

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

| MICROBIOLOGY LAB NO.   | DATE RECEIVED    | DATE TEST SET                  | DATE OF RESULTS       |  |   |        |
|--|------------------|--------------------------------|-----------------------|--|---|--------|
| BIOL/001/2016  | 2015-08-06       | 26-Jan-201                     | 09-Feb-2016           |  |   |        |
| METHODOLOGY: Method Used   | MF               | Membrane Filtration            | (Tick as appropriate) |  |   |        |
|  |                  | Direct Inoculation             |                       |  |   |        |
| Quantity Used per filtration/per media:  |                  | 6 Ampules                      |                       |  |   |        |
| <b>SAMPLE PREPARATION</b>  |                  |                                |                       |  |   |        |
|  |                  |                                |                       |  |   |        |
| <b>RESULTS</b>   |                  |                                |                       |  |   |        |
|  | Sample           | Positive Control               | Negative Control      | Positive Sample Control                |   |        |
| <b>Fluid Thioglycolate Medium</b>  |                  | <i>B. subtilis</i> (NC10400)   | Growth                | <b>No Growth</b>                       | <i>B. subtilis</i> (NC10400)                        | Growth |
|  | <b>No Growth</b> | <i>P. aeruginosa</i> (NC12924) | Growth                |  | <i>P. aeruginosa</i> (NC12924)                      | Growth |
| <b>Soya Bean Digest Medium</b>   |                  | <i>B. subtilis</i> (NC10400)   | Growth                | <b>No Growth</b>                       | <i>B. subtilis</i> (NC10400)                        | Growth |
|  | <b>No Growth</b> | <i>C. albicans</i> (NCPF3179)  | Growth                |  | <i>C. albicans</i> (NCPF3179)                       | Growth |
| <b>Key:</b> (Tick: ✓) - Indicates turbidity, hence microbial growth;<br>(Cross: X) - Indicates clear, hence no microbial growth. |                  |                                |                       |  |   |        |
| <b>REMARKS</b>   |                  |                                |                       |  |   |        |
| *Inoculation of Soya Bean Digest Agar & Sabourauds Dextrose Agar   |                  |                                |                       |  |   |        |
|  |                  | <b>Sample</b>                  |                       | <b>Negative Control</b>                |   |        |
| <b>Soya Bean Digest Agar</b>   |                  |                                |                       |  |   |        |
| <b>Sabourauds Dextrose Agar</b>  |                  |                                |                       |  |   |        |
| <b>CONCLUSION:</b><br>The Product  | Yes              | Complies                       |                       |  | <b>With the requirements of the Sterility Test.</b> |        |
|  |                  | Does Not Comply                |                       |  |   |        |
| <b>Analyst:</b>  |                  |                                |                       | <b>Head, Biological Analysis Unit:</b> |   |        |
| Date:  |                  |                                |                       | Date:                                  |   |        |
| <b>Analyst:</b>  |                  |                                |                       |  |   |        |
| 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.