## MICROBIAL COUNT

## REFERENCE DOCUMENT: SOP NO. BIOL 007

| MICROBIOLO<br>BIOL/00  |                 | 2017-09-29 09                                    |                   |  | SET  | DATE OF RESULTS 09-Oct-2017 |                     |  |  |  |  |
|--|-----------------|--|-------------------|--|------|-----------------------------|---------------------|--|--|--|--|
| SAMPLE PREPARATION   |                 |  |                   |  |      |                             |                     |  |  |  |  |
| 10ml 10ml 1ml ————————————————————————————————————   |                 |  |                   |  |      |                             |                     |  |  |  |  |
|  |                 |  | 0                 |  |      | 0                           |                     |  |  |  |  |
| RESULTS 0 0  |                 |  |                   |  |      |                             |                     |  |  |  |  |
|  |                 |  | 10¹ CFU <1        | 10 <sup>2</sup> CF                                       | TU 1 | 0 <sup>3</sup> CFU<br>0     | Negative<br>Control |  |  |  |  |
|  | Plate 1         |  |                   |  |      |                             |                     |  |  |  |  |
| Nutrient Agar  | Plate 2         |  | 0                 |  |      | 0                           |                     |  |  |  |  |
|  | Average (A): Cl | FU<br>Microbial Count)                           | 0                 |  |      | 0                           |                     |  |  |  |  |
|  | (               | ,  |                   | 10   |      | 0                           | Negative            |  |  |  |  |
| Sabourauds<br>Dextrose<br>Agar   | Plate 1         |  | <1                |  |      |                             | Control             |  |  |  |  |
|  | Plate 2         |  | <del>&lt;</del> 1 | 0  |      | 0                           |                     |  |  |  |  |
|  |                 | Average (B): CFU<br>Total Yeast Microbial Count) |                   |  |      |                             |                     |  |  |  |  |
| NB: Acceptance Criteria is interpreted as follows depending on route of administration  — 10 <sup>1</sup> cfu: maximum acceptable count = 20; 10 <sup>2</sup> cfu: maximum acceptable count = 200; 10 <sup>3</sup> cfu: maximum acceptable count = 2000; and so forth. |                 |  |                   |  |      |                             |                     |  |  |  |  |
| CONCLUSION The Production  |                 | Complies   |                   | With the requirements of the Microbial Enumeration Test. |      |                             |                     |  |  |  |  |
|  |                 | Does Not Comp                                    | ly                |  |      |                             |                     |  |  |  |  |
| 1  | Analyst:        |  |                   | Head, Biological<br>Analysis Unit:                       |      |                             |                     |  |  |  |  |
|  | Date:           |  |                   | Date:  |      |                             |                     |  |  |  |  |
| 1  | Analyst:        |  | — Signature:      |  |      |                             |                     |  |  |  |  |
|  | Date:           |  |                   |  |      |                             |                     |  |  |  |  |

## TEST FOR SPECIFIED MICROORGANISMS

REFERENCE DOCUMENT: SOP NO. BIOL 007

2017-09-29 09:53:37 04-Oct-2017

| MICROBIOLOGY LAB NO.       |                        | DATE RECEIVED        |                          | DATE TEST SET                                   | DATE        | DATE OF RESULTS |  |  |  |  |  |
|----------------------------|------------------------|----------------------|--------------------------|---|-------------|-----------------|--|--|--|--|--|
|                            |                        | C 1 2 577 1          |                          | 1.ET.0.1.                                       |             |                 |  |  |  |  |  |
| SAMPLE PREPARATION         |                        |                      |                          |   |             |                 |  |  |  |  |  |
| 10ml<br>—<br>100ml B       | — x ——                 | 0ml X —<br>11 BPW 11 | 1ml<br>———<br>ml Plating | Replicates: 2                                   |             |                 |  |  |  |  |  |
|                            |                        |                      |                          | 0   | 0           |                 |  |  |  |  |  |
| Microorganism              | Toot                   |                      | RESULTS                  | Observation                                     | 0           | Negative        |  |  |  |  |  |
| Wilcioorganism             | Test Media             |                      |                          | <10   | 0           | Control         |  |  |  |  |  |
|                            |                        |                      |                          | 3.0   | v           |                 |  |  |  |  |  |
|                            |                        |                      |                          | 0   | 0           |                 |  |  |  |  |  |
|                            |                        |                      | 0                        |   |             |                 |  |  |  |  |  |
|                            |                        |                      |                          | <10   | 0           |                 |  |  |  |  |  |
|                            |                        |                      |                          | <10   | 0           |                 |  |  |  |  |  |
|                            |                        |                      |                          |   |             |                 |  |  |  |  |  |
| Observation – Indic        | ate wheth <b>eg</b> he | re is growth/        | turbidity/               | colour change in the to                         | est media o | r Not.          |  |  |  |  |  |
| CONCLUSION:<br>The Product | Com                    | plies                |                          | With the requirements of the Test for Specified |             |                 |  |  |  |  |  |
|                            | Doe                    | s Not Compl          | y Mic                    | roorganisms.                                    |             |                 |  |  |  |  |  |
| Analyst:                   |                        |                      |                          | Head, Biological<br>Analysis Unit:              |             |                 |  |  |  |  |  |
| Date:                      |                        |                      |                          | Date:   |             |                 |  |  |  |  |  |
| Analyst:                   |                        |                      |                          | Signature:                                      |             |                 |  |  |  |  |  |
| Date:                      |                        |                      |                          | Signature.                                      |             |                 |  |  |  |  |  |