Cold Filterable Vegetable Peptone Broth

CODE: VG0104

A GAMMA-IRRADIATED POWDER SUITABLE FOR MICROBIOLOGICAL MEDIA FILL TRIALS (MFT) IN THE PHARMACEUTICAL INDUSTRY.

NUTRITIOUS

Cold Filterable Vegetable Peptone Broth (Cold Filterable VPB) is a highly nutritious, general purpose medium which can support the growth of a wide range of bacteria, yeasts and moulds when incubated under appropriate conditions.

EASY TO USE

Each component of Cold Filterable VPB has been specially screened and selected to ensure easy filtration without the need to heat. A V_{cap} value for each batch has been determined with three different filter types.

CONVENIENT

Packs of Cold Filterable VPB 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 myco-plasmas.

ANIMAL-FREE

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

OXOID
VEGGIETONES

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INTENDED USE

A medium completely free from all animal-derived materials, particularly suitable for use in Media Fill Trials (MFT) for the pharmaceutical industry. Dehydrated Cold Filterable VPB 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 of 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 Cold Filterable VPB 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 VPB may be calculated before starting a MFT[1]. At Oxoid a filter management system is used with a test filter to determine V_{cap} values for each batch of Cold Filterable VPB. The final filterable volume of Cold Filterable VPB will depend on the membrane type, pore size and area of the process filter used. See typical example below.

Typical V_{cap} values for Oxoid Cold Filterable VPB:

FILTER MEMBRANE	V_{cap} (ML) 47 MM DISC (AREA 14 CM^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.** Cold Filterable VPB should not be used to validate the suitability of the chosen filtration system for its ability in providing a sterile drug product. The components of Cold Filterable VPB 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 5th Edition 2005[2], the British Pharmacopoeia 2004[3], the United States Pharmacopoeia USP 28 2005[4] and the Japanese Pharmacopoeia JP 14 2001[5].

Packs of Cold Filterable VPB have been given a sterilising dose of gamma-irradiation (minimum 25 KGy) validated as a lethal dose for all yeasts, moulds and bacteria including bacterial spores and mycoplasmas.

FORMULA

	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 7.1 ± 0.2 at 25°C

DIRECTIONS

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

Incubation of media fills is usually carried out for 14 days[6] 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 sub-cultured, purified and identified to species level. Refer to the appropriate regulatory body for full guidelines[2,3,4,5].

APPEARANCE

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

PRECAUTIONS, STORAGE & STABILITY

Cold Filterable VPB is for Laboratory Use Only. Do not use beyond the stated expiry date, or if the product shows any sign of deterioration. Cold Filterable VPB 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-loop® 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

REFERENCES: **1**. 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. **2**. European Pharmacopoeia 5th Edition 2005. **3**. British Pharmacopoeia 2004. **4**. United States Pharmacopoeia USP 28 2005. **5**. Japanese Pharmacopoeia JP 14 2001. **6**. Halls N., (2002) Microbiological Media Fills Explained. Sue Horwood Publishing Ltd, UK.

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