**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/817

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| **PRODUCT** | Claritine(R) tablet | | **REF. NO: NDQA201511561** |
| **DATE RECEIVED:** 2015-11-17 | **LABEL CLAIM:** | Each tablet contains 10 mg loratadine | |
| **BATCH NO.:** 004025 | **PRESENTATION:** | Off white coloured, ovoid shaped, biconvex faced tablets, single scored and embossed '10' and the manufacturer's logo on either side of the score on one face and plain on the other, packed in a blister strip of 10 tablets and 2 such strips packed in a unit box. | |
| **MGF. DATE:** Jan 1970 | **MANUFACTURER:** | ZENTIVA Saglik Urunleri San. ve Tic. A.S. (ensure the letters are as in the product description.) | |
| **EXP. DATE:**  Mar 2017 | **ADDRESS:** | Kucukkaristiran 39780, Luleburgaz, TURKEY.(ensure the letters are as in the product description.) | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| PV/15/65 | **TEST(S) REQUESTED:** | Uniformity of Weight, Uniformity of Content, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Identification** | HPLC | USP 38 NF 33 Page 4141 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 12.3 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Page 4141 | NMT 85% | 92% (RSD=5.6%; n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 4141 | 90.0 - 110.0% | 95.9% (RSD=0.9%; n=9) | **COMPLIES** |
| **Uniformity of Weight** |  |  |  |  | **COMPLIES** |
| **Uniformity of Content** | HPLC | USP 38 NF 33 Page 4141 | Acceptance value (AV) of 10 dosage Units is < 15% | AV = 6 (n=10) | **COMPLIES** |

**CONCLUSION:** The sample complies with the specifications for the tests performed. However, it was noted that the labelling on the packaging material and the insert was in Turkish language.

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| **ANALYST:** | DAVID MOENGA | .......................................................... | DATE: 12-28-2015 |
| **ANALYST:** | NICHOLAS MWAURA | .......................................................... | DATE: 05-06-2016 |
| **ANALYST:** | EMMANUEL TANUI | .......................................................... | DATE: 06-02-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 06-22-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 07-18-2016 |