**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/014

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| **PRODUCT** | ONBREZ(R) BREEZHALER(R) CAPSULES | | **REF. NO: NDQD201509255** |
| **DATE RECEIVED:** 08.09.2015 | **LABEL CLAIM:** | Each capsule contains 150 micrograms indacaterol. Equivalent to 194 micrograms of indacaterol maleate, Excipients: Lactose monohydrate, gelatin. | |
| **BATCH NO.:** B0002 | **PRESENTATION:** | Transparent hard gelatin capsule imprinted 'IDL 150' on the body and company logo on the cap, filled with a free flowing white coloured powder for inhalation, packed in an aluminium blister pack of 10 capsules and 3 such strips packed along with a plastic inhaler in a unit box. | |
| **MGF. DATE:** Aug. 2014 | **MANUFACTURER:** | NORVATIS Pharma Stein AG. | |
| **EXP. DATE:**  Jul.2016 | **ADDRESS:** | Stein, SWITZERLAND. | |
| **CLIENT REF NO:** | **CLIENT:** | NOVARTIS PHARMA SERVICES INC. P.O BOX 46057 -00100-NAIROBI, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Content, Microbial Load, Identification, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Plate Count | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/g Total Combined Yeasts/ Moulds Count (TYMC) NMT 20 CFU/g | < 10 CFU/g < 10 CFU/g | **COMPLIES** |
| **Uniformity of Content** | HPLC | Manufacturer's In-House Method | The acceptance value (AV) of ten (10) dosage units is NMT 15% | AV = 7% (n=10) | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's In-House Method | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 4.6 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | Manufacturer's In-House Method | 95.0 - 105.0% | 95.9% (RSD=0.7%; n=9) | **COMPLIES** |

**CONCLUSION:**

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| **ANALYST:** | MR. F. NAULA | .......................................................... | DATE: 23-05-2016 |
| **ANALYST:** | MR. D. MOENGA | .......................................................... | DATE: 23-05-2016 |
| **ANALYST:** | DR. N. MWAURA | .......................................................... | DATE: 23-05-2016 |
| **ANALYST:** | EMMANUEL TANUI | .......................................................... | DATE: 06-02-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 06-22-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 07-18-2016 |