**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/527

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| **PRODUCT** | ZINNAT(TM) SUSPENSION | | REF. NO: NDQA201509335 |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each 5 mL contains 125 mg Cefurixime as Cefuroxime Axetil. | |
| **BATCH NO.:** C687278 | **PRESENTATION:** | Off white coloured, flavored, fine granules for reconstitution into suspension for oral administration packed in a amber coloured glass bottle with a child proof lid,packed along with a 20 mL plastic measuring cap and (a 2.5 mL dispensing spoon) (confirm, was not present in the sample provided) in a unit box. | |
| **MGF. DATE:** Jun. 2014 | **MANUFACTURER:** | GLAXO Operations UK Limited. | |
| **EXP. DATE:**  Jun. 2016 | **ADDRESS:** | Bernard Castle, UNITED KINGDOM. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| CEF/09/11.03.2015/259 | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Microbial Load | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL :Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/mL | < 10 CFU/mL | **COMPLIES:COMPLIES** |
| **Microbial Load** | Microbial Load | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL :Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/mL | < 10 CFU/mL | **COMPLIES:COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 2708 | RT of the Component Peaks in the assay sample preparation corresponds to those in the assay standard preparation | Super-imposable peak at RT 14.6 and 17.0 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2708 | 90.0 - 110.0% | Day 1 | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2708 | 90.0 - 110.0% | 104.4% (RSD=0.9%; n=9) Day 7 | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2708 | 90.0 - 110.0% | 97.8% (RSD=1.4; n=9) | **COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 Page 2708 | 4.5 - 6.5 | 4.5 | **COMPLIES** |

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

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| ANALYST: | MR. F. NAULA |  | DATE:23-10-2015 |
| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:09-02-2016 |
| ANALYST: | DR. M. KWENA |  | DATE:24-03-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:04-12-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-19-2016 |