**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | MYCLAV POWDER FOR ORAL SUSPENSION 228.5 mg /5 mL | | REF. NO: NDQD201501039 |
| **DATE RECEIVED:** 20.01.2015 | **LABEL CLAIM:** | Each 5 mL after reconstitution contains Amoxicillin Trihydrate USP equivalent to Amoxicillin 200 mg, Potassium Clavulanate diluted Ph. Eur. equivalent to Clavulanic Acid 28.5 mg. | |
| **BATCH NO.:** BMPM14001 | **PRESENTATION:** | Off white coloured, free flowing powder for reconstitution into suspension for oral administration, contained in a 100 mL clear glass bottle, packed along with 10 mL translucent graduated measuring cup in a unit box. | |
| **MGF. DATE:** Jul. 2014 | **MANUFACTURER:** | UNICHEM Laboratories Ltd. | |
| **EXP. DATE:** Jun. 2016 | **ADDRESS:** | Village Bhatauli Kalan, Baddi,Dist. Solan (H.P.) - 173 205, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Europa Healthcare Limited P.O. Box 6654 - 00800, Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Plate Count | B.P. 2012 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL Total Combined Yeasts/ Moulds Count (TYMC) NMT 20 CFU/mL | TAMC < 200 CFU/mL TYMC < 20 CFU/mL | **COMPLIES** |
| **Identification** | HPLC | U.S.P. 38 N.F. 33 Vol. 2 Page 2226 | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 3.6 and 5.6 +/- 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | U.S.P. 38 N.F. 33 Vol. 2 Page 2226 | Freshly Reconstituted; Amoxicillin 90.0 - 120.0%: Freshly Reconstituted; Clavulanate 90.0 - 125.0%:7 Days After Reconstitution; Amoxicillin 90.0 - 120.0%:7 Days After Reconstitution; Clavulanate 90.0 - 125.0% | 97.0%, (n=9; RSD=1.3%), | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | U.S.P. 38 N.F. 33 Vol. 2 Page 2226 | Freshly Reconstituted; Amoxicillin 90.0 - 120.0%: Freshly Reconstituted; Clavulanate 90.0 - 125.0%:7 Days After Reconstitution; Amoxicillin 90.0 - 120.0%:7 Days After Reconstitution; Clavulanate 90.0 - 125.0% | 103.9% (n=6; RSD=1.8%), | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | U.S.P. 38 N.F. 33 Vol. 2 Page 2226 | Freshly Reconstituted; Amoxicillin 90.0 - 120.0%: Freshly Reconstituted; Clavulanate 90.0 - 125.0%:7 Days After Reconstitution; Amoxicillin 90.0 - 120.0%:7 Days After Reconstitution; Clavulanate 90.0 - 125.0% | 99.4% (n=6; RSD=1.1%) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | U.S.P. 38 N.F. 33 Vol. 2 Page 2226 | Freshly Reconstituted; Amoxicillin 90.0 - 120.0%: Freshly Reconstituted; Clavulanate 90.0 - 125.0%:7 Days After Reconstitution; Amoxicillin 90.0 - 120.0%:7 Days After Reconstitution; Clavulanate 90.0 - 125.0% | 95.9% (n=9; RSD=0.2%) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Acidity/Alkalinity** | pH | U.S.P. 38 N.F. 33 Vol. 2 Page 2226 | 3.8 - 6.6 | 5.0 | **COMPLIES** |

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

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| ANALYST: | DR . E. TANUI |  | DATE:06-26-2015 |
| ANALYST: | DR. L. KARANJA |  | DATE:16-10-2015 |
| REVIEWER: | DR. R. MANANI |  | DATE:28-10-2015 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:11-03-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:11-06-2015 |