

# 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 Vials	(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 Vials		
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	Growth
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 Vials

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

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

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