STERILITY TEST

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

| MICROBIOL/001/2018 NO. | | DA | DATE RECEIVED | | DATE TEST SET | | DATE OF 06-Jun-2018 RESULTS | | |
|---|------------|-------------------------|--|--------|-----------------------------------|--|-----------------------------------|----------|--|
| | | ı | MF | | | | 102 | 30213 | |
| SAMPLE PREPARATION | | | | | | | | | |
| METHODOLOGY: Method Used | | Memb | Membrane Filtr | | 6 Items | /7 | (Tick as appropriate) | | |
| | | Direct | Direct Inoculat | | | (1 | | | |
| Quantity Used per filtration/per media: | | | | | | | | | |
| Any other Procedu | res Done: | | | | | | | | |
| | | | | | | | | | |
| RESULTS Compared Projection Compared | | | | | | | | | |
| | Sample | Positive Con | | | Negative Cont | | Positive Sample Control | | |
| Fluid | No Growth | | sporogenes Gro (C00532) aeruginosa Gro | | No Growth | | . sporogenes NC00532) | Growth | |
| Thioglycolate Medium | NO GIOWIII | , | | | NO GIOWIII | | . aeruginosa | Growth | |
| 1,10d1d11 | | (NC12924 | C12924) | | | | VC12924) | | |
| Soya Bean Digest | | | A. brasiliensis G | | No Consude | | . brasiliensis | Growth | |
| Medium | No Growth | (NC02275 C. albicans | | rowth | No Growth | _ ` | VC02275) | Growth | |
| | | | ' | Owtii | | | . albicans NCPF3179) | Growth | |
| $(NCPF3179)$ $(NCPF3179)$ $(NCPF3179)$ Key: $(Tick:)$ - Indicates turbidity, hence microbial growth; | | | | | | | | | |
| (Cross: X) - Indicates clear, hence no microbial growth. | | | | | | | | | |
| REMARKS | | | | | | | | | |
| *Inoculation of Soya Bean Digest Agar & Sabourauds Dextrose Agar | | | | | | | | | |
| | | | | Sample | | | Negative Control | | |
| Soya Bean Digest Agar | | | | | | | | | |
| Sabourauds Dextrose Agar | | | | | | | | | |
| Yes | | | | | | | | | |
| CONCLUSION: The Product | | Complies | | | | With the requirements of the Sterility Test. | | ments of | |
| | | Does Not Comply | | | | | | | |
| Analyst: | | 1 | 1 | | ead, 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.