STERILITY TEST

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

| MICROBIOLOGIAZOTAB NO. | | DAT | 7-8FS | EIVED | DATE TEST SET | | | 08-Feb-2017 RESULTS | |
|--|------------|--------------------------|---------------------|--------|------------------------------------|---------------|--------------------------|------------------------|--------|
| | | N | MF | | | | | | |
| SAMPLE PREPARATION 6 Vials | | | | | | | | | |
| METHODOLOGY: Method Used | | Membi | Membrane Filtration | | | | (T: 1 ' () | | |
| | | Direct 1 | Inocula | ition | | | (Tick as appropriate) | | |
| Quantity Used per filtration/per media: | | | | | | | | | |
| Any other Procedu | res Done: | | | | | | | | |
| | | | | | | | | | |
| RESULTS Complete Position Control Position C | | | | | | | | | |
| | Sample | Positive Co | | | Negative Control | | | | |
| Fluid | No Growth | C. sporoger (NC00532) | ics | owth | No Grow | ıth. | | orogenes 10532) | Growth |
| Thioglycolate Medium | NO GIOWIII | P. aerugino | | owth | NO GIOW | , LII | ` | ruginosa | Growth |
| | | (NC12924) | 2924) | | | | | 12924) | |
| Soya Bean Digest | No Growth | A. brasilier | | | No Grow | | | rasiliensis | Growth |
| Medium | No Growin | (NC02275) C. albicans | | owth | No Grow | | | 02275) bicans | Growth |
| | | (NCPF317 | ' | | | | | PF3179) | |
| Key: (Tick: $\sqrt{\ }$) - 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 Dextro | | | | | | | | | |
| | Yes | | | | | | | | |
| CONCLUSION: The Product | | Comp | Complies | | | W | With the requirements of | | |
| | | Does l | Does Not Comply | | | the Sterility | | | |
| Analyst: | | | | | Head, Biological Analysis Unit: | | | | |
| Date: | | | | | Date: | | | | |
| Analyst: | | | | | C: . | | | | |
| Date: | | | | | Signatu | re: | | | |

^{*} 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.