**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | 0 | | REF. NO: NDQD201501038 |
| **DATE RECEIVED:** 20.01.2015 | **LABEL CLAIM:** | Each 5 mL after reconstitution contains:Amoxicillin Trihydrate USP equivalent to Amoxicillin 125 mg potassium Clabvulanate diluted Ph. Eur. equivalent to Clavulanic Acid 31.25 mg. | |
| **BATCH NO.:** BMPL14001 | **PRESENTATION:** | Off white granulated powder for reconstitution into suspension for oral administration, contained in a 100 mL clear glass bottle, packed along with a 10 mL 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.)-173205 INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Europa Healthcare Limited P.O. Box 6654 - 00800, Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | pH, Microbial Load, Identification, Assay | |

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **pH** | pH | USP 38 NF 33 Vol 2 Page 2226 | 3.8 - 6.6 | 4.5 | **COMPLIES** |
| **Microbial Load** | Plate Count | In House Method | Total Aerobic Microbial Counts (TAMC) NMT 200 CFU/mL :Total Combined Yeast/Moulds Counts( TYMC) NMT 20 CFU/mL | TAMC < 200 CFU per mL | **COMPLIES:COMPLIES** |
| **Microbial Load** | Plate Count | In House Method | Total Aerobic Microbial Counts (TAMC) NMT 200 CFU/mL :Total Combined Yeast/Moulds Counts( TYMC) NMT 20 CFU/mL | TYMC < 20 CFU per mL | **COMPLIES:COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Vol 2 Page 2226 | RT of the Component Peaks in the assay sample preparation correspond to those in the assay standard preparation |  | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 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 5.7 Ã‚Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 Vol 2 Page 2226 | Clavulanate 90%-125%:Amoxicillin 90%-120% | Amoxicillin Day 1 101.1% RSD=1.6%,n=6 | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 Vol 2 Page 2226 | Clavulanate 90%-125%:Amoxicillin 90%-120% | Clavulanic Acid Day 1 113.2% RSD=0.3%,n=9 | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 Vol 2 Page 2226 | Clavulanate 90%-125%:Amoxicillin 90%-120% | Amoxicillin Day 7 92.2% RSD=1.9%,n=6 | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 Vol 2 Page 2226 | Clavulanate 90%-125%:Amoxicillin 90%-120% | Clavulanic Acid Day 7 103.3% RSD=0.2%,n=9) | **COMPLIES:COMPLIES:COMPLIES:COMPLIES** |

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

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| ANALYST: | MR. F. LAULA |  | DATE:01-09-2015 |
| ANALYST: | DR. L. WANGARI |  | DATE:01-09-2015 |
| ANALYST: | DR. E. MBAE |  | DATE:23-09-2015 |
| ANALYST: | SERAH MUTERU |  | DATE:10-05-2015 |
| DIRECTOR: |  |  | DATE:10-07-2015 |