STERILITY TEST

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

MICROBIOLOGY LAB NO.		DAT	16-11-29	EIVED	DATE TEST SET		22-Dec- RES	22-Dec-2016 RESULTS	
		N	ЛF						
		SAN	APLE P	REPAR	ATION				
METHODOLOGY M. (1. 111. 1			rane Fil	tration	6 Ampules	6 Ampules			
METHODOLOGY: Method Used Di		Direct	Inocula	ition		(Tick as appropriate)			
Quantity Used per filtration/per media:									
Any other Procedu	res Done:								
				SULTS					
	Sample	Positive Co		rol	Negative Cont	rol Po	-		
Fluid		C. sporoger	1165	owth			sporogenes	Growth	
Thioglycolate Medium	No Growth	(NC00532)			No Growth	_ `	C00532)	a	
Medium		P. aerugino (NC12924)		owth			ieruginosa C12924)	Growth	
Soya Bean Digest		A. brasiliensis		owth			brasiliensis	Growth	
Medium	No Growth	(NC02275)			No Growth		C02275)		
		C. albicans	,	owth			albicans	Growth	
(NCPF3 Key: (Tick: √) - Indicates turbia				microh	 crohial grozyth:		CPF3179)		
		•			crobial growth	,			
REMARKS	,		<u> </u>		-				
*In a gulation of Corr	a Poor Diagot	1 may 8 Ca	1	da Davie	A				
*Inoculation of Soya	a bean Digest	Agar & Sa	bourau				Jogativa Co	ntrol	
Soya Bean Digest Agar				Sample			Negative Control		
Soyu Beam Bigest rigar									
Sabourauds Dextrose Agar									
	Yes	<u> </u>							
CONCLUSION:		Comp	Complies			With the requirements of		nents of	
The Product		Door Not Complex				4	terility Test.		
		Does Not Comply							
Analyst:					Head, Biological Analysis Unit:				
Date:					Date:				
Analyst:									
Date:					Signature:				

^{*} 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.