**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | Zaha-250 | | REF. NO: NDQD201508076 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each film coated tablet contains Azithromycin Dihydrate USP 262.02 mg equivalent to Azithromycin 250 mg. | |
| **BATCH NO.:** P04715B | **PRESENTATION:** | Off white coloured, circular shaped, biconvex faced, bevel edged tablets, plain on both faces, packed in a blister strip of 6 tablets, in a unit box and 10 such boxes in a larger box. | |
| **MGF. DATE:** Feb.2015 | **MANUFACTURER:** | AJANTA Pharma Limited. | |
| **EXP. DATE:** Jan.2017 | **ADDRESS:** | Factory B-4/5/6, MIDC rea, Paithan 431 148, Regd./Corp. Office 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:** | Uniformity of Weight, Identification, Dissolution, Assay | |

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | B.P. 2012 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | U.S.P. 38 N.F. 33 Vol. 2 Page 2348 | RT of the Component Peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT | **COMPLIES** |
| **Identification** | HPLC | U.S.P. 38 N.F. 33 Vol. 2 Page 2348 | RT of the Component Peak in the assay sample preparation corresponds to that in the assay standard preparation | 15.7 +/- 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | U.S.P. 38 N.F. 33 Vol. 2 Page 2348 | No Tablet Less than 85% [n=6] | 98.8% (RSD = 1.6% ; n = 6) | **COMPLIES** |
| **Assay** | HPLC | U.S.P. 38 N.F. 33 Vol. 2 Page 2348 | 90.0% - 110.0% | 95.2% (RSD = 1.0% ; n = 9) | **COMPLIES** |

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

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| ANALYST: | DR. K. BOTA |  | DATE:24-08-2015 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:03-09-2015 |
| ANALYST: | ERNEST MBAE |  | DATE:09-04-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:09-08-2015 |