**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/156

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| **PRODUCT** | MUCOLEX EXPECTORANT | | **REF. NO: NDQD201605919** |
| **DATE RECEIVED:** 16-05-2016 | **LABEL CLAIM:** | Each 5 mL contains: Salbutamol Sulphate BP equivalent to Salbutamol 1 mg, Ambroxol Hydrochloride BP 30 mg, Guaifenensin BP 50 mg and Menthol BP 0.5 mg. | |
| **BATCH NO.:** CJ5002 | **PRESENTATION:** | Orange coloured flavoured syrup for oral administration contained in an 100 mL amber coloured glass bottle packed along with a 5 mL graduated plastic dispensing cap in a printed box. | |
| **MFG. DATE:** Aug. 2015 | **MANUFACTURER:** | S. KANT Healthcare Ltd. | |
| **EXP. DATE:**  Jul. 2017 | **ADDRESS:** | 1802 - 1805, G.I.D.C., Phase III, Vapi - 396 195, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | S. Kant Healthcare Ltd c/o Crown Healthcare, P. O. Box 40449 - 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 | BP 2016 Vol. V App XVI B | Total Aerobic Microbial Counts (TAMC) NMT 200 CFU/mL Total Combined Yeast/Moulds Counts (TYMC) NMT 20 CFU/mL | < 10 CFU/mL | **COMPLIES** |
| **Microbial Load** |  |  |  | < 10 CFU/mL | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's In - House Method | RT of the Major Peak in the sample preparation corresponds to that in the standard preparation | Super-imposable peak at RT 3.2,4.2 & 10.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | Manufacturer's In - House Method | 3.40 - 3.80 | 3.6 | **COMPLIES** |
| **Assay** | HPLC | Manufacturer's In - House Method | 90.0 - 110.0% | Salbutamol 96.4% (RSD=0.5%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Ambroxol Hydrochloride 107.0% RSD=0.2%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Guaifenesin 110.1% (RSD=0.2%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | FRANCIS NAULA | .......................................................... | DATE: 05-10-2016 |
| **ANALYST:** | LORNA WANGARI | .......................................................... | DATE: 06-03-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 03-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-03-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-07-2016 |