**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/315

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| **PRODUCT** | CHLORAMPHENICOL CAPSULES BP 250 mg | | **REF. NO: NDQD2016061178** |
| **DATE RECEIVED:** 16-06-2016 | **LABEL CLAIM:** | Each capsule contains: Chloramphenicol BP 250 mg. | |
| **BATCH NO.:** 150005 | **PRESENTATION:** | Hard gelatin capsule with white coloured cap imprinted 'Shelys' and a white coloured body imprinted 'CPL 250' filled with a pale yellow powder, 1000 such capsules packed in a clear polythene bag in a white plastic multidose container. | |
| **MFG. DATE:** Feb. 2015 | **MANUFACTURER:** | SHELYS Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Jan. 2018 | **ADDRESS:** | Plot No. 696, New Bagamayo Road, Mwenge, P.O. Box 3016, Dar Es Salaam, TANZANIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Beta Healthcare International Ltd, P. O. Box 42569-00100, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPENDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | Not More Than 2 capsule content weights deviate by more than 7.5% from mean capsule content weight and none deviates by more than 15% | Four Deviate (-17.2%, -8.6%, -7.9%,+7.6%) | **DOES NOT COMPLY** |
| **Identification** | HPLC | USP 38 NF 33 Page 2743 | Retention time of the major peak in the assay sample preparation corresponds to that in the assay standard preparation. | Super-imposable peak at RT 3.7 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Page 2743 | No capsule less than 90% | Average | **COMPLIES** |
| **Dissolution** |  |  |  | 96% (Range |  |
| **Dissolution** |  |  |  | 92 - 99%) (RSD=2.4%; n=6) |  |
| **Assay** | HPLC | USP 38 NF 33 Page 2743 | 90.0 - 120.0% | 92.6% (RSD=1.0%; n=9) | **COMPLIES** |

**CONCLUSION:** The product fails to comply with the specifications for the uniformity of weight.

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| **ANALYST:** | SARAH MWANGI | .......................................................... | DATE: 06-27-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-11-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 12-02-2016 |