

# Certificate of Analysis



Lot status: APPROVED

MODEL: RODAC ø55mm Triple Wrapped Sterile Irradiated      PRODUCT CODE: 449PEN4000/21  
 MEDIA: TSA+Lec+T80+PEN4000  
 BATCH: 39303      STORAGE CONDITIONS: at 2-25°C until expiry date  
 DATE OF MANUFACTURING: 12 May 2023      EXPIRY DATE: 12 Jan 2024

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
Media composition	Tryptone Soy Agar + 0.07% Lecithin + 0.5% Tween80 + 4000U.I./Lt Penicillinase Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer	Conforms
Packaging	Triple Wrapped Sterile Irradiated (T.W.S.I.)	Conforms
Dose of irradiation	10-25 KGy	Conforms Irradiation certificate Nr: 3346714

## 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%	84,3%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	93,9%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	101,6%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	102,1%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	86,7%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	87,0%	Conforms

- Enzimatic Activity Test**

Control strain	Incubation Conditions	Antibiotics	Response
<i>S. aureus</i> ATCC 6538	24 h at 32.5 ± 2.5°C	Penicillin 10IU	Conforms

Start analysis	12 May 2023	End analysis	05 Jun 2023
Quality Control	Giulia Brusati		
Quality Assurance	Celeste Annovazzi		