**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | SULFADOXINE & PYRIMETHAMINE TABLETS USP | | REF. NO: NDQD201508238 |
| **DATE RECEIVED:** 24.08.2015 | **LABEL CLAIM:** | Each tablet contains: Sulfadoxine USP 500 mg and Pyrimethamine USP 25 mg. | |
| **BATCH NO.:**  SPUH045 | **PRESENTATION:** | White coloured, circular shaped, flat faced tablets, double scored on one face and plain on the other, packed in a white plastic multi-dose container carrying 100 tablets. | |
| **MGF. DATE:** Jun. 2013 | **MANUFACTURER:** | MICRO Labs Limited. | |
| **EXP. DATE:**  Jun. 2017 | **ADDRESS:** | 92, Sipcot, Hosur-635 126, Tamil Nadu, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy Board Of Sierra Leone, Central Medical Stores, Free Town, SIERRA LEONE | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 7.8 and 9.5 +/- 10% min. present in both the assay sample and standard preparations | **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] | 89.6%, (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] | 86.5%, (RSD = 3.0%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 Vol.3 Page 5390 | 90.0 - 110.0% | Pyrimethamine | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 Vol.3 Page 5390 | 90.0 - 110.0% |  | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 Vol.3 Page 5390 | 90.0 - 110.0% | 94.1%, (RSD = 1.6%; n=7) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 Vol.3 Page 5390 | 90.0 - 110.0% | Sulfadoxine | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 Vol.3 Page 5390 | 90.0 - 110.0% |  | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | USP 38 NF 33 Vol.3 Page 5390 | 90.0 - 110.0% | 94.7%, (RSD = 1.8%; n=6) | **COMPLIES:COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | DR. L. KARANJA |  | DATE:28-11-2015 |
| ANALYST: | DR. S. MUTERU |  | DATE:28-11-2015 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:11-30-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:12-03-2015 |