## STERILITY TEST

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

| MICROBIOLOGY LAB NO.   |           | DAT                       | DATE RECEIVE    |                | 24-Jan-201      | ST SET                                       | OSET 08-Feb-2017<br>RESULTS |         |  |
|--|-----------|---------------------------|-----------------|----------------|-----------------|--|-----------------------------|---------|--|
|  |           | N                         | MF              |                |                 |  |                             |         |  |
| SAMPLE PREPARATION   |           |                           |                 |                |                 |  |                             |         |  |
|  |           |                           | rane Fi         | ltration       | 6 Items         | 6 Items                                      |                             |         |  |
| METHODOLOGY: Method Used   |           | Direct Inocula            |                 | ation          |                 | (11  | (Tick as appropriate)       |         |  |
| Quantity Used per filtration/per media:                                  |           |                           |                 |                |                 |  |                             |         |  |
| Any other Procedures Done:   |           |                           |                 |                |                 |  |                             |         |  |
|  |           |                           |                 |                |                 |  |                             |         |  |
|  |           |                           |                 |                |                 |  |                             |         |  |
|  |           |                           |                 |                |                 |  |                             |         |  |
| RESULTS  |           |                           |                 |                |                 |  |                             |         |  |
|  | Sample    | Positive Con              |                 |                | Negative Cont   | rol Po                                       | Positive Sample Control     |         |  |
| Fluid  | -         | C. sporoge                | orogenes Growth |                |                 | C.   | sporogenes G                | Frowth  |  |
| Thioglycolate  | No Growth | (NC00532                  |                 |                | No Growth       |  | (C00532)                    |         |  |
| Medium   |           |                           |                 | owth           |                 |  | O                           | Frowth  |  |
|  |           | (NC12924                  |                 |                |                 |  | (C12924)                    | Frowth  |  |
| Soya Bean Digest<br>Medium   | No Growth | A. brasiliensis (NC02275) |                 |                | No Growth       |  | brasiliensis                |         |  |
| Medium   |           |                           |                 | owth           |                 |  | (C02275) albicans           | Frowth  |  |
|  |           | (NCPF3179)                |                 |                |                 |  | (CPF3179)                   |         |  |
| 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 A   |           |                           |                 |                |                 |  |                             |         |  |
| Sabourauds Dextrose Agar   |           |                           |                 |                |                 |  |                             |         |  |
| Sabourauus Dexire  |           |                           |                 |                |                 |  |                             |         |  |
|  | Comer     | Complies                  |                 |                |                 |  |                             |         |  |
| CONCLUSION: The Product  |           | Complies  Does Not Comply |                 |                |                 | With the requirements of the Sterility Test. |                             | ents of |  |
|  |           |                           |                 |                |                 |  |                             |         |  |
|  |           |                           | He              |                | ead, Biological |  |                             |         |  |
| Analyst:   |           |                           |                 | Analysis Unit: |                 |  |                             |         |  |
| Date:  |           |                           |                 |                | Date:           |  |                             |         |  |
| Analyst:   |           |                           |                 |                | C:t             |  |                             |         |  |
| Date:  |           |                           |                 | Signature:     |                 |  |                             |         |  |

<sup>\*</sup> 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.