**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/505

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| **PRODUCT** | CLAXY 625 TABLETS | | REF. NO: NDQA201509354 |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each film coate tablet contains: Amoxicillin Trihydrate USP Equivalent to Amoxicillin 500 mg, Diluted Potassium Clavulanate BP Equivalent to Clavulanic Acid 125 mg, Excipients q.s. | |
| **BATCH NO.:** EBT140047 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets,single scored on one face and plain on the other, packed in an aluminium blister strip of 10 tablets in a unit box. | |
| **MGF. DATE:** Aug. 2014 | **MANUFACTURER:** | THEON Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Jul. 2016 | **ADDRESS:** | Vill. Saini Majra, Tehsil Nalagarh, Distt. Solan (H.P.) 174 101, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| AMOXCLAV/02/13/2015/00246 | **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 2227 | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT; 3.9 & 5.7 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 2227 | No tablet less than 90%[n=6] No tablet less than 85% [n=6] | Amoxicillin; 98.0% (RSD=3.2%; n=5) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 2227 | No tablet less than 90%[n=6] No tablet less than 85% [n=6] | Clavulanic Acid; 95.0% (RSD=2.4%; n=5) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2227 | 90.0 - 120.0% | Amoxicillin; 108.9% (RSD=1.8%; n=7) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2227 | 90.0 - 120.0% | Clavulanic Acid; 101.2% (RSD=1.9%; n=6) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. E. MUTUA |  | DATE:22-03-2016 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:22-03-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:03-24-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-13-2016 |