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TECHNICAL DATA SHEET

DESCRIPTION SABOURAUD DEXTROSE BROTH, BOTTLED

SGL PRODUCT CODE 0535

Sabouraud dextrose broth is a medium for the cultivation of dermatophytes, yeasts and moulds. It can also be used for sterility testing and for the determination of the fungi-static activity of pharmaceutical and cosmetic products.

The medium complies with the European Pharmacopoeia (EP) 2.6.12, United States Pharmacopeia (USP) <61> and ISO 11133.

FORMULATION

Typical product composition*:

COMPONENT	WEIGHT / VOLUME
Dextrose	20.0g
Enzymatic digest of animal tissue	5.0g
Enzymatic digest of casein	5.0g
Purified water	1000 ml

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

QUALITY CONTROL SPECIFICATION

PHYSICAL TESTS	SPECIFICATION CRITERIA
Appearance	Clear, yellow to golden brown liquid
pH at 20-25°C	5.6 ± 0.4

STERILITY TESTS	SPECIFICATION CRITERIA
Incubation at 22-25°C for 14 days	No growth detected
Incubation at 35-37°C for 14 days	No growth detected
Incubation at 42-45°C for 14 days	No growth detected

GROWTH PROMOTION / INHIBITION TESTS	SPECIFICATION CRITERIA
Candida albicans ATCC 10231 NCPF 3179	Good growth at 35-37°C incubation after not
NMT 100 CFU inoculum	more than 2 days
Escherichia coli ATCC 8739 NCIB 8545	May be inhibited at 35-37°C incubation after
NCTC 12923	not more than 2 days
NMT 100 CFU inoculum	

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).

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