**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | SULFADOXINE & PYRIMETHAMINE TABLETS USP | | REF. NO: NDQD201508239 |
| **DATE RECEIVED:** 24.08.2015 | **LABEL CLAIM:** | Each tablet contains: Sulfadoxine USP 500 mg, Pyrimethamine USP 25 mg. | |
| **BATCH NO.:** SPUH0037 | **PRESENTATION:** | White coloured, circular shaped, flat faced, bevel edged tablets, double scored on one face and plain on the other, packed in a white plastic multidose container carrying 100 tablets. | |
| **MGF. DATE:** Jun. 2012 | **MANUFACTURER:** | MICRO Labs Limited. | |
| **EXP. DATE:** 14. Jun. 2016 | **ADDRESS:** | 92,Sipcot, Hosur-635 126, 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 preparation | **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 |  | **COMPLIES** |
| **Dissolution** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | No tablet less than 65% [n=6] | Pyrimethamine | **COMPLIES:COMPLIES** |
| **Dissolution** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | No tablet less than 65% [n=6] |  | **COMPLIES:COMPLIES** |
| **Dissolution** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | No tablet less than 65% [n=6] | 88.5%, (RSD = 2.7%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | No tablet less than 65% [n=6] | Sulfadoxine | **COMPLIES:COMPLIES** |
| **Dissolution** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | No tablet less than 65% [n=6] |  | **COMPLIES:COMPLIES** |
| **Dissolution** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | No tablet less than 65% [n=6] | 87.0%, (RSD = 3.3%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | 90.0 -110 % | Pyrimethamine | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | 90.0 -110 % |  | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | 90.0 -110 % | 101.3%, (RSD = 1.5%; n=7) | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | 90.0 -110 % | Sulfadoxine | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | 90.0 -110 % |  | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | USP 38 NF 33 Vol.3 Page 5390 | 90.0 -110 % | 91.7% (RSD = 1.9%; n=7) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. L. KARANJA |  | DATE:24-11-2015 |
| ANALYST: | DR. S. MUTERU |  | DATE:24-11-2015 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:11-24-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:12-03-2015 |