**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/182

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| **PRODUCT** | CLAMOXIN(TM) 312.5 ORAL SUSPENSION | | **REF. NO: NDQD201510434** |
| **DATE RECEIVED:** 13-10-2015 | **LABEL CLAIM:** | Each 5 mL of reconstituted suspension contains: Amoxicillin Trihydrate BP equivalent to Amoxicillin 250 mg and Diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 62.5 mg. | |
| **BATCH NO.:** 14CADS70510 | **PRESENTATION:** | Off white coloured, free flowing, powder for reconstitution into oral suspension contained in a 100 mL translucent plastic bottle and packed along with a 15 mL graduated clear plastic measuring cap in a printed box. | |
| **MFG. DATE:** Oct. 2014 | **MANUFACTURER:** | MEDOPHARM Pvt. Ltd. | |
| **EXP. DATE:**  Sep. 2016 | **ADDRESS:** | No. 50, Kayarambedu Village, Guduvanchery - 603 202, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pan Pharmaceuticals Ltd, House of Vanguard, Fuji Plaza, Chiromo Road, Westlands. P. O. Box 47393 - 00100, Nairobi, KENYA. | |
| - | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Microbial Load | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Counts (TAMC) NMT 200 CFU/g Total Combined Yeast/Moulds Counts (TYMC) NMT 20 CFU/g | < 10 CFU/g | **COMPLIES** |
| **Microbial Load** |  |  |  | < 10 CFU/mL | **COMPLIES** |
| **Identification** | HPLC | USP 38 - NF 33 page 2226 | RT of the Major Peaks in the assay sample preparation corresponds to those in the assay standard preparation | Super-imposable peak at RT 3.8 & 5.9 -/+ 10% min present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 - NF 33 2015 VOL 2 PAGE 2227 | 3.8 - 6.6 | 4.8 | **COMPLIES** |
| **Assay** | HPLC | USP 38 - NF 33 2015 VOL 2 PAGE 2227 | 90.0 - 120.0% | Amoxicillin Day 1 98.5% (RSD =2.0%; n=6) Day 7 102.1% (RSD =1.5%; n=6) | **COMPLIES** |
| **Assay** |  |  | 90.0 - 125.0% | Clavulanic Acid Day 1 94.1% (RSD=1.7%; n=9) Day 7 90.9% (RSD=0.8%; n=9) | **COMPLIES** |

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

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| **ANALYST:** | FRANCIS NAULA | .......................................................... | DATE: 10-14-2015 |
| **ANALYST:** | ERIC MUTUA | .......................................................... | DATE: 12-21-2015 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 04-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-05-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-13-2016 |