

# STERILITY TEST

REFERENCE DOCUMENT: SOP NO: NQCL/SOP/BIOL – 006

MICROBIOLOGY LAB NO. BIOL/001/2016	DATE RECEIVED 2016-05-17	DATE TEST SET 18-May-201	DATE OF RESULTS 01-Jun-2016	
DI				
SAMPLE PREPARATION				
METHODOLOGY: Method Used	Membrane Filtration	6 Ampules	(Tick as appropriate)	
	Direct Inoculation			
Quantity Used per filtration/per media:				
Any other Procedures Done:				
RESULTS				
	Sample	Positive Control	Negative Control	Positive Sample Control
Fluid Thioglycolate Medium	No Growth	<i>B. subtilis</i> (NC10400) Growth	No Growth	<i>B. subtilis</i> (NC10400) Growth
		<i>P. aeruginosa</i> (NC12924) Growth		<i>P. aeruginosa</i> (NC12924) Growth
Soya Bean Digest Medium	No Growth	<i>B. subtilis</i> (NC10400) Growth	No Growth	<i>B. subtilis</i> (NC10400) Growth
		<i>C. albicans</i> (NCPEF3179) Growth		<i>C. albicans</i> (NCPEF3179) Growth
Key: (Tick: √) - Indicates turbidity, hence microbial growth; (Cross: X) - Indicates clear, hence no microbial growth.				
REMARKS				
*Inoculation of Soya Bean Digest Agar & Sabourauds Dextrose Agar				
	Sample		Negative Control	
Soya Bean Digest Agar				
Sabourauds Dextrose Agar				
	Yes			
CONCLUSION: The Product		Complies		With the requirements of the Sterility Test.
		Does Not Comply		
Analyst:			Head, Biological Analysis Unit:	
Date:			Date:	
Analyst:			Signature:	
Date:				

\* Done as a confirmation test where any turbidity observed is suspected to be due to particles from the sample, or due to a reaction between the sample and the media.

REAGENTS USED						
	Reagent Name	Manufacturer	Lot/Batch No.	Date Opened	Expiry Date	Remarks
1.	BIOL-001/2016	2016-05-17		18-May-201		01-Jun-2016
2.		DI		6 Ampules		
3.						
4.						
5.						
6.						
7.						
8.			Growth			Growth
No Growth			No Growth			

EQUIPMENT USED						Growth
	Equipment Name	NQCL No./Code	Date of Last Calibration	Date of Next Calibration		Remarks
1.						
2.						
3.						
4.						
5.						
6.	Yes					
7.						
8.						

## APPENDIX

**Describe in Summary the reagent preparation procedures including mobile phase and buffers.**

BIOL/001/2016

2016-05-17

18-May-201

01-Jun-2016

DI

6 Ampules

**Report any other tests carried out on the sample.**

No Growth      Growth      Growth  
No Growth      No Growth      Growth  
Growth      Growth      Growth  
Growth      Growth      Growth  
No Growth      No Growth      Growth

WORKSHEET TRACKING						
No.	ACTIVITY	FROM: OFFICER/ ANALYST	SIGNATURE	TO: OFFICER/ ANALYST	SIGNATURE	DATE
1						
2						
3						
4						
5						
6		Yes				
7						