

Certificate of Analysis



Lot status: APPROVED

MODEL: RODAC ø55mm Triple Wrapped Sterile Irradiated PRODUCT CODE: 449PEN4000/21
 MEDIA: TSA+Lec+T80+PEN4000
 BATCH: 39304 STORAGE CONDITIONS: at 2-25°C until expiry date
 DATE OF MANUFACTURING: 23 Jun 2023 EXPIRY DATE: 23 Feb 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: 3371902

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%	99,0%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	92,5%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	79,4%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	92,6%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	76,1%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	88,0%	Conforms

- Enzymatic 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	23 Jun 2023	End analysis	17 Jul 2023
Quality Control	Giulia Brusati		
Quality Assurance	Celeste Annovazzi		