STERILITY TEST

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

MICROBIOLOGY LAB NO.		DAT	16-12-08	EIVED	DATE TEST SET		DATE OF RESULTS	
		N	ИF					
		SAN	MPLE P	REPARA	ATION			
METHODOLOGY M. (1. 111. 1 Memb			rane Fil	tration	6 Vials	(T.:	T: 1	
METHODOLOGY: Method Used		Direct	Inocula	ition		(Tick as appropriate)		
Quantity Used per filtration/per media:					•			
Any other Procedu	res Done:							
,								
				SULTS				
	Sample	Positi	ve Cont		Negative Cont	rol Pos	Positive Sample Control	
Fluid		C. sporoge	1100	owth			sporogenes	Growth
Thioglycolate Medium	No Growth	(NC00532			No Growth	,	C00532)	
Meaium		P. aerugin (NC12924		owth			ieruginosa C12924)	Growth
Soya Bean Digest		A. brasiliensis		owth			A. brasiliensis Growth	Growth
Medium	No Growth	(NC02275	·		No Growth		C02275)	
		C. albicans	,	owth			albicans	Growth
Tr. 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		(NCPF3179)		. 1.	. 1	(NO	CPF3179)	
	k: √) - Indicat oss: X) - Indi		•		ai growtn; robial growth			
REMARKS	755. 1 1) 111111	cutes etcu	i, nenec	ino mic	rooini growin	•		
*Inoculation of Soya	a Bean Digest	Agar & Sa	bourau			_		
			Sample			Negative Control		
Soya Bean Digest	Agar							
Sabourauds Dextrose Agar								
Yes Yes								
Comr			lies					
CONCLUSION: The Product		Complies				With the requirements of		
		Does Not Comply				the Sterility Test.		
Analyst				Head, Biological				
Analyst:				Analysis Unit:				
Date:					Date:			
Analyst:					Signature:			
Date:					oignature.			

^{*} 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.