**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/673

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| **PRODUCT** | COSATRIM R SUSPENSION | | REF. NO: NDQB201604871 |
| **DATE RECEIVED:** 26.04.2016 | **LABEL CLAIM:** | Each 5 mL contains: Sulphamethoxazole BP 200 mg and Trimethoprim BP 40 mg. | |
| **BATCH NO.:** 60307 | **PRESENTATION:** | Pink coloured, viscous suspension for oral administration, contained in a 100 mL amber coloured plastic bottle, packed along with a 15 mL graduated plastic measuring cap in a unit box. | |
| **MGF. DATE:** Feb. 2016 | **MANUFACTURER:** | COSMOS Limited. | |
| **EXP. DATE:**  Jan. 2019 | **ADDRESS:** | Rangwe Rd; Off Lunga Lunga Rd, P.O. Box 41433 - 00100, Nairobi, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P.O. Box 47715 - 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** | Plate Count | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL:Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/mL | < 10 CFU / mL | **COMPLIES:COMPLIES** |
| **Microbial Load** | Plate Count | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL:Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/mL | < 10 CFU / mL | **COMPLIES:COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 5397 | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 5.2 and 9.6 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5397 | 90.0 - 110.0% | Sulphamethoxazole 96.9% (RSD=0.3%, n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5397 | 90.0 - 110.0% | Trimethoprim 97.3% (RSD=0.4%, n=6) | **COMPLIES:COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 Page 5397 | 5.0 - 6.5 | 5.80 | **COMPLIES** |

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

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| ANALYST: | MR. F. NAULA |  | DATE:10-05-2016 |
| ANALYST: | DR. S. MWANGI |  | DATE:12-05-2016 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:18-05-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:05-26-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:06-07-2016 |