

Certificate of Analysis



Lot status: **APPROVED**

MODEL RODAC ø55mm Triple Wrapped Sterile Irradiated	PRODUCT CODE	449PEN4000/21
MEDIA TSA+Lec+T80+PEN4000	MEDIA COMPOSITION	Tryptone Soy Agar + 0.07% Lecithin + 0.5% Tween80 + 4000U.I./Lt Penicillinase
BATCH 39401	STORAGE CONDITIONS	at 2-25°C until expiry date
DATE OF MANUFACTURING 03 Jan 2024	EXPIRY DATE	03 Sep 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:3478390

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%	98,5%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	111,3%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	118,8%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	102,8%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	91,8%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	95,4%	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
		Meropenem 10µg	Conforms
		Cefuroxime 30µg	Conforms
		Ceftazidime 30µg	Conforms
		Cefoxitin 30µg	Conforms

Start analysis	03 Jan 2024	End analysis	16 Jan 2024
Quality Control	Elisabetta Peri		
Quality Assurance	Celeste Annovazzi		

Certificate of Processing

STERIGENICS Via Marzabotto, 4 Minerbio BO 40061 Italy
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8-Jan-24 8:23:04 GMT
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Customer Name:	CPC Biotech S.r.L.	Processing Facility:	Minerbio	Work Order #	3478390
P.O.#	84001			Sales Order #	3466395
10-25 kGy		CPCB gamma treatment	Irradiation Date/Time:	5-Jan-24 11:27:31 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900723	DDT 84001
			270_CPCB_870/20	Std cycle 15kGy		
102.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900724	DDT 84001
			270_CPCB_870/20	Std cycle 15kGy		
	2	PL	Total			

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail
450.00	Minimum Dose	10.0 kGy	25.0 kGy	16.1 KGY	Pass
450.00	Maximum Dose	10.0 kGy	25.0 kGy	18.4 KGY	Pass

Sterigenics certifies that the materials listed above (as described by the Manufacturer) received the indicated doses within the precision and accuracy of the dosimetry system employed.

Electronically Signed By: MILENA TAMPELLINI
 Reason: Work Order Completions

Date: 8-Jan-24 08:21:39 GMT