**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/627

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| **PRODUCT** | CO-CORITHERÃ‚Â® DRY SYRUP | | REF. NO: NDQA201511461 |
| **DATE RECEIVED:** 02.11.2015 | **LABEL CLAIM:** | Each 60 mL suspension (after reconstitution) contains: Artemether 180 mg, Lumefantrine 1080 mg & Excipients q.s. | |
| **BATCH NO.:** UCU1401 | **PRESENTATION:** | Yellow granules for reconstitution into suspension for oral administration, contained in a 60 mL transluscent plastic bottle, packed along with 10 mL transparent plastic measuring cap in a unit box. | |
| **MGF. DATE:** Feb. 2014 | **MANUFACTURER:** | CORAL Laboratories Ltd. | |
| **EXP. DATE:**  Jan. 2016 | **ADDRESS:** | Plot No.27/28, Pharmacity, Selaqui, Dehradun, Uttarakhand-248 197, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| KEN/AL/KSI/09/09/2014/50 | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Plate Count | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) 102 CFU/mL Total Combined Yeasts /Moulds Count (TYMC) 101 CFU/mL | TAMC | **COMPLIES** |
| **Microbial Load** | Plate Count | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) 102 CFU/mL Total Combined Yeasts /Moulds Count (TYMC) 101 CFU/mL | < 10 CFU Per mL TYMC | **COMPLIES** |
| **Microbial Load** | Plate Count | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) 102 CFU/mL Total Combined Yeasts /Moulds Count (TYMC) 101 CFU/mL | < 10 CFU Per mL | **COMPLIES** |
| **Identification** | HPLC/UV | Adopted In-house Method | RT of the component Peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peak at RT 5.50 -/+ 10% min for artemether present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC/UV | Adopted In-house Method | 90.0 - 110.0% | Artemether 73.8% (RSD=\*\*%; n=9) Lumefantrine 101.1% (RSD=1.8%; n=9) |  |
| **Acidity/Alkalinity** | pH | Adopted In-house Method | 3.0 - 5.0 | 4.2 | **COMPLIES** |

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

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| ANALYST: | MR. F. NAULA |  | DATE:21-12-2015 |
| ANALYST: | DR. E. MUTUA |  | DATE:21-12-2015 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:21-12-2015 |
| ANALYST: | ERNEST MBAE |  | DATE:12-23-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-10-2016 |