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Sterility (EP and USP)

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CERTIFICATE OF ANALYSIS

Product Code: Product:				cture Date: 07-	9MB062 07-Aug-2019 07-Aug-2021	
TEST (Method)	SPECIFICATIONS				
		Min.	Max.	Results		
pH @ 20-25°C (EP)		7.12	7.48	7,22		
Osmolality (mOsm/kg)		271	315	308		
Endotoxin		***	= 1.000</td <td>< 0,010 E</td> <td>:U/ml</td>	< 0,010 E	:U/ml	

Negative

Negative

This product was manufactured aseptically according to the requirements of ISO:9001 using a validated sterile filtration method and tested where appropriate using EP methodology or approved alternative methods. This product is intended for research use only.

It is the end user#s responsibility to ensure that the final product meets the requirements of the application for which it is to be used.

Test results are determined using Lonza#s currently approved protocols.

This product is manufactured using exclusively raw material of non-

animal origin based on our supplier declaration on file in our quality system.

This lot has been reviewed by Quality Assurance in compliance with requirements of Lonza's Quality System. This document was generated from a validated Part 11-compliant electronic system and thus handwritten signatures are not required.



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Negative