**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/848

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| **PRODUCT** | CLAXY 625 TABLETS | | REF. NO: NDQA201509356 |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Amoxicillin Trihydrate USP equivalent to Amoxicillin 500 mg and Diluted Potassium Clavulanate BP equivalent to Clavulanic acid 125 mg. | |
| **BATCH NO.:** EBT140050 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, single scored on one face and plain on the other, packed in an aluminium foil blister strip of 10 tablets in a unit box. | |
| **MGF. DATE:** 01.Aug.2014 | **MANUFACTURER:** | THEON Pharmaceuticals Ltd. | |
| **EXP. DATE:**  31. 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 | |
| AMOCLAV/05/12.03.2015/00117 | **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 standard preparation | Super-imposable peaks at RT 3.5 and RT 5.2 -/+ 10% min present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 2227 | Average 85% No tablet less than 70.0% [n=12]:Clavulanic Acid No tablet less than 85% [n=6] | Average 93% Range | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 2227 | Average 85% No tablet less than 70.0% [n=12]:Clavulanic Acid No tablet less than 85% [n=6] | 70% - 101% (RSD=11.4%, n=12) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 2227 | Average 85% No tablet less than 70.0% [n=12]:Clavulanic Acid No tablet less than 85% [n=6] | Average 93% Range | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 2227 | Average 85% No tablet less than 70.0% [n=12]:Clavulanic Acid No tablet less than 85% [n=6] | 87% - 97% (RSD=4.0%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2227 | 90.0 - 120.0% | Amoxicillin 105.3% (RSD=0.7%, n=9) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2227 | 90.0 - 120.0% | Clavulanic acid 104.4% (RSD=0.4%, n=9) | **COMPLIES** |

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

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| ANALYST: | DR. E. MUTUA |  | DATE:30-05-2016 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:15-06-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:07-04-2016 |
| DIRECTOR: |  |  | DATE:07-20-2016 |