

Product	Batch	Production date	Expiration date
R.P.M.I. AGAR	062524120	25.06.2024	2024.12.22

Physical quality control		Result of conformity	
Expected pH-value (25°C)	7.0 ± 0.2	Measured pH	7.0
Appearance	Slightly opalescent	Observed appearance	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
Colour	Light to medium pinkish	Observed colour	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

Microbiological contamination		This product was sampled according to ISO 2859-1:1999) Special Inspection Level :S-2	
N° of tested plates	Incubation	Criteria	Result of conformity
5	35 ± 2°C (after 7 days)	Samples ensure product meets acceptable levels of sterility	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
5	20 ± 2°C (after 7 days)	Samples ensure product meets acceptable levels of sterility	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
All plates of this batch have been checked before packaging.			

Microbiological growth acc. to NCCLS M22-A3: Productivity			Method of control: Quantitative	
Reference media: Sabouraud Agar			Working culture :CFU= 10-100 CFU	
Control strains	Incubation Atmosphere,Length and Temperature	Criteria	Result of conformity	Inoculum verification on Reference Medium
Trichophyton mentagrophytes ATCC 9533	Aerobic, 7 days 30°C ± 2°C	P _R ≥ 0,7	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Candida krusei ATCC 6258	Aerobic, 24-48 h 30°C ± 2°C	P _R ≥ 0,7	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Candida albicans ATCC 90028	Aerobic,24-48-72 h 30°C ± 2°C	P _R ≥ 0,7	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Candida parapsilosis ATCC 22019	Aerobic,24-48-72 h 30°C ± 2°C	P _R ≥ 0,7	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Aspergillus niger ATCC 16404	Aerobic,24-48-72 h 30°C ± 2°C	P _R ≥ 0,7	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Release batch	
<input checked="" type="checkbox"/> Approved	<input type="checkbox"/> Non Idoneo / Not approved
Date	03.07.2024
Signature	Quality Control Manager (This document has been established electronically and is valid without signature)