**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No.:** CAN/2018-19/

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| **PRODUCT** | SALBOGET INHALER | | **REF. No.:** NDQD201807026 |
| **DATE RECEIVED:** 18. Jul. 2018 | **LABEL CLAIM:** | Each metered dose contains: Salbutamol 100 mcg (as Salbutamol Sulfate Ph. Eur.) | |
| **BATCH No.:** 0011M04 | **PRESENTATION:** | Off white coloured suspension for oral inhalation contained in a pressurized aluminium canister with a metered valve inserted into a plastic mouthpiece with cap and packed in a unit box, 200 metered doses per canister. | |
| **MFG. DATE:**  Jan. 2018 | **MANUFACTURER:** | GETZ Pharma (Pvt.) Limited | |
| **EXP. DATE:** Jan. 2020 | **ADDRESS:** | 29-30/27, K.I.A.,  Karachi - 74900,  PAKISTAN. | |
| **CLIENT REF. No.:**  - | **CLIENT:** | Getz Pharma Pvt. Ltd. ℅ Surgipharm Ltd.  P. O. Box 46043 - 00100, Nairobi,  KENYA. | |
| **TEST(S) REQUESTED:** | Microbial Load, Identification and Assay. | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Plate Count | BP 2017 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL | < 10 CFU/mL | **COMPLIES** |
| Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/mL | < 10 CFU/mL | **COMPLIES** |
| **Identification** | HPLC | BP 2017 Vol. III  Page 1138 | RT of the principal peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at  RT: 3.6 ± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | BP 2017 Vol. III  Page 1138 | 80.0 - 120.0% | 104.4%  (RSD=0.8%; n=9) | **COMPLIES** |

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

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| **ANALYST:** | MR. D. OLUOCH |  | **DATE:** | 03. Sep. 2018 |
| **ANALYST:** | MS. K. RUTTO |  | **DATE:** | 03. Sep. 2018 |
| **ANALYST:** | DR. N. MWAURA |  | **DATE:** | 03. Sep. 2018 |
| **DIRECTOR:** | DR. H. K. CHEPKWONY |  | **DATE:** | 03. Sep. 2018 |

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| **INVOICE** |

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| **INVOICE No.: /18-19** | **Date: 3rd September, 2018** |

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| **Getz Pharma Pvt. Ltd. ℅ Surgipharm Ltd,** |
| **P.O. Box 46043 – 00100, Nairobi,** |
| **KENYA.** |

**Re: ANALYSIS OF LISTED PRODUCT**.

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| **PRODUCT:** | SALBOGET INHALER |
| **BATCH No.:** | 011M04 |
| **CERTIFICATE No.:** | CAN/2018-19/ |
| **LABORATORY REF. No.:** | NDQD201807026 |
| **CLIENT REF. No.:** | - |
| **TEST(S) REQUESTED:** | Microbial Load, Identification and Assay. |

**COST OF ANALYSIS:**

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| **TEST** | **METHOD** | **COMPENDIA** | **COST (KShs)** |
| **Microbial Load** | Plate Count | BP 2017 Vol. V | **31,920.00** |
| **Identification and Assay** | HPLC | BP 2017 Vol. III | **37,870.00** |
|  | | **TOTAL COST** | **69,790.00** |
| **AMOUNT PAYABLE** | **69,790.00** |

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| **DIRECTOR:** | DR. H. K. CHEPKWONY |  | **DATE**: | 03. Sep. 2018 |