

G. PAPANIKOLAOU & SIA E.E.

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QUALITY CONTROL CERTIFICATE

FINAL PRODUCT DATA

Description	TRICHOMONAS BROTH
Code	080117
Lot number	2789r226
Production date	26/03/24
Expiration date	26/07/24

PHYSICAL AND CHEMICAL CONTROL OF FINAL PRODUCT

Control	Expected results	Observed results
Final pH at 25°C	7.0 +/- 0,2	7.0 (Confirmed)
Quantity of material	3ml (080117)	Confirmed
Color & cleanliness of the material	Beige clear with pink ring	Confirmed

STERILITY TEST OF FINAL PRODUCTS

Number of controlled products	Incubation	Number of suitable products	Number of inappropriate products
(3‰)			
2/080117	36 ± 1 °C for 48 hours	2/080117	0

FINAL PRODUCT PERFORMANCE TEST (Incubate at 32 - 36 °C for 1 - 4 days)

Microorganism	Expected results	Observed results
Trichomonas vaginalis (≤10 cfu/ml)	Growing (1-2)	Confirmed
ATCC 30001 (productivity)	(Moderate to good)	(Growth in TB checked)
Escherichia coli (≤1000 cfu/ml)	Inhibited (0)	Confirmed
ATCC: 25922. Lot: 00207501		(Growth in TSB 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

Release of	f the batch	DATE	Iniotaki Fofi
YES V	NO	30/03/2024	Afrilas
			Quality Control Manager