

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> (NCPF3179)	Growth		<i>C. albicans</i> (NCPF3179)	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
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						