**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | LEVOTOP 0.5% EYE DROPS | | REF. NO: NDQD201508080 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each mL contains: Levofloxacin Hemihydrate equivalent to Levofloxacin Base 5 mg. | |
| **BATCH NO.:** CA0305B | **PRESENTATION:** | Pale yellow coloured solution for ophthalmic administration, contained in a 5 mL dropper bottle in a unit box and 25 such boxes in a larger box. | |
| **MGF. DATE:** Feb. 2015 | **MANUFACTURER:** | AJANTA Pharma Ltd. | |
| **EXP. DATE:** Jan. 2017 | **ADDRESS:** | Ajanta House, Charkop, Kandivli (W), Mumbai 400 067, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Centrale Humanitaire Medico Pharmaceutique P.O. Box 10397 - 00400, Nairobi, Kenya | |
|  | **TEST(S) REQUESTED:** | Sterility, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Sterility** | Membrane Filtration | B.P. 2013 Vol. V App XVI A | No Microbial Growth | No Microbial Growth | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's In-House Method | RT of the component peaks in the assay sample preparations correspond to those in the assay standard preparations. | Super-imposable peaks at RT 4.4 (Levofloxacin) and 4.2 and 6.3 (Benzalkonium) +/- 10% min present in the assay sample and standard preparations. | **COMPLIES** |
| **Assay** | :HPLC | Manufacturer's In-House Method | 95.0 - 105.0 % : 90.0 - 110.0 % | Levofloxacin | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | Manufacturer's In-House Method | 95.0 - 105.0 % : 90.0 - 110.0 % |  | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | Manufacturer's In-House Method | 95.0 - 105.0 % : 90.0 - 110.0 % | 98.6% (RSD = 0.4%; n = 9) | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | Manufacturer's In-House Method | 95.0 - 105.0 % : 90.0 - 110.0 % | Benzalkonium | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | Manufacturer's In-House Method | 95.0 - 105.0 % : 90.0 - 110.0 % |  | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | Manufacturer's In-House Method | 95.0 - 105.0 % : 90.0 - 110.0 % | 90.9% (RSD = 1.4%; n = 9) | **COMPLIES:COMPLIES** |
| **Acidity/Alkalinity** | :pH | Manufacturer's In-House Method | 5.5 - 7.5 | 6.5 | **COMPLIES** |

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

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| ANALYST: | MR. F. NAULA |  | DATE:01-12-2015 |
| ANALYST: | DR. S. MWANGI |  | DATE:01-12-2015 |
| ANALYST: | DR. N. MWAURA |  | DATE:01-12-2015 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:12-01-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:12-03-2015 |