## STERILITY TEST

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

MICROBIOLOGY LAB NO.		DAT	18-01-03	EIVED	DATE TEST SET		08-Feb RES	08-Feb-2018 RESULTS	
		N	ИF						
		SAN	MPLE P	REPARA	ATION				
METHODOLOGY M. 1. 111. 1 Memb			rane Fil	tration	6 Vials	6 Vials			
METHODOLOGY: Method Used D		Direct	Inocula	ition	(Tick as appropriate)				
Quantity Used per filtration/per media:					•				
Any other Procedu	res Done:				I				
				SULTS					
	Sample	Positive Co		rol	Negative Cont	rol Po	=		
Fluid		C. sporoge	1165	owth			sporogenes	Growth	
Thioglycolate	No Growth	(NC00532			No Growth	_ `	C00532)		
Medium		P. aerugin (NC12924		owth			aeruginosa C12924)	Growth	
Soya Bean Digest		A. brasiliensis		owth			brasiliensis	Growth	
Medium	No Growth	(NC02275	,		No Growth		C02275)		
		C. albicans	,	owth			albicans	Growth	
V (Tielus) Indiana		(NCPF3179) es turbidity, hen		i su o bi	al augustle	(N	CPF3179)		
č			•		ai growin; robial growth				
REMARKS			<del>-,</del>		3				
*Inoculation of Soy	a Bean Digest	Agar & Sa	bourau						
G B B: (A			Sample			Negative Control			
Soya Bean Digest Agar									
Sabourauds Dextrose Agar									
Yes									
			Complies			TAY'N A			
CONCLUSION: The Product		1				With the requirements of the Sterility Test.			
		Does Not Comply				the Stermty Test.			
Analyst:		<u>'</u>			Head, Biological				
				Analysis Unit:					
Date:					Date:				
Analyst:					Signature:				
Date:					2-0-141416.				

<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.