**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**  CAN/2015-16/XYZ

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| **PRODUCT** | ULTIBRO BREEZHALER CAPSULES | | REF. NO: NDQD201504177 |
| **DATE RECEIVED:** 14.04.2015 | **LABEL CLAIM:** | Each inhalation Powder capsule contains 143 micrograms Indacaterol maleate equivalent to 110 mcg indacaterol and 63 mcg glycopyrronium bromide equivalent to 50 mcg glycopyrronium. | |
| **BATCH NO.:** S0058 | **PRESENTATION:** | Hard gelatin capsule with a yellow transparent cap printed with the manufacturer's log and a clear transparent body printed 'IGP110.50',filled with free flowing white coloured powder for inhalation, packed in an aluminium blister pack of 6 capsules and 5 such strips packed along with a plastic inhaler in a unit box. | |
| **MGF. DATE:** May.2014 | **MANUFACTURER:** | Novartis Pharma Stein AG | |
| **EXP. DATE:** Oct.2015 | **ADDRESS:** | Stein, SWITZERLAND. | |
| **CLIENT REF NO:** | **CLIENT:** | NOVARTIS PHARMA SERVICES INC. P.O BOX 46057 -00100-NAIROBI, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Uniformity of Content, Microbial Load, Identification, Assay | |

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Uniformity of Dosage | B.P. 2012 Vol. V App XII C | Acceptance Value of the 10 dosage units is < 15% | AV(< 15) = 13% | **COMPLIES** |
| **Microbial Load** | Plate Count Method | In - House Method | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL :Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/mL | < 200 TAMC CFU Per mL | **COMPLIES:COMPLIES** |
| **Microbial Load** | Plate Count Method | In - House Method | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL :Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/mL | < 20 TYMC CFU Per mL | **COMPLIES:COMPLIES** |
| **Identification** | HPLC:HPLC | Manufacturer's In - House Method | RT of the major peakS in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT Value | **COMPLIES** |
| **Identification** | HPLC:HPLC | Manufacturer's In - House Method | RT of the major peakS in the assay sample preparation correspond to those in the assay standard preparation | 11.7 and 12.3 Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | :HPLC | Manufacturer's In - House Method | 95.0-105.0% | Glycopyronium 97.7 (RSD= 1.8%;n = 9) | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | Manufacturer's In - House Method | 95.0-105.0% | Indacaterol 97.1 (RSD= 0.8%;n = 9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | MR. F. NAULA |  | DATE:04-17-2015 |
| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:04-17-2015 |
| ANALYST: | DR. E. MBAE |  | DATE:06-08-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:10-09-2015 |