**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-17/

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| **PRODUCT** | PERGOVERIS® 150 I.U/75 I.U POWDER AND SOLVENT FOR SOLUTION FOR INJECTION | | **REF. NO:** NDQD201604844 |
| **DATE RECEIVED:** 07.04.2016 | **LABEL CLAIM:** | Each vial of lyophilized powder contains follitropin alfa 150 I.U. and lutropin Alfa 75 I.U. | |
| **BATCH NO.:** Powder:AU013142 Diluent: 132F009 | **PRESENTATION:** | Off white coloured, lyophilized powder for subcutaneous administration contained in a clear colourless glass vial fitted with a grey rubber closure, metallic cap and a straw coloured plastic flip off cap, packed along with sterile water for injection in a 1 mL glass vial fitted with a grey rubber closure, metallic cap and a purple coloured plastic flip off cap on a plastic rack in a printed box. | |
| **MFG. DATE:** Powder: Mar. 2015  Diluent: Mar. 2015 | **MANUFACTURER:** | MERCK Serono S.A. (MSA). | |
| **EXP. DATE:**  Powder: Feb. 2017  Diluent: Feb. 2018 | **ADDRESS:** | Succursale d’ Aubonne Zone Industrielle de l’Ouriettaz,  CH – 1170, Aubonne,  SWITZERLAND. | |
| **CLIENT REF NO:** | **CLIENT:** | Ripple Pharmaceuticals Ltd.  P.O. Box 10935 - 00100, Nairobi,  KENYA. | |
|  | **TEST(S) REQUESTED:** | Sterility and Bacterial Endotoxin. | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Sterility** | Direct Inoculation | BP Vol V 2016 Appendix XVI A | **Powder and Diluent:**  No Microbial Growth | **Powder and Diluent:** No Microbial Growth | **COMPLIES** |
| **Bacterial Endotoxin** | LAL | Manufacturer’s In-House Method | **Powder:**  Less than 8 EU/mg | 1.1 × 10-3 EU/Vial | **COMPLIES** |
| USP 38 NF 33  Page 5806 | **Diluent:**  Less than 0.25 EU/mL | 3.4 × 10-7 EU/mL | **COMPLIES** |

**CONCLUSION:** The product complies with the specifications for the tests performed.

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| **ANALYST:** | MR. F. NAULA |  | **DATE**: 23-05-2017 |
| **ANALYST:** | DR. S. MUTERU |  | **DATE**: 23-05-2017 |
| **DIRECTOR:** | DR. H. K. CHEPKWONY |  | **DATE**: 23-05-2017 |

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| INVOICE |

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| **INVOICE No: -/16-17** | Date: 23rd May, 2017 |

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| **Ripple Pharmaceuticals Ltd.**  **P.O. Box 10935 - 00100, Nairobi,**  **KENYA.** |

**Re: ANALYSIS OF LISTED PRODUCT**.

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| **PRODUCT:** | PERGOVERIS® 150 I.U/75 I.U POWDER FOR INJECTION |
| **BATCH NO:** | Powder:AU013142  Diluent: 132F009 |
| **CERTIFICATE NO:** | CAN/2016-17/- |
| **LABORATORY REF NO:** | NDQD201604844 |
| **CLIENT REF NO:** | - |
| **TEST(S) REQUESTED:** | Sterility and Bacterial Endotoxin. |

**COST OF ANALYSIS:**

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| **TEST** | **METHOD** | **COMPENDIA** | COST (KShs) |
| **Sterility** | Direct Inoculation | BP 2016 Vol. V | **135,360.00** |
| **Bacterial Endotoxin** | LAL | U.S.P. 38 N.F. 33 | **92,640.00** |
|  | | TOTAL COST | **228,000.00** |
| **AMOUNT PAYABLE** | **228,000.00** |

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| **DIRECTOR:** | DR. H. K. CHEPKWONY |  | **DATE:** | 23-05-2017 |

All cheques should be made payable to: **NATIONAL QUALITY CONTROL LABORATORY**