**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/190

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| **PRODUCT** | DAPSONE TABLETS BP 100 mg | | **REF. NO: NDQB201608080** |
| **DATE RECEIVED:** 23-08-2016 | **LABEL CLAIM:** | Each tablet contains: Dapsone BP 100 mg. | |
| **BATCH NO.:** 60899 | **PRESENTATION:** | White coloured, circular shaped, biconvex faced tablets, embossed 'COSMOS' on one face and single scored on the other, packed in a blister pack of 10 tablets and 10 such strips in a printed box. | |
| **MFG. DATE:** Aug. 2016 | **MANUFACTURER:** | COSMOS Limited. | |
| **EXP. DATE:**  Jul. 2018 | **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:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App. XII C | NMT 2 tablets deviate by more than 7.5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 page 3003 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 8.8 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 page 3003 | No Tablet Less Than 80.0% | Average = 90% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 88 - 94% (RSD = 2.3% ; n = 6) |  |
| **Assay** | HPLC | USP 38 NF 33 page 3003 | 92.5%-107.5% | 98.0% (RSD = 0.6% ; n = 6) | **COMPLIES** |

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

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| **ANALYST** | MR. KENNEDY RUTTO | .......................................................... | DATE: 05-10-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 13-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-14-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-18-2016 |