**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/306

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| **PRODUCT** | PARACETAMOL TABLETS | | **REF. NO: NDQD201609095** |
| **DATE RECEIVED:** 08-09-2016 | **LABEL CLAIM:** | Each tablet contains: Paracetamol BP 500 mg. | |
| **BATCH NO.:** 6F28 | **PRESENTATION:** | Off white coloured, circular shaped, flat faced, bevel edged tablets, single scored and embossed â€˜PARAâ€™ and '500' on alternate sides of the score on one face and plain on the other, 1000 tablets packed in a white plastic multidose container. | |
| **MFG. DATE:** Jun. 2016 | **MANUFACTURER:** | ELYS Chemical Industries Ltd. | |
| **EXP. DATE:**  May 2020 | **ADDRESS:** | Road B, Off Enterprise Road, P. O. Box 40411 - 00100, Nairobi, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | Elys Cemical Industries Ltd. P. O. Box 40411 - 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 | NMT 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 page 2009 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 5.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 page 2009 | No Tablet Less Than 85% | Average | **COMPLIES** |
| **Dissolution** |  |  |  | 89% (Range |  |
| **Dissolution** |  |  |  | 86 - 92%) (RSD = 2.0%; n = 6) |  |
| **Assay** | HPLC | USP 38 NF 33 page 2009 | 90.0 - 110.0% | 104.1% (RSD = 0.7%; n = 9) | **COMPLIES** |

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

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| **ANALYST:** | LORNA WANGARI | .......................................................... | DATE: 10-03-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 01-11-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 11-01-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-29-2016 |