Sabouraud Dextrose Agar + Lactamator 500 IU + Neutralizing (Irradiated)

Contact Plate for enumeration of yeasts and moulds on sanitized surface and personnel.

TYPICAL FORMULA	(g/l)
Pancreatic Digest of Casein	5.0
Peptic Digest of Animal Tissue	5.0
Dextrose	40.0
Agar	15.0
Histidine	1.0
Lecithin	0.7
Polysorbate 80	5.0
Sodium Thiosulfate	0.5
Lactamator	500 IU
Final pH 5.6 ± 0.2	

DESCRIPTION

Sabouraud Dextrose Agar + Lactamator 500 IU + Neutralizing (Irradiated) is a medium used for the determination of the total viable count of yeasts and moulds in environmental monitoring with inactivation of β-lactam antibiotics (penicillins, cephalosporins and carbapenems) and disinfectants.

The formulation of the basic medium complies to the recommendations of Harmonized USP/EP/JP Pharmacopoeia.

These gamma-irradiated, triple-bagged contact plates are particularly suitable for use in restricted areas like isolators and clean rooms.

PRINCIPLE

Pancreatic digest of casein and peptic digest of animal tissue provide amino acids, nitrogen, carbon, minerals, vitamins and other nutrients which support the growth of microorganism. The high concentration of dextrose along with the low pH of the medium promotes the growth of fungi while inhibiting most of bacteria. Agar is the solidifying agent. Histidine inactivates aldehydes. Lecithin neutralizes quaternary ammonium compounds. Polysorbate 80 (Tween 80) is effective against phenolic compounds and mercurial derivates. Sodium thiosulfate neutralizes halogen compounds. Lactamator is a mixture of Penicillinase and Cephalosporinase, designed for the inactivation of a wide range of beta-lactam antibiotics.

- 1 International Unit (IU) is defined as the amount of enzyme needed to hydrolyze 1 µmole of Penicillin G (Penicillinase) or 1 µmole of Cephalosporin C (Cephalosporinase) per minute at 25°C.

TECHNIQUE

Contact plates are recommended for use in air sampling equipment as well as for surface sampling. Selected surfaces are sampled by firmly pressing the agar medium against the test area. Plates are in intended for personnel hygiene monitoring (clothing, gloves or hands) as well.

For total yeast and mould count incubate the plates at 20-25°C for 5-7 days.

INTERPRETATION OF RESULTS

Observe daily for the formation of colonies.

STORAGE AND TRANSPORT CONDITIONS

2-8°C away from light, until the expiry date on the label. However, our stability studies have shown that the transport at 18-25°C for 4 days, or at 35-39°C for 48 hours, does not alter in any way the performance of the product. Eliminate if signs of deterioration or contamination are evident.

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product must be used by properly trained operators only.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to the national and local regulations in force.

REFERENCES

1. United States Pharmacopoeia 41 NF 36 (2018) <61> Microbiological examination of non-sterile products: Microbial Enumeration Tests.
2. European Pharmacopoeia 9.0 (2016) 2.6.12. Microbiological examination of non-sterile products: Microbial Enumeration Tests.
3. Japanese Pharmacopoeia 4.05 (2011) Microbiological examination of non-sterile products: Microbial Limit Test.

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PRODUCT SPECIFICATIONS

NAME
Sabouraud Dextrose Agar + Lactamator 500 IU + Neutralizing (Irradiated)

PRESENTATION
Ready-to-use Contact plates (55 mm) containing 17 ± 1 ml of medium

STORAGE
2-8°C

PACKAGING

Ref.	Content	Packaging
15345S	20 plates	• packed one by one in a blister packs of two pieces • five blisters wrapped in film thermally welded • vacuum bag and cardboard box

pH OF THE MEDIUM
5.6 ± 0.2

USE
Sabouraud Dextrose Agar + Lactamator 500 IU + Neutralizing (Irradiated) is used for microbial monitoring of air and personnel in isolators and clean rooms

TECHNIQUE
Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM
Slightly opalescent, light amber

SHELFLIFE
6 months

QUALITY CONTROL
1. Control of general characteristics, label and print
2. Sterility control
   7 days at 22.5 ± 2.5°C, in aerobiosis
   7 days at 32.5 ± 2.5°C, in aerobiosis
3. Microbiological control
   Inoculum for productivity: 50-100 CFU
   Incubation Conditions: 2-5 days at 22.5 ± 2.5°C

Microorganism		Growth
Candida albicans + 50 µl Aerodesin 2000	ATCC® 10231	Good
Aspergillus brasiliensis + 50 µl Aerodesin 2000	ATCC® 16404	Good

TABLE OF SYMBOLS

LOT Batch code	Do not reuse	Manufacturer	Use by	Fragile, handle with care
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Caution, consult instructions for use	

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