**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/618

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| **PRODUCT** | FANLAR TABLETS | | REF. NO: NDQA201511492 |
| **DATE RECEIVED:** 02.11.2015 | **LABEL CLAIM:** | Each tablet contains; Sulfadoxine BP 500 mg, Pyrimethamine BP 25 mg. | |
| **BATCH NO.:** 1405142 | **PRESENTATION:** | Off white coloured, circular shaped, flat faced bevel edged tablets, single scored on one face and plain on the other, packed in an aluminium foil strip of 3 tablets and 25 such strips, packed in a unit box. | |
| **MGF. DATE:** May 2014 | **MANUFACTURER:** | DAWA Limited. | |
| **EXP. DATE:**  Apr.2019 | **ADDRESS:** | Plot No.7879/8, Baba Dogo Road, Ruaraka, P.O BOX 16633-00620, Nairobi, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 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 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 5390 | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peak at RT 9.1 & 11.8 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 5390 | No Tablet Less than 65% [n=6] | Pyrimethamine 100.8% (RSD=2.5%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 5390 | No Tablet Less than 65% [n=6] | Sulfadoxine 97.7% (RSD=2.4%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5390 | 90.0 - 110.0 % | Pyrimethamine 99.2% (RSD=1.4%; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5390 | 90.0 - 110.0 % | Sulfadoxine 97.8% (RSD=1.3%; n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | MR. M. SANGALE |  | DATE:11-04-2016 |
| ANALYST: | DR. S. MWANGI |  | DATE:11-04-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:04-26-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-10-2016 |