**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/282

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| **PRODUCT** | ELAXIC P TABLETS | | **REF. NO: NDQD201510452** |
| **DATE RECEIVED:** 22-10-2015 | **LABEL CLAIM:** | Each film coated tablet contains: Aceclofenac BP 100 mg and Paracetamol BP 500 mg. | |
| **BATCH NO.:** DAAI1501 | **PRESENTATION:** | Orange coloured, biconvex faced, caplet shaped tablets, single scored on one face and plain on the other packed in aluminium blister strips of 10 tablets in a printed box carrying 3 such packs. | |
| **MFG. DATE:** Feb. 2015 | **MANUFACTURER:** | CORAL Laboratories Ltd. | |
| **EXP. DATE:**  Jan. 2018 | **ADDRESS:** | Plot No.57/1 (16), Bhenslore, Dunetha, Nani Daman - 396 210, INDIA.. | |
| **CLIENT REF NO:** | **CLIENT:** | Twokay Chemicals Limited, P.O Box 46169-00100 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 | Manufacturer's In-House Method | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 2.8 and 7.0 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | No tablet less than 80% [n=6] | Aceclofenac Average | **DOES NOT COMPLY** |
| **Dissolution** |  |  |  | 62% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 56 - 66% (RSD = 5.1%; n = 12) |  |
| **Dissolution** |  |  |  | Paracetamol Average |  |
| **Dissolution** |  |  |  | 86% Range |  |
| **Dissolution** |  |  |  | 81 - 91% (RSD = 2.9%; n = 12) |  |
| **Assay** | HPLC | Manufacturer's In-House Method | 90.0 - 110.0% | Aceclofenac 91.7% (RSD = 1.0%; n = 6) | **COMPLIES** |
| **Assay** |  |  |  | Paracetamol 99.9% (RSD = 0.8%; n = 9) |  |

**CONCLUSION:** The product fails to comply with the specifications for Dissolution test of Aceclofenac.

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| **ANALYST:** | DR. L. WANGARI | .......................................................... | DATE: 05-27-2016 |
| **ANALYST:** | DR. M. KWENA | .......................................................... | DATE: 05-30-2016 |
| **ANALYST:** |  | .......................................................... | DATE: 08-26-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-18-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-23-2016 |