## STERILITY TEST

Method of Analysis No.: Micro/MoA 005

| MICROBIOLOGY LAB NO.  |           |      | DA               | TE R                             | ECEIVED          | DATE TEST SET     |                          | DATE OF<br>RESULTS     |           |             |
|---|-----------|------|------------------|----------------------------------|------------------|-------------------|--------------------------|------------------------|-----------|-------------|
| BIOL/001/2015   |           |      | 2015-09-11       |                                  |                  | 17/09/2015        | j                        | 01/10/2015             |           |             |
| METHODOLOGY: Method Used  |           |      | MF               | Membra                           | brane Filtration |                   |                          |                        |           |             |
|   |           |      |                  | Direct Inc                       |                  | oculation         | (1                       | (Tick as appropriate)  |           |             |
| Quantity Used per filtration/per m  |           |      | media            | media:                           |                  | 4 Ampules         | ;<br>;                   |                        |           |             |
| SAMPLE PREPARATION  |           |      |                  |                                  |                  |                   |                          |                        |           |             |
|   |           |      |                  |                                  |                  |                   |                          |                        |           |             |
| RESULTS   |           |      |                  |                                  |                  |                   |                          |                        |           |             |
|   | Sample    |      | Positive Co      |                                  | Control          | Negative Cont     |                          | Positive Sample Contro |           | ole Control |
| Fluid<br>Thioglycolate  |           |      | B. subt<br>(NC10 |                                  | Growth           | No Consult        |                          | ıbtilis<br>1040        |           | Growth      |
| Medium  | No Gr     | owth | P. aeru<br>(NC12 |                                  | Growth           | No Growth         |                          | rugii<br>1292          |           | Growth      |
| Soya Bean Digest<br>Medium  | No Growth |      |                  | subtilis Growth                  |                  | No Groundh        |                          | ıbtilis<br>1040        | i Giowiii |             |
|   |           |      |                  | albicans<br>CPF3179) <b>Grov</b> |                  | No Growth         |                          | bican<br>PF31          | Growth    |             |
| 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  |           |      |                  |                                  |                  |                   |                          |                        |           |             |
|   |           |      |                  |                                  | Sa               | N                 | Negative Control         |                        |           |             |
| Soya Bean Digest Agar   |           |      |                  |                                  |                  |                   |                          |                        |           |             |
| Sabourauds Dextrose Agar  |           |      |                  |                                  |                  |                   |                          |                        |           |             |
| CONCLUSION: Yes The Product   |           | Yes  | Co               | mplie                            | es               |                   | With the requirements of |                        | nents of  |             |
|   |           |      | Does Not Comply  |                                  |                  |                   | the Sterility Test.      |                        |           |             |
| Analyst:  |           |      |                  |                                  | Не               | ad, Biological Aı | nit:                     |                        |           |             |
| Date:   |           |      |                  |                                  |                  |                   | Da                       | ite:                   |           |             |
| Analyst:  |           |      |                  |                                  |                  |                   |                          |                        |           |             |
| Date:   |           |      |                  |                                  |                  |                   |                          |                        |           |             |

<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.