TRUE TESTING SERVICES
TTS LABORATUVAR HİZMETLERİ

Test
TS EN ISO/IEC 17025
AB-1802-T

TEST REPORT

AB-1802-T
TTS-0002404
08-23

Report No./Rev. No./Report Date	:	TTS-0002404 /0/ 23.08.2023
Sample Name/Description	:	Standard Sterilization Container—Bottom-Sealed with Paper Filter—Square Container Sterilization Barrier Container—Top-Sealed with Valve System—Rectangular Container
Product/License Holder	:	CEYLAN MEDİKAL İmalat İthalat İhracat Dış Tic. (Fatma CEYLAN)
Manufacturing Location Address	:	Yenicami OSB Mah. 5. Cadde No: 6/4 KAVAK/SAMSUN/TÜRKİYE
Lot No./Batch-Serial No.	:	C1031072326001 C2031072326001
Formulation Ingredients	:	-
Formulation Type	:	Solid
Sample Packaging	:	Non-Sterile
Sample Receipt Date	:	31.07.2023
Source of the Sample	:	Yenicami OSB Mah. 5. Cadde No: 6/4 KAVAK/SAMSUN/TÜRKİYE
Submission of the Sample and Seal Status	:	Special Request / Unsealed
Number of Samples / Quantity	:	9 Adet
Manufacturing - Expiration Date	:	NA
Notes	:	This was conducted as part of the test validation process.
Analysis Method	:	ISO 11737-1, ISO 11737-2, TS EN 868-8, ISO 11607-1, ISO 11607-2, DIN 58953-9 These standards and the guidelines in Ph. Eur. Method 2.6.1 have been applied.
Test Start–End Date	:	31.07.2023-28.08.2023

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When reported, the expanded measurement uncertainty is the value obtained by multiplying the standard uncertainty by the coverage factor k=2, and it provides a 95% level of confidence.

1. No part of this analysis report may be used on its own or separately.
2. This report may not be used for legal or administrative proceedings or for advertising purposes.
3. The test results are valid only for the samples defined and tested in this test report.
4. Sampling is not performed by TTS. Measurement uncertainty arising from sampling has not been accounted for. Any issues resulting from sampling are the Customer's responsibility.
5. This report may not be reproduced without the laboratory's approval.
6. Reports without a signature and seal are invalid.
7. The units of the limit values are the same as the units of the findings.
8. Analyses marked with an * are within the scope of accreditation.
9. Abbreviations: D: Evaluation. U: Acceptable. U.D.: Unacceptable. D.Y.: Evaluation Not Performed. G.K.: Recovery. Ö.B: Measurement Uncertainty. Ö.L: Measurement Limit.

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Analyzer
Yeşim RUMELİLİ
Microbiology Analysis Laboratory Unit Staff

TTS LABORATUVAR HİZMETLERİ
Tarih
28.08.2023

Approved by
Damla DAMAR BAŞSU
Laboratory Manager

TEST REPORT

AB-1802-T
TTS-0002404
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Test Name	:	* MICROORGANISM POPULATION DETERMINATION (BIOBURDEN) TEST STERILITY TEST
Methodology	:	ISO 11737-1/A1 :2021, ISO 11737-2:2020, ISO 11607-1, ISO 11607-2, DIN 58953-9, EP. 11.0 2.6.1
Analysis of Additions	:	**Temperature:** 23.6 °C **Hayır:** % 49 RH
Date of Analysis	:	31.07.2023-28.08.2023
Media Used	:	Tryptic Soy Agar, Buffered Peptone Water Mantar ve Aerobik Bakteri; Soya-bean Casein Digest Medium Anaerobik ve Aerobik Bakteri; Fluid Thioglycollate Medium
Incubation Period	:	Bioburden: 7 days; Sterility: 14 days
Incubation Temperature	:	Fungi and Aerobic Bacteria; 22±2 °C Anaerobic and Aerobic Bacteria; 32±2 °C
Deviation from the Protocol	:	The analysis was conducted in accordance with the protocol; no deviations were observed.

Analysis	Test Sample	Microbial load	C Factor	Unit	Result	Method	Evaluation
* Determination of Microorganism Population (Bioburden)	Surgical Hand Instrument	10	-	cfu/test sample	10	ISO 11731-1	U
		8			8		

The surgical instrument was placed in a sterilization container after being subjected to 500 cycles, then sterilized at 134°C for 3 minutes, followed by a sterility test.

Analysis	Limit	Result		Method	Evaluation
		CKK-26-001 Square Container C1031072326001	CKB-B-26-001 Rectangular Container C2031072326001		
Sterility Test for Fungi and Aerobic Bacteria	No Reproduction	No Reproduction	No Reproduction	ISO 11731-2 EP. 2.6.1	U
Sterility Test for Anaerobic and Aerobic Bacteria	No Reproduction	No Reproduction	No Reproduction		U
Negative Control	No Reproduction	No Reproduction			U
Positive Control	Reproduction	Reproduction			U

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