

# G. PAPANIKOLAOU & SIA E.E.

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## **QUALITY CONTROL CERTIFICATE**

### FINAL PRODUCT DATA

Description	ACETAMIDE BROTH (ISO 16266 UNE-EN 12780)	
Code	070561	
Lot number	2740r215	
Production date	15/01/24	
Expiration date	15/07/24	

#### PHYSICAL AND CHEMICAL CONTROL OF FINAL PRODUCT

Control	Expected results	Observed results
Final pH at 25°C	7,0 +/- 0,5	7,0 (Confirmed)
Quantity of material	5ml (070561)	Confirmed
Color & cleanliness of the material	Colorless clear broth.	Confirmed

### STERILITY TEST OF FINAL PRODUCTS

Number of controlled products (3‰)	Incubation	Number of suitable products	Number of inappropriate products
2/070561	36 ± 1 °C for 48 hours	2/070561	0

#### **FINAL PRODUCT PERFORMANCE TEST** Incubation: According to ISO 16266. Incubate $30 \pm 1$ °C for $(24 \pm 2)h - (48 \pm 2)h$

Microorganism	Expected results	Observed results
Pseudomonas aeruginosa (≤1000 cfu)	Growing (2)	It is confirmed.
ATCC: 27853. Lot: 01007301 (identification)	Ammonia production (+)	(ACET reference material. BR. checked)

- Production and quality control tests were carried out at the premises of Bioprepare G. Papanikolaou & Co. According to EN ISO 9001:2015 / EAOT 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. IV: Inoculum Value

**Release of the batch** 

YES V

NO

DATE

20/01/24

Iniotaki Fofi

**Quality Control Manager**