**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/30

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| **PRODUCT** | ONBREZ(R) BREEZHALER(R) INHALER | | **REF. NO: NDQD201509256** |
| **DATE RECEIVED:** 08.09.2015 | **LABEL CLAIM:** | Each capsule contains 300 micrograms Indacaterol. Equivalent to 389 micrograms of indacaterol maleate, Excipients: Lactose monohydrate, gelatin. | |
| **BATCH NO.:** B0006 | **PRESENTATION:** | Transparent hard gelatin capsule imprinted 'IDL 300' on the body and company logo on the cap, filled with 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:** Sep. 2014 | **MANUFACTURER:** | NORVATIS Pharma Stein AG. | |
| **EXP. DATE:** Feb. 2016 | **ADDRESS:** | Stein, SWITZZERLAND. | |
| **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** |
| **Uniformity of Content** | HPLC | Manufacturer's In-House Method | The Acceptance Value (AV) of ten dosage units is NMT 15% | AV = 5% (n=10) | **COMPLIES** |
| **Microbial Load** | Plate Count | BP 2016 Vol. V App. XVI B | otal Aerobic Microbial Count (TAMC) NMT 200 CFU/g Total Combined Yeasts/ Moulds Count (TYMC) NMT 20 CFU/g | TAMC < 10 CFU/g TYMC < 10 CFU/g | **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% | 98.7% (RSD=1.0%; n=9) | **COMPLIES** |

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

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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: 07-18-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 07-27-2016 |