



Veggietones

Oxoid Cold Filterable Vegetable Peptone Broth: VG104



A gamma-irradiated powder suitable for microbiological Media Fill Trials (MFT) in the pharmaceutical industry.

NUTRITIOUS

Cold Filterable Vegetable Peptone Broth (cfVPB) is a highly nutritious, general purpose medium which supports the growth of a wide range of bacteria, yeasts and moulds¹.

EASY TO USE

Each component of cfVPB has been specially screened and selected to ensure easy filtration without the need to heat. Filtration performance (V_{cap}) is determined with three different filter types for every batch.

CONVENIENT

Packs of cfVPB have been given a sterilising dose of gamma-irradiation (minimum 25 kGy) validated to be lethal for all yeasts, moulds and bacteria, including bacterial spores and mycoplasmas.

ANIMAL-FREE

This medium is suitable for use as an alternative to Tryptone Soya Broth where a product free of animal raw material is required.



VEGGIETONES

Oxoid Cold Filterable Vegetable Peptone Broth: VG104

Intended Use

A medium free from animal-derived raw materials, particularly suitable for use in pharmaceutical Media Fill Trials (MFT). Dehydrated cfVPB can be substituted for the powdered components that go into making sterile aqueous drugs or added as a sterile liquid downstream of processing a placebo for sterile solid dosage form. After carrying out MFT, the medium is incubated under appropriate conditions for the recovery of any bacteria, yeasts and moulds.



Principles

Oxoid pre-screen and select the raw materials that go into cfVPB so that every batch of product will have a high V_{cap} value. V_{cap} is the theoretical maximum volumetric throughput for the filter under test. With this information the maximum filterable volume of cfVPB may be calculated before starting a MFT². At Oxoid, a filter management system is used with a test filter to determine V_{cap} values for each batch of cfVPB. The final filterable volume of cfVPB will depend on the membrane type, pore size and area of the process filter used. See typical example below.

Typical V_{cap} values for cfVPB:

Filter membrane	V_{cap} (ml) 47mm disc (area 14cm ²)	V_{cap} (litres/m ²)
Polyvinylidene fluoride (PVDF)	913	652
Polyethersulfone (PES)	1,274	950
Nylon (NR)	1,817	1,298

V_{cap} is the extrapolation to a "flow = zero" point; the time to this point may be very long. Therefore, V_{cap} is good for comparative analysis but is not practical for MFT where time for a process is limited. A more useful value is V_{90} , which is calculated as 68% of V_{cap} and is the point at which flow has decayed to 10% of the initial rate. Contact your filter manufacturer for guidance. **N.B.** cfVPB should not be used to validate the suitability of the chosen filtration system for its ability to provide a sterile drug product. The components of cfVPB will be quite different to those found in an aqueous drug formulation, and validation for this purpose should be carried out on the drug preparation itself.

Summary

Cold Filterable VPB is a highly nutritious, general purpose medium which can support the growth of a wide range of bacteria, yeasts and fungi when incubated under the appropriate conditions. The peptone in this medium is derived from the kernel of the split yellow pea which is digested using fungal enzymes.

Each component of this medium has been specially screened and selected to give a highly filterable solution. The performance of the medium is tested according to the specifications for growth of control micro-organisms in Tryptone Soya Broth laid down in the European Pharmacopoeia 6th Edition 2008³, the British Pharmacopoeia 2004⁴, the United States Pharmacopoeia USP 30 2008⁵ and the Japanese Pharmacopoeia JP 15 2006⁶.

Formula

cfVPB (VG104)

	Grams per litre
Vegetable peptone	18.0
Dextrose	2.5
Di-potassium hydrogen phosphate	2.5
Yeast extract	3.0
Sodium chloride	5.0
Final pH 7.3 ± 0.2 at 25°C	

Directions

Suspend 31g of dehydrated powder in 1 litre of distilled water. Mix well to dissolve completely. Sterilise by autoclaving at 121°C for 15 minutes. 1kg of cfVPB dehydrated powder will make 32.2 litres of medium.

Incubation of media fill units is usually carried out for 14 days⁷ at both 20-25°C and 30-35°C. Where possible, 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 subcultured, purified and identified to species level. Refer to the appropriate regulatory body for full guidelines^{3,4,5,6}.

Appearance

Dehydrated Medium: straw coloured, free-flowing powder
Prepared Medium: clear, straw coloured liquid

Precautions, Storage and Stability

Do not use beyond the stated expiry date, or if the product shows any sign of deterioration. Dehydrated cfVPB must be stored tightly capped in the original container at 10-30°C. Material Safety Data Sheet (MSDS) and Batch Quality Control Certificates are available from the Oxoid website: www.oxoid.com

Quality Control Testing

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

References

1. Data on file at Oxoid. 2. Badmington F., Wilkins R., Payne M. and Nonig E.S. (1995) Vmax Testing for Practical Microfiltration Train Scale-Up in Biopharmaceutical Processing, *Pharmaceutical Technology*, September, p64-76. 3. European Pharmacopoeia 6th Edition 2008. 4. British Pharmacopoeia 2008. 5. United States Pharmacopoeia USP 30 2008. 6. Japanese Pharmacopoeia JP 15 2006. 7. Halls N., (2002) Microbiological Media Fills Explained. Sue Horwood Publishing Ltd, UK.



Oxoid, Wade Road, Basingstoke,
Hants, RG24 8PW, UK

Tel: +44 (0) 1256 841144
Fax: +44 (0) 1256 329728
Email: oxoid.info@thermofisher.com

www.oxoid.com
www.thermofisher.com

DEDICATED TO MICROBIOLOGY