**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/472

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| **PRODUCT** | COSATRIM SUSPENSION | | REF. NO: NDQB201602768 |
| **DATE RECEIVED:** 23.02.2016 | **LABEL CLAIM:** | Each 5 mL contains: Sulphamethoxazole BP 200 mg and Trimethoprim BP 40 mg. | |
| **BATCH NO.:** 60301 | **PRESENTATION:** | Pink coloured, viscous suspension for oral administration, contained in a 100 mL amber coloured plastic bottle, packed along with a 10 mL graduated plastic measuring cap. | |
| **MGF. DATE:** Feb. 2016 | **MANUFACTURER:** | COSMOS Limited. | |
| **EXP. DATE:**  Jan. 2019 | **ADDRESS:** | Rangwe Rd; Off Lunga Lunga Road, 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** | Microbial Load | 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 TAMC CFU / mL | **COMPLIES:COMPLIES** |
| **Microbial Load** | Microbial Load | 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 TAMC CFU / mL | **COMPLIES:COMPLIES** |
| **Identification** | HPLC | Adopted 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 4.4 and 7.4 -/+ 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 98.6% (RSD=1.6%, n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5397 | 90.0 - 110.0% | Trimethoprim 101.5% (RSD=1.6%, n=9) | **COMPLIES:COMPLIES** |
| **Acidity/Alkalinity** | pH | BP 2016 Vol .V App XII C | 5.0 - 6.5 | 5.4 | **COMPLIES** |

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

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| ANALYST: | MR. F. NAULA |  | DATE:09-03-2016 |
| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:22-03-2016 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:01-04-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:04-06-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-06-2016 |