**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | MALAFIL TABLETS | | REF. NO: NDQD201508234 |
| **DATE RECEIVED:** 24.08.2015 | **LABEL CLAIM:** | Each uncoated tablet contains: Sulfadoxine USP 500 mg and Pyrimethamine USP 25 mg. | |
| **BATCH NO.:** A1302 | **PRESENTATION:** | White coloured, circular shaped, flat faced, bevel edged tablets, single scored on one face and plain on the other, packed in an aluminium foil blister strip of 3 tablets in a foldable envelop pack with 50 such packs in a unit box. | |
| **MGF. DATE:** Aug. 2013 | **MANUFACTURER:** | FOURRTS (India) Laboratories Pvt.limited. | |
| **EXP. DATE:** Jul. 2016 | **ADDRESS:** | Vandalur Road, Kelambakkam-603 103, Tamil Nadu, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy Board Of Sierra Leone New England Ville, Central Medical Stores, Free Town | |
|  | **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 2012 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Vol.3 Page 5390 | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 7.3 and 9.4 +/- 10% min. present in both assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | No tablet less than 65.0% [n=6] | Pyrimethamine | **COMPLIES:COMPLIES** |
| **Dissolution** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | No tablet less than 65.0% [n=6] |  | **COMPLIES:COMPLIES** |
| **Dissolution** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | No tablet less than 65.0% [n=6] | 84.4% (RSD = 2.9%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | No tablet less than 65.0% [n=6] |  | **COMPLIES:COMPLIES** |
| **Dissolution** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | No tablet less than 65.0% [n=6] | Sulphadoxine | **COMPLIES:COMPLIES** |
| **Dissolution** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | No tablet less than 65.0% [n=6] |  | **COMPLIES:COMPLIES** |
| **Dissolution** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | No tablet less than 65.0% [n=6] | 82.7% (RSD = 4.9%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | 90.0 - 110.0% | Pyrimethamine | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | 90.0 - 110.0% |  | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | 90.0 - 110.0% | 96.0% (RSD = 1.7%; n=7) | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | 90.0 - 110.0% | Sulphadoxine | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | 90.0 - 110.0% | 93.4%, (RSD = 1.8%; n=6) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. L. KARANJA |  | DATE:27-11-2015 |
| REVIEWER: | DR. S. MUTERU |  | DATE:27-11-2015 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:11-27-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:12-03-2015 |