**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/851

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| **PRODUCT** | BACTOCLAV-375 TABLETS | | **REF. NO: NDQD201509363** |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Amoxicillin Trihydrate BP Equivalent to Amoxicillin 250 mg and Potassium ClavulanateBP (as Potassium Clavulanate Diluted BP) Equivalent to Clavulanic acid 125 mg. | |
| **BATCH NO.:** BAABV0002 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, single scored on one face and embossed 'AC' on the other, packed in an aluminium foil strip of 10 tablets, 2 such strips in a unit box. | |
| **MGF. DATE:** Mar. 2014 | **MANUFACTURER:** | MICRO Labs Limited. | |
| **EXP. DATE:**  Feb. 2016 | **ADDRESS:** | Plot No. 16, Veerasandra Industrial Area, Anekal Taluk, Bangalore Ã¢â‚¬â€œ 560 100, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| AMOCLAV/08/10/03/2015/00080 | **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 3.8 and 7.4 -/+ 10% min present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 2227 | S2 | Amoxicillin 92.1% (RSD=8.9%, n=12) | **COMPLIES** |
| **Dissolution** |  |  | Average 85% No tablet less than 70.0% [n=12] | Clavulanic acid 95.4% (RSD=7.3%, n=12) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2227 | 90.0 - 120.0% | Amoxicillin 97.6% (RSD=2.0%, n=5) | **COMPLIES** |
| **Assay** |  |  |  | Clavulanic acid 115.0% (RSD=1.7%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | DR. E. MUTUA | .......................................................... | DATE: 5-06-2016 |
| **ANALYST:** | DR. G. WANGANGA | .......................................................... | DATE: 16-06-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 07-04-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 07-20-2016 |