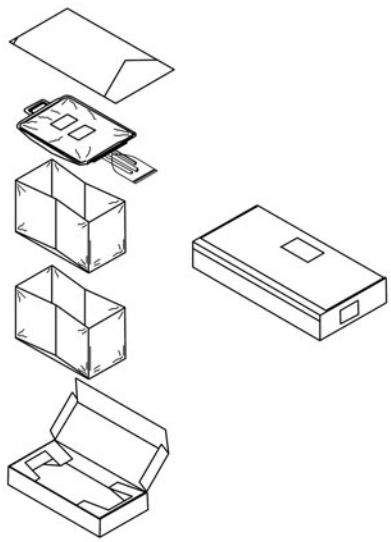
Quality Control Testing

Organism	Oxoid Culti-Loops® order code	Typical appearance
Staphylococcus aureus ATCC®6538	C7016L	Turbid growth
Pseudomonas aeruginosa ATCC®9027	C5210L	Turbid growth
Bacillus subtilis ATCC®6633	C1221L	Flocculent/surface growth
Aspergillus niger ATCC®16404	C1100L	White mycelia, black spores or no spores
Candida albicans ATCC®10231	C1503L	Flocculent/surface growth
Un-inoculated medium	N/A	No growth

Ordering Information

Size	Product Code
10 litres	BP0100C
20 litres	BP0100E
50 litres	BP0100K
100 litres	BP0100R

To place an order please speak to your local Oxoid representative or contact us at the address shown below.



REFERENCES: 1. Oxoid Manual 8th Edition, 1998, p2-208. 2.European Pharmacopoeia 4th Edition 2002. 3. US Pharmacopoeia 27 NF22 2004. 4. Japanese Pharmacopoeia XIV 2001. 5. FDA Guidelines "Guidance for Industry-Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice", September 2004.

OXOID

DEDICATED TO MICROBIOLOGY

www.oxoid.com
Oxoid Ltd, Wade Road, Basingstoke, Hants, RG24 8PW, UK. Tel: +44 (0) 1256 841144 Fax: +44 (0) 1256 463388 Email: oxoid@oxoid.com

Folio: 1096/07/06