## STERILITY TEST

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

MICROBIOLOGY LAB NO.		DATE RECEIVE		EIVED	08-Sep-201	ST SET	22-Sep-2016 RESULTS	
		MF						
SAMPLE PREPARATION								
M. M			rane Fil	ltration	6 Ampules	•		
METHODOLOGY: Method Used		Direct Inoculat		ation		(11	(Tick as appropriate)	
Quantity Used per filtration/per media:					<u> </u>			
Any other Procedures Done:								
RESULTS								
	Sample	Positive Cont			Negative Cont	rol Po	Positive Sample Control	
Fluid	-	C. sporoge	sporogenes   Growth				sporogenes Growth	
Thioglycolate	No Growth	(NC00532			No Growth		(C00532)	
Medium		P. aerugin	osa Gr	owth		Р.	aeruginosa Growth	
		(NC12924					(C12924) Growth	
Soya Bean Digest	No Growth	A. brasiliensis			No Growth		brasiliensis	
Medium		(NC02275) C. albicans		owth		_ `	(C02275) albicans Growth	
			(NCPF3179)				(CPF3179)	
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								
CONCLUSION:		Complies				With the requirements of the Sterility Test.		
The Product		Does Not Comply						
	2000							
Analyst:				Head, Biological Analysis Unit:				
Date:					Date:			
Analyst:					Signature:			
Date:				1				

<sup>\*</sup> 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.