



TECHNICAL DATA SHEET

DESCRIPTION R2A DEEP FILL, 90MM PLATES
SGL PRODUCT CODE 7683

A low nutrient agar medium designed to recover water borne micro-organisms as described in the European Pharmacopoeia (EP) monographs for Water for Injections and Water, Purified.

FORMULATION

Typical product composition*:

COMPONENT	WEIGHT / VOLUME
Yeast extract	0.5 g
Enzymatic digest of casein	0.25 g
Enzymatic digest of animal tissue	0.25 g
Casein hydrolysate	0.5 g
Glucose	0.5 g
Starch	0.5 g
Dipotassium hydrogen phosphate	0.3 g
Magnesium sulphate, anhydrous	0.024 g
Sodium pyruvate	0.3 g
Agar	15.0 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 gel
pH at 20-25°C	7.2 ± 0.2

STERILITY TESTS	SPECIFICATION CRITERIA
Incubation at 20-25°C for 5 days	No growth detected
Incubation at 35-37°C for 5 days	No growth detected
Incubation at 42-45°C for 5 days	No growth detected

GROWTH PROMOTION / INHIBITION TESTS	SPECIFICATION CRITERIA
<i>Bacillus subtilis</i> ATCC 6633 NCTC 10400 NMT 100 CFU inoculum	≥70% CFU recovery compared to control at 30-35°C incubation after not more than 3 days
<i>Pseudomonas aeruginosa</i> ATCC 9027 NCTC 12924 NCIMB 8626 NMT 100 CFU inoculum	≥70% CFU recovery compared to control at 30-35°C incubation after not more than 3 days
<i>Escherichia coli</i> ATCC 8739 NCTC 12923 NCIMB 8545 NMT 100 CFU inoculum	≥70% CFU recovery compared to control at 35-37°C incubation after not more than 1 day
<i>Staphylococcus aureus</i> ATCC 6538 NCTC 10788 NMT 100 CFU inoculum	≥70% CFU recovery compared to control at 35-37°C incubation after not more than 1 day



GROWTH PROMOTION / INHIBITION TESTS	SPECIFICATION CRITERIA
<i>Pseudomonas aeruginosa</i> ATCC 27853 NCTC 12903 NMT 100 CFU inoculum	≥70% CFU recovery compared to control at 35-37°C incubation after not more than 1 day

NMT = Not more than

NLT = Not less 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).