**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/531

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| **PRODUCT** | ZINNAT TM TABLETS 250 mg | | REF. NO: NDQA201509331 |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each tablet contains 250 mg Cefuroxime as Cefuroxime Axetil. | |
| **BATCH NO.:** C668355 | **PRESENTATION:** | White coloured, caplet shaped, biconvex faced tablets, embossed 'GX ES7' on one face and plain on the other, packed in an aluminium foil blister of 10 tablets in a unit box. | |
| **MGF. DATE:** Jan. 2014 | **MANUFACTURER:** | GLAXO Operations UK Limited | |
| **EXP. DATE:**  Jan. 2017 | **ADDRESS:** | Bernard Castle UNITED KINGDOM. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 2708 | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 13.1 and 15.1 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Page 2708 | 15 min run No tablet less than 65% [n=6]:45 min run No tablet less than 80% [n=6] | 88% (RSD=5.5%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Page 2708 | 15 min run No tablet less than 65% [n=6]:45 min run No tablet less than 80% [n=6] | 97% (RSD=2.6%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2708 | 90.0 - 110.0% | 94.9% (RSD=1.2%, n=9) | **COMPLIES** |

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

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| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:09-02-2016 |
| ANALYST: | DR. M. KWENA |  | DATE:04-04-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-20-2016 |