**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**  CAN/2016-17/XYZ

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| **PRODUCT** | CO-CORITHERÂ® DRY SYRUP | | REF. NO: NDQA201511463 |
| **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, Phamacity, Selaqui, Dehradun, Uttarakhand - 248 197, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| KEN/MIG/AL/09/09/2014/054 | **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) <= 200 CFU/mL Total Combined Yeasts /Moulds Count (TYMC) < 20 CFU/mL | < 10 TAMC CFU Per mL < 10 TYMC CFU Per mL | **COMPLIES** |
| **Identification** | HPLC | Adopted In-house Method | RT of the component Peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 5.4 & 5.6 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | Adopted In-house Method | 90.0 - 110.0% | Artemether 102.1% (RSD = 1.8%; n = 6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Adopted In-house Method | 90.0 - 110.0% | Lumefantrine 97.8% (RSD = 1.6%; n = 7) | **COMPLIES:COMPLIES** |
| **Acidity/Alkalinity** | pH | Adopted In-house Method | 3.0 - 5.0 | 3.4 | **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:01-15-2016 |