**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/423

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| **PRODUCT** | DAPSONE TABLETS BP 100 mg | | REF. NO: NDQB201601717 |
| **DATE RECEIVED:** 26.01.2016 | **LABEL CLAIM:** | Each tablet contains: Dapsone BP 100 mg. | |
| **BATCH NO.:** 51520 | **PRESENTATION:** | Off white coloured, circular shaped, biconvex faced tablet,single scored on one face and embossed 'COSMOS'on the opposite, unscored face, packed in a blister strip of 10 tablets and 10 such strips in a unit box. | |
| **MGF. DATE:** Oct 2015 | **MANUFACTURER:** | COSMOS Limited. | |
| **EXP. DATE:**  Sep 2017 | **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:** | 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 major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 9.4 -/+ 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% [n=6] | 98.4% (RSD=4.1%; n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 3003 | 92.5 - 107.5% | 99.1% (RSD=0.3%; n=9) | **COMPLIES** |

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

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| ANALYST: | DR. E. MUTUA |  | DATE:16-02-2016 |
| ANALYST: | DR. E. TANUI |  | DATE:02-03-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:03-03-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-07-2016 |