STERILITY TEST

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

MICROBIOLOGY LAB NO.		DAT	18-05-17	EIVED	DATE TEST SET		07-Jun- RES	07-Jun-2018 RESULTS	
		N	ИF						
		SAN	MPLE P	REPARA	ATION				
METHODOLOGY M. (1. 111. 1 Memb			nbrane Filtration		6 Vials				
METHODOLOGY: Method Used I		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		owth			sporogenes	No Growth	
Thioglycolate Medium	No Growth	(NC00532			No Growth		200532)		
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		l l	albicans	Growth	
(NCPF31 Key: (Tick: √) - Indicates turbidi				microhi	al grozyth:	(IV	CPF3179)		
			•		robial growth	•			
REMARKS	,								
*In a gulation of Core	a Page Diggs	1 may 8 Ca	la ou mou	da Davim	222 1 224				
*Inoculation of Soy	a bean Digest	Agar & Sa	lbourau				Nogotivo Co	ntrol	
Soya Bean Digest Agar				Sample			Negative Control		
Soya Bean Digest rigar									
Sabourauds Dextrose Agar									
Yes									
CONCLUSION:		Comp	Complies			With the requirements of the Sterility Test.		nents of	
The Product		Dogs Not Committee							
		Does Not Comply							
Analyst:				Head, Biological					
Date:					Analysis Unit:				
Analyst:					Date.				
•					Signature:				
	Date:			_		I			

^{*} 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.