MEDIA FILL TRIALS: CASE STUDY

pharma update

Oxoid cold filterable Vegetable Peptone Broth (cf-VPB) an effective, meat-free alternative for Vetter Pharma

Vetter Pharma-Fertigung GmbH & Co. KG (Ravensburg, Germany) is a worldwide specialist in the aseptic production of pre-filled application systems, supporting clients from the pharmaceutical and biotechnology industries in every phase of production - from product development through to product launches and commercial manufacturing. Recently, the company has started using Oxoid cold filterable Vegetable Peptone Broth (cf-VPB) in their media fill trials. Quality Assurance Team Leader, Karin Metzger, explains why cf-VPB was a good choice for them.

SELECTING A GOOD ALTERNATIVE

At the end of 2006, we reviewed our use of tryptic soy broth (casein-peptone, soymeal-peptone) for our media fill trials. We were having difficulties from a regulatory point of view because the broth contained material of animal origin and was not gamma irradiated, which meant that to eliminate mycoplasmas the nutrient solution had to be sterilised prior to the first filtration.

Oxoid cold filterable Vegetable Peptone Broth is gamma-irradiated and free from materials of animal origin. This made the product attractive to us because it eliminates the need for sterilisation of the nutrient solution to eliminate mycoplamas. In addition, due to issues concerning BSE/TSE, it is advantageous for us to use animal-free products with the equipment used in media fills.

We evaluated Oxoid cf-VPB alongside three other gamma-irradiated, animal-free media and one gamma-irradiated, animal-based TSB. With respects to our production needs, tests were performed according to our criteria for the selection of growth media, namely:

- The microbiological growth medium selected for process simulation runs should be capable of growing a designated group of indicator micro-organisms (Pharm Eur., USP).
- The selection of the medium should be based on clarity, medium concentration, filterability and suitability for sterilisation.

Study continues overleaf ...

SUPPORT FROM A WORLD-CLASS COMPANY

Karin was impressed with the documentation for Oxoid cf-VPB. She explains her impressions after her first experience of working with Oxoid products.

The medium also comes with excellent documentation. All the necessary certificates required by the regulatory authorities are supplied, such as the certificates of GMO-free, free from any material of animal origin, and full Quality Assurance certification. So, in addition to eliminating the sterilisation step and simplifying the media preparation process, Oxoid cfVPB helps us to comply with our regulatory requirements.

This was our first experience of working with Oxoid products. We have received good support from our local Key Account Manager, and there has been good availability and supply of Oxoid cfVPB throughout the evaluation. Since our study, we have switched to using Oxoid cfVPB in our process simulations.

Oxoid Cold-Filterable Vegetable Peptone Broth is one of a range of Cold Filterable products from Oxoid. For more details and ordering information please see opposite or visit www.oxoid.com.

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FASTER AND EASIER PREPARATION

The following table shows the steps required before performing a media fill trial - using our previous medium and using Oxoid cf-VPB:

Pre-trial steps using:

PREVIOUS TSB	OXOID CF-VPB
DAY 1	**DAY 1**
1. Media preparation	**1. Media preparation**
2. Sterilisation to eliminate mycoplasmas	**2. First filtration**
3. Cooling	
DAY 2	
4. First filtration	

Using our previous method, the filtration step had to be performed the following day in order to allow the solution to cool adequately. Furthermore, the appearance of our previous method's solution was dark brown, which hindered evaluation of the medium for clarity and turbidity post incubation.

By introducing Oxoid cf-VPB, sterilization and cooling steps were no longer required, which simplified the process and saved us a day in preparation.

In addition, the appearance of the solution is clear and pale yellow, which is important for evaluating the medium prior to filling.

IMPROVED GROWTH OF TARGET ORGANISMS

The evaluation results showed that all the nutrient media were suitable for our media fills in terms of clarity, medium concentration, filterability and suitability for sterilisation.

However, the media performed differently when it came to the growth of indicator micro-organisms (Pharm. Eur, USP) and other relevant micro-organisms (gram-positive cocci, gram-positive rods, yeasts, moulds and gram-negative rods).

Of all the media tested, Oxoid cf-VPB demonstrated the best Growth Promotion Test results.

In addition, we observed the following desirable qualities in Oxoid cf-VPB:

- Convenient pack sizes
- Easy handling of the medium during preparation
- Good solubility and filterability
- Clear, pale yellow appearance of the medium in solution
- No requirement for sterilisation to eliminate mycoplasmas.

This last point is particularly important as it gives us greater capacity and flexibility in media preparation.

Ordering Information

Cold Filterable Vegetable Peptone Broth

a gamma-irradiated, cold filterable Vegetable Peptone Broth suitable for microbiological media fill trials in the pharmaceutical industry, made using raw materials free from animal-derived material

	ORDER CODE
500g for 16.1 litres medium	VG0104B
5kg for 161.0 litres medium	VG0104T

Cold Filterable Vegetable Peptone Broth in BPCs

ready-to-use cold filterable Vegetable Peptone Broth, a vegetable based alternative to TSB, in BPCs

	ORDER CODE
1 litre	BP0200A
10 litres	BP0200C
20 litres	BP0200E
50 litres	BP0200K
100 litres	BP0200R

Cold Filterable Tryptone Soya Broth

a gamma-irradiated, cold filterable Tryptone Soya Broth suitable for microbiological media fill trials in the pharmaceutical industry

	ORDER CODE
500g for 16.7 litres medium	CM1065B
2.5kg for 83.3 litres medium	CM1065R
5kg for 167.0 litres medium	CM1065T
25kg for 833.0 litres medium	CM1065K

Cold Filterable Tryptone Soya Broth in BPCs

BPCs are intended for use in process simulations, either as a liquid placebo prior to sterile filtration or as a growth medium for a solid placebo added downstream of processing. Bags of 50 litres and over are supported in a drum.

	ORDER CODE
1 litre	BP0100A
10 litres	BP0100C
20 litres	BP0100E
50 litres	BO0100K
100 litres	BP0100R

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