**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/260

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| **PRODUCT** | AXCEL LORATADINE SYRUP | | **REF. NO: NDQD201509257** |
| **DATE RECEIVED:** 08-09-2015 | **LABEL CLAIM:** | Each 5 mL contains: Loratadine 5 mg. | |
| **BATCH NO.:** B1412034 | **PRESENTATION:** | Clear colourless syrup for oral administration contained in an amber coloured 60 mL glass bottle packed along with a clear 12.5 mL graduated plastic cup in a printed box. | |
| **MFG. DATE:** Dec. 2014 | **MANUFACTURER:** | KOTRA Pharma (M) Sdn. Bhd. | |
| **EXP. DATE:**  Dec. 2017 | **ADDRESS:** | 1, Jalan TTC 12, Cheng Industrial Estate, 75250 Melaka, MALAYSIA. | |
| **CLIENT REF NO:** | **CLIENT:** | KOTRA PHARMA C/O HARLEYS LTD P.O. BOX 42718 - 00100 Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Microbial Load | B.P. 2016 Vol. V App XVI B | Total Aerobic Microbial Counts (TAMC) NMT 200 CFU/mL | < 10 CFU/mL | **COMPLIES** |
| **Microbial Load** |  |  | Total Combined Yeast/Moulds Counts (TYMC) NMT 20 CFU/mL | < 10 CFU/mL | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 4139 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 25.3 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 Page 4139 | 2.2 - 3.1 | 3.1 | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 4139 | 94.0 - 105.0% | 102.1% (RSD=1.0%; n=6) | **COMPLIES** |

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

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| **ANALYST:** | FRANCIS NAULA | .......................................................... | DATE: 09-10-2015 |
| **ANALYST:** | MICHAEL SANGALE | .......................................................... | DATE: 10-11-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 28-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 11-01-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-17-2016 |