

PRODUCT SPECIFICATION

OXOID BUFFERED SODIUM CHLORIDE PEPTONE WATER pH 7.0 (acc. to E.P) BO0322J**Typical Formula***

	grams per litre
Disodium hydrogen orthophosphate (anhydrous)	5.77
Monopotassium phosphate	3.56
Sodium chloride	4.3
Pancreatic digest of casein	1.0

*adjusted as required to meet performance standards

Preparation

Suspend components, as above (14.63 grams / litre) in de-ionised water. Heat to dissolve. Cool and dispense 90ml into final containers, 125ml sirop bottles. Sterilise at 121°C for 15 minutes. Label each bottle and pack in units of 10 into labelled boxes.

Format

Ten sirop bottles with screw cap closures in a box.

Labels

Label gives details of product name, product code, recommended storage temperature, lot number and expiry date.

Physical Characteristics

pH	7.0 ± 0.2
Colour	Colourless
Clarity	Clear
Fill weight	90.0 – 91.5g

Packaging and presentation

General appearance of bottle and label should be satisfactory. Label data should be correct.

Contamination Check

Samples are filtered through 0.45µl filters, these filters are placed onto Tryptone Soya Agar and incubated at 30-34°C for ≥ 72 hours. Macroscopic examination of filters should show no evidence of microbial growth.

Microbiological Tests Using Optimum Inoculum Dilution

Tested in accordance with the harmonised methods described in the current European, United States and Japanese pharmacopoeias for the detection of specified microorganisms in non-sterile products.

Inoculum 10 – 77 colony forming units (cfu)

Escherichia coli ATCC®8739 1-3mm cream colonies

Recovery shall be ± 30% of the control cfu (0 minutes) after holding at 23°C ± 2°C for two hours. Colony counts are performed on Tryptone Soya Agar which is incubated at 35 – 39°C for 18 – 24 hours.

Storage conditions

Store away from light between 2 – 25 °C.

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