

Liofilchem®

Certificate of Analysis

Page 1 of 1

Product	Batch	Expiration date
Sabouraud Dextrose Agar (Irradiated)	083121052	2022.02.27

Ref. 10035S

Treatment	Irradiation Dose (kGy)	Date
Treatment Certificate No. 240.892	12.5	17.09.2021

Physical quality control	Specification	Results
Expected pH-value (25°C)	5.6 ± 0.2	5.6
Appearance of medium	Slightly opalescent	Conforms
Colour of medium	Light amber	Conforms

Microbiological State

Sampled according to ISO 2859-1, Special Inspection Level: S-2

Incubation	Specification	Results
32.5 ± 2.5°C (after 48 h and 7 days)	No growth	Conforms
22.5 ± 2.5°C (after 48 h and 7 days)	No growth	Conforms

All units of this batch were checked before packaging.

Microbiological Performance

Tested according to CLSI M22-A3, EN ISO 11133, Harmonized USP/EP/JP
Reference media: Sabouraud Dextrose Agar – batch already validated

Productivity, Method of control: Quantitative

Inoculum: 50-100 CFU

Control strains	Incubation	Expected Results	Specification	Results
<i>Saccharomyces cerevisiae</i> WDCM 00058	Aerobic, 72 ± 2 h 22.5 ± 2.5°C	$P_R \geq 0.7$	Good growth	Conforms
<i>Aspergillus brasiliensis</i> WDCM 00053	Aerobic, 3-5 d 22.5 ± 2.5°C	$P_R \geq 0.7$	Good growth	Conforms
<i>Candida albicans</i> WDCM 00054	Aerobic, 46 ± 2 h 22.5 ± 2.5°C	$P_R \geq 0.7$	Good growth	Conforms
<i>Candida albicans</i> ATCC® 10231	Aerobic, 24-48 h 32.5 ± 2.5°C	$P_R \geq 0.7$	Good growth	Conforms

Batch Release

Approved

Date **22.09.2021**

Signature

Quality Control
(D. Vitagliano)

The results reported were obtained at the time of release.

