

# STERILITY TEST

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

|   |                             |                                  |                                 |  |
|---|-----------------------------|----------------------------------|---------------------------------|--|
| MICROBIOLOGY LAB NO.<br>BIOL/001/2016   | DATE RECEIVED<br>2016-10-26 | DATE TEST SET<br>2-Nov-2016      | DATE OF RESULTS<br>16-Nov-2016  |  |
|   | MF                          |                                  |                                 |  |
| SAMPLE PREPARATION  |                             |                                  |                                 |  |
| METHODOLOGY: Method Used  | Membrane Filtration         | 6 Ampules                        | (Tick as appropriate)           |  |
|   | Direct Inoculation          |                                  |                                 |  |
| Quantity Used per filtration/per media:   |                             |                                  |                                 |  |
| Any other Procedures Done:  |                             |                                  |                                 |  |
| RESULTS   |                             |                                  |                                 |  |
|   | Sample                      | Positive Control                 | Negative Control                | Positive Sample Control                      |
| Fluid Thioglycolate Medium  | No Growth                   | C. sporogenes (NC00532) Growth   | No Growth                       | C. sporogenes (NC00532) Growth               |
|   |                             | P. aeruginosa (NC12924) Growth   |                                 | P. aeruginosa (NC12924) Growth               |
| Soya Bean Digest Medium   | No Growth                   | A. brasiliensis (NC02275) Growth | No Growth                       | A. brasiliensis (NC02275) Growth             |
|   |                             | C. albicans (NCPF3179) Growth    |                                 | C. albicans (NCPF3179) Growth                |
| Key: (Tick: √) - Indicates turbidity, hence microbial growth;<br>(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:<br>The Product  |                             | Complies                         |                                 | With the requirements of the Sterility Test. |
|   |                             | Does Not Comply                  |                                 |  |
| Analyst:  |                             |                                  | Head, Biological Analysis Unit: |  |
| Date:   |                             |                                  | Date:                           |  |
| Analyst:  |                             |                                  | Signature:                      |  |
| 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.