TECHNICAL DATA SHEET

DESCRIPTION BUFFERED SODIUM CHLORIDE PEPTONE BROTH, HARMONISED, BOTTLED
SGL PRODUCT CODE 3190

A diluent specified by the harmonised pharmacopoeia for the suspension and dilution of test samples from pharmaceutical and other materials.

The medium is a combination of phosphate buffer (for stable pH), sodium chloride (for osmotic balance) and peptone (to increase the viability of sensitive microorganisms in particular). The diluent maintains viability without significant growth.

The medium performs as specified in the European Pharmacopoeia (EP) 2.6.12, United States Pharmacopeia (USP) <61> and ISO 11133.

FORMULATION

Typical product composition*:

COMPONENT	WEIGHT / VOLUME
Potassium dihydrogen phosphate	3.6 g
Disodium hydrogen phosphate dihydrate	7.2 g
Sodium chloride	4.3 g
Peptic digest of animal tissue	1.0 g
Purified water	1000 ml

*Product may be adjusted and/or supplemented to meet performance criteria

QUALITY CONTROL SPECIFICATION

PHYSICAL TESTS	SPECIFICATION CRITERIA
Appearance	Clear, colourless to slightly yellowish liquid
pH at 20-25°C	7.0 ± 0.2

STERILITY TESTS	SPECIFICATION CRITERIA
Incubation at 20-25°C for 14 days	No growth detected
Incubation at 30-35°C for 14 days	No growth detected
Incubation at 42-45°C for 14 days	No growth detected

GROWTH PROMOTION / INHIBITION TESTS	SPECIFICATION CRITERIA
Staphylococcus aureus ATCC 6538 NMT 100 CFU/50µl inoculum	±30% recovery after 240 mins compared to original count
Staphylococcus aureus ATCC 25923 NMT 100 CFU/50µl inoculum	±30% recovery after 240 mins compared to original count
Escherichia coli ATCC 8739 NMT 100 CFU/50µl inoculum	±30% recovery after 240 mins compared to original count

NMT = Not more than
CFU = Colony forming units

Additional specification testing may be performed as requested by the customer.

Manufactured in compliance with ISO 9001 (Ref No FM37824) and tested in accordance with ISO 11133 by a UKAS (ISO 17025) accredited laboratory (Ref No. 4356).