

STERILITY TEST
Method of Analysis No.: Micro/MoA 005

| MICROBIOLOGY LAB NO. | DATE RECEIVED | DATE TEST SET | DATE OF RESULTS | | | |
|--|------------------|--------------------------------|-----------------------|--|---|--------|
| BIOL/001/2016 | 2015-10-27 | 01-Feb-201 | 15-Feb-2016 | | | |
| METHODOLOGY: Method Used | MF | Membrane Filtration | (Tick as appropriate) | | | |
| | | Direct Inoculation | | | | |
| Quantity Used per filtration/per media: | | 6 Ampules | | | | |
| SAMPLE PREPARATION | | | | | | |
| | | | | | | |
| RESULTS | | | | | | |
| | Sample | Positive Control | Negative Control | Positive Sample Control | | |
| Fluid Thioglycolate Medium | | <i>B. subtilis</i> (NC10400) | Growth | No Growth | <i>B. subtilis</i> (NC10400) | Growth |
| | No Growth | <i>P. aeruginosa</i> (NC12924) | Growth | | <i>P. aeruginosa</i> (NC12924) | Growth |
| Soya Bean Digest Medium | | <i>B. subtilis</i> (NC10400) | Growth | No Growth | <i>B. subtilis</i> (NC10400) | Growth |
| | No Growth | <i>C. albicans</i> (NCPF3179) | Growth | | <i>C. albicans</i> (NCPF3179) | Growth |
| 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 | | | | | | |
| CONCLUSION: The Product | Yes | Complies | | | With the requirements of the Sterility Test. | |
| | | Does Not Comply | | | | |
| Analyst: | | | | Head, Biological Analysis Unit: | | |
| Date: | | | | Date: | | |
| Analyst: | | | | | | |
| Date: | | | | | | |

* 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.