

Certificate of Analysis



Lot status: **APPROVED**

MODEL	Petri ø90mm Triple Wrapped Sterile Irradiated	PRODUCT CODE	449INHY/22
MEDIA	TSA+Lec+T80+Hys+ThioS	MEDIA COMPOSITION	Tryptone Soy Agar + 0.07% Lecithin + 0.5% Tween80 + 0.1% L-Hystidine + 0.05% S-Thiosulphate
BATCH	87402	STORAGE CONDITIONS	at 2-25°C until expiry date
DATE OF MANUFACTURING	02 Feb 2024	EXPIRY DATE	02 Oct 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	30ml±1ml	Conforms
Packaging	Triple Wrapped Sterile Irradiated (T.W.S.I.)	Conforms
Dose of irradiation	10-25 KGy	Conforms Irradiation certificate Nr: 3498257

MICROBIOLOGICAL TEST CONTROLS

- Sterility control**

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

- 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%	95,5%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	75,2%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	100,0%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	104,7%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	95,7%	Conforms

Start analysis	02 Feb 2024	End analysis	21 Feb 2024
Quality Control	Elisabetta Peri	<i>Elisabetta Peri</i>	
Quality Assurance	Celeste Annovazzi	<i>Celeste Annovazzi</i>	

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Customer Name:	CPC Biotech S.r.L.	Processing Facility:	Minerbio	Work Order #	3498257
P.O.#	84034			Sales Order #	3488889
	10-25 kGy	CPCB gamma treatment	Irradiation Date/Time:	9-Feb-24 09:36:55 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	WWW0539900743	DDT 84034
			270_CPCB_870/20	Std cycle 15kGy		
102.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900744	DDT 84034
			270_CPCB_870/20	Std cycle 15kGy		
103.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900745	DDT 84034
			270_CPCB_870/20	Std cycle 15kGy		
104.000	1	PL	2684/20_870/20	Microbiological culture media	WWW0539900746	DDT 84034
			270_CPCB_870/20	Std cycle 15kGy		
	4	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	16.0 KGY	Pass
450.00	Maximum Dose	10.0 kGy	25.0 kGy	19.6 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: CLAUDIA SQUARZANTI
 Reason: Work Order Completions

Date: 12-Feb-24 07:22:41 GMT