


Request-Tender no	TLF-21-946	STERILITY TEST REPORT (European Pharmacopeia)	 Test TS EN ISO/IEC 17025 AB-0052-T AB-0052-T M21-1723 07-21
Receiving Date	22.06.2021		
Test Initiation Date	24.06.2021		
Test Final Date	08.07.2021		
Publication Date of the Report	08.07.2021		

|| CUSTOMER-ADDRESS

ZEUS BIOSCIENCE BİYOMEDİKAL A.Ş.
ÇANKAYA MAH. CİNNAH CADDESİ 47/2 06690 ÇANKAYA/ANKARA

|| SAMPLE TRANSMISSION TYPE

It was sent by the customer.

|| METHOD DESCRIPTION

Sterility test was performed under Laminar Air Flow by direct transfer method.

Sample or sample prepared as per SIP was transferred to the jar, filled with TSB growth medium enough to cover the sample.

Prepared, TSB medium with product was incubated at (20-25)°C.

Other were transferred to the jar, filled with TFM growth medium enough to cover the whole product.

Prepared, TFM medium was incubated at (30-35)°C.

The jars containing the products were controlled for growth of microorganisms for 14 days.

|| REFERENCE STANDARD

European Pharmacopoeia (EP 2.6.1.)

|| SAMPLE IDENTIFICATION - SAMPLE NO

ZEUS Electro Dish /LotNo:ED210406301 /RefNo:ZPS19-002 / M21-1723-1

▮ SAMPLE QUANTITY

2 Piece

▮ SAMPLE ITEM PORTION (SIP)

NA

▮ TEST RESULTS

	for TSB	for TFM
Number of product controlled	1	1
Number and date of product growth observed	0	0

It has been declared by the customer that the product does not have reproductive preventive or supportive properties.

▮ DECLARATION OF CONFORMITY

Declaration of conformity is not provided according to the test method.

▮ LIMITS

Shall be determined by the customer


▮ DEVIATIONS

NA

▮ REVISION HISTORY

Rev No - Date	Revision Reason
00 - 08.07.2021	New Publication

APPROVALS

	Name - Title	Signature - Date
Laboratory Approval:	Ayşegül İSFENDİYAR CHEMIST	
Quality Approval:	Özenç EFE ÖZTÜRK CHEMIST	
Seal		

Test results are valid only for the tested samples identified in this test report

The laboratory is not responsible for deviations in analysis results if the declared information is incomplete or inaccurate, or if the customer is requested to work it although the samples are not delivered in accordance with the acceptance criteria.

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