STERILITY TEST

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

MICROBIOLOGY JAB NO.		DA	78-85-9	FIVED	DATE TEST SET		08-Jun	DATE OF 08-Jun-2018 RESULTS	
		1	MF				2.20		
		SAI	MPLE P	REPARA					
METHODOLOGY: Method Used		Memb	rane Fi	ltration	6 items	6 Items			
		Direct	Inocula	ation		(1	(Tick as appropriate)		
Quantity Used per filtration/per media:									
Any other Procedu	res Done:								
	0 1	D '		SULTS	N. 41 C) ''' C	1.0.1.1	
	Sample	Positive Co			Negative Control		Positive Sample Control		
Fluid Thioglycolate	No Growth	C. sporoge (NC00532	1103	rowth	No Growth		C. sporogenes NC00532)	Growth	
Medium	140 Growth	P. aerugin		Growth	No Grown	<u>, , , , , , , , , , , , , , , , , , , </u>	. aeruginosa	Growth	
		(NC12924	1)			(1	NC12924)		
Soya Bean Digest	No Growth	A. brasilie	nsis	rowth	No Growth		A. brasiliensis	Growth	
Medium	110 Olowaii	(NC02275		rowth	No Growin	(1	NC02275) C. albicans	Growth	
		(NCPF31)	3				NCPF3179)		
· ·	k: √) - Indica		0.		•		•		
	oss: X) - Ind	icates clea	r, henc	e no mic	robial growti	h			
REMARKS									
*Inoculation of Soya	a Bean Diges	t Agar & Sa	abourau	ıds Dextro	ose Agar				
			Sample				Negative Control		
Soya Bean Digest Agar									
Sabourauds Dextro	ose Agar								
Yes									
CONCLUSION: The Product		Comp	Complies			With	With the requirements of		
		Does Not Comply				the Sterility Test.			
					ead, Biological	1			
Analyst:					Analysis Unit:				
Date:					Date:				
Analyst:					Signature				
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.