**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | PALUDOXIN TABLETS | | **REF. NO: NDQ201508232** |
| **DATE RECEIVED:** 24.08.2015 | **LABEL CLAIM:** | Each tablets contains: Sulfadoxine BP 500 mg, Pyrimethamine BP 25 mg, Excipient q.s. | |
| **BATCH NO.:** PAL 004 | **PRESENTATION:** | White coloured, circular shaped, flat faced tablets, single scored on one face and plain on the other, packed in an aluminium blister pack in a foldable envelope and 50 such envelopes in a box. | |
| **MFG. DATE:** Aug. 2014 | **MANUFACTURER:** | BLISS GVS Pharma Ltd. | |
| **EXP. DATE:**  Jul. 2017 | **ADDRESS:** | 10, Dewan Udyog Nagar , Aliyali Palghar, Maharashtra-401404 INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy Board Of Sierra Leone, Central Medical Stores, Free Town, SIERRA LEONE | |
|  | **TEST(S) REQUESTED:** | Uniformity of Content, Identification, Dissolution, Assay | |

**RESULTS**

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| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Content** | kukkuktest | 555 | 0 | 0 | **0** |
| **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 7.4 and 9.4 +/- 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Vol.3 Page 5390 | No tablet less than 65.0% [n=6] | Pyrimethamine 89.8%, (RSD = 7.5%; n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Pyrimethamine 89.8%, (RSD = 7.5%; n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Vol.3 Page 5390 | 90.0 - 110.0% | Pyrimethamine 95.9% (RSD = 1.5%; n=9) | **COMPLIES** |
| **Assay** |  |  |  | Sulfadoxine 98.6%, (RSD = 1.8%; n=9) |  |

**CONCLUSION:**

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| **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 |