**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | FANSIDAR 500/25 mg TABLETS | | REF. NO: NDQD201508236 |
| **DATE RECEIVED:** 24.08.2015 | **LABEL CLAIM:** | Each tablet contains 500 mg Sulfadoxine(USP)and 25 mg Pyrimethamine (USP). | |
| **BATCH NO.:** P02720 | **PRESENTATION:** | White coloured, circular shaped, flat faced, bevel edged tablets, double scored on one face and plain on the other, packed in blister strips of 10 tablets and 15 such strips in a unit box. | |
| **MGF. DATE:** Aug. 2013 | **MANUFACTURER:** | MARTIN Dow Pharmaceuticals(Pakistan)Limited. | |
| **EXP. DATE:** Aug. 2018 | **ADDRESS:** | Plot 37, Sector 19,Korangi Industrial Area, Karachi, PAKISTAN. | |
| **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 2015 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 2015 Vol.3 Page 5390 | No tablet less than 65.0% [n=6] | Pyrimethamine | **COMPLIES:COMPLIES** |
| **Dissolution** | :HPLC | USP 38 NF 33 2015 Vol.3 Page 5390 | No tablet less than 65.0% [n=6] |  | **COMPLIES:COMPLIES** |
| **Dissolution** | :HPLC | USP 38 NF 33 2015 Vol.3 Page 5390 | No tablet less than 65.0% [n=6] | 89.5% (RSD = 6.3%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | :HPLC | USP 38 NF 33 2015 Vol.3 Page 5390 | No tablet less than 65.0% [n=6] | Sulfadoxine | **COMPLIES:COMPLIES** |
| **Dissolution** | :HPLC | USP 38 NF 33 2015 Vol.3 Page 5390 | No tablet less than 65.0% [n=6] |  | **COMPLIES:COMPLIES** |
| **Dissolution** | :HPLC | USP 38 NF 33 2015 Vol.3 Page 5390 | No tablet less than 65.0% [n=6] | 85.9% (RSD = 7.0%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | USP 38 NF 33 2015 Vol.3 Page 5390 | 90.0 - 110.0% | Pyrimethamine | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | USP 38 NF 33 2015 Vol.3 Page 5390 | 90.0 - 110.0% |  | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | USP 38 NF 33 2015 Vol.3 Page 5390 | 90.0 - 110.0% | 98.2% (RSD = 1.5%; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | USP 38 NF 33 2015 Vol.3 Page 5390 | 90.0 - 110.0% | Sulfadoxine | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | USP 38 NF 33 2015 Vol.3 Page 5390 | 90.0 - 110.0% |  | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | USP 38 NF 33 2015 Vol.3 Page 5390 | 90.0 - 110.0% | 94.5% (RSD = 1.8%; n=9) | **COMPLIES:COMPLIES** |

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

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|  |  |  | DATE: |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:12-03-2015 |