

# G. PAPANIKOLAOU & SIA E.E.

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# **QUALITY CONTROL CERTIFICATE**

#### **FINAL PRODUCT DATA**

Description	X.L.D. AGAR (European Pharmacopoeia)	
Code	060702	
Lot number	2722u108	
Production date	08/12/23	
Expiration date	08/06/24	

### PHYSICAL AND CHEMICAL CONTROL OF FINAL PRODUCT

Control	Expected results	Observed results
Final pH at 25°C	7,4 +/- 0,2	7.2 (Confirmed)
Quantity of material	100ml (060702)	Confirmed
Color & cleanliness of the material	Red clear	Confirmed

### STERILITY TEST OF FINAL PRODUCTS

Υ

Number of controlled products	Incubation	Number of suitable products	Number of inappropriate products
(3‰)			
1/060702	36 ± 1 °C for 48 hours	1/060702	0

FINAL PRODUCT PERFORMANCE TEST (According to European Pharmacopoeia Incubate at 30-35 °C for 18-48 h)

Microorganism	Expected results	Observed results			
Salmonella typhimurium (≤300 cfu/ml)	Growing (2)	Confirmed			
ATCC: 14028. Lot: 01102103 (productivity)	Clear Red (black center)	Growth in XLD checked			
Enterococcus faecalis (≤1000 cfu)	Inhibited (0)	Confirmed			
ATCC: 29212. Lot: 01804803 (selectivity)		Growth in TSA checked			

- Production and quality control tests were carried out at the premises of Bioprepare G. Papanikolaou & Co. According to EN ISO 9001:2015 / E∧OT EN ISO 13485:2016. In addition, the company's audit department implements to ISO 11133: 2014.
- The products of this batch will have the results reported once the user receives them cool (8-25 °C) then keep them at the temperature indicated on the packaging until the expiration date and follow the using instructions of the brochure.
- 0: Growth zero. 1: Weak growth. 2: Good growth. PR: Productivity Rate.

Release of the batch	DATE	Iniotaki Fofi
ES V NO	11/12/2023	Afrika
		<b>Quality Control Manager</b>