

Certificate of Analysis



Lot status: **APPROVED**

MODEL RODAC ø55mm Triple Wrapped Sterile Irradiated	PRODUCT CODE 449/21
MEDIA TSA+Lec+T80	MEDIA COMPOSITION Tryptone Soy Agar + 0.07% Lecithin + 0.5% Tween80
BATCH 35308	STORAGE CONDITIONS at 2-25°C until expiry date
DATE OF MANUFACTURING 18 Oct 2023	EXPIRY DATE 18 Jun 2024

Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	light amber coloured, clear to slightly opalescent gel forms in plates	Conforms
pH specification	7.3±0.2	Conforms
Filling media volume	17ml±1ml	Conforms
Packaging	Triple Wrapped Sterile Irradiated (T.W.S.I.)	Conforms
Dose of irradiation	10-25 KGy	Conforms Irradiation certificate Nr: 3436646 3441045

MICROBIOLOGICAL TEST CONTROLS

- Sterility control**

TESTS	SPECIFICATION	RESULT
32.5±2.5°C aerobic for 120 hours 22.5±2.5°C aerobic for 120 hours	No growth	Conforms

- Fertility – Growth Promotion Test** according to USP/EP

Control strain	Medium inoculation level	Incubation Conditions	Recovery Specifications	Recovery Results	Cultural Response
<i>E. coli</i> ATCC 8739	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	85,4%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	89,4%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	94,1%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	78,7%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	71,4%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	70,7%	Conforms

Start analysis	18 Oct 2023	End analysis	13 Nov 2023
Quality Control	Elisabetta Peri	<i>Elisabetta Peri</i>	
Quality Assurance	Celeste Annovazzi	<i>Celeste Annovazzi</i>	