


Request-Tender no	TLF-21-948	BACTERIAL ENDOTOXIN(LAL) TEST REPORT (KINETIC TURBIDIMETRIC METHOD)	 Test TS EN ISO/IEC 17025 AB-0052-T AB-0052-T M21-1722 06-21
Receiving Date	22.06.2021		
Test Initiation Date	23.06.2021		
Test Final Date	23.06.2021		
Publication Date of the Report	23.06.2021		

❑ 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

Endotoxin value has been analysed on product by using kinetic turbidimetric method.

❑ REFERENCE STANDARD

European Pharmacopoeia (EP 2.6.14 Metot C)
American Pharmacopeia (USP<85>)

❑ SAMPLE IDENTIFICATION - SAMPLE NO

ZEUS Electro Dish - Lot:ED-210406301- Ref:ZPS19-002 - M21-1722-1

❑ SAMPLE QUANTITY

1 Piece

TEST RESULTS

	Results
Endotoxin Value for Sample	<0,01 EU/ml
Determined Endotoxin Value for Product Positive control	%98
Determined Endotoxin Value for Negative Control	<0,01
I R I Value	≥0,980
Lysate Sensivity	0,01
Measurement Uncertainty	%1,29
Evaluation	Pass
*Limit	0,5 EU/ml

* The limit is set by the customer.

DECLARATION OF CONFORMITY

Declaration of conformity decision rule 2 are provided.

Note:Rule 2 applies unless otherwise specified by the customer.

NOTE

* Rule 1- A declaration of conformity is given by taking into account the measurement uncertainty within the legal limits.

* Rule 2- A declaration of conformity is given without taking into account the measurement uncertainty within the legal limits.


DEVIATIONS

NA

REVISION HISTORY

Rev No - Date	Revision Reason
00 - 23.06.2021	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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