**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**  CAN/2015-16/XYZ

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| **PRODUCT** | SALBUMOL SUSPENSION | | REF. NO: NQDQ201508057 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Salbutamol Sulphate equivalent to Salbutamol BP 2 mg and syrup base to 5 mL. | |
| **BATCH NO.:** 141695 | **PRESENTATION:** | Pink coloured syrup for oral administration contained in a 100 mL amber coloured glass bottle packed along with a 2 mL Syringe with a dust cap and a 10 mL measuring cap in a unit box. | |
| **MGF. DATE:** Oct.2014 | **MANUFACTURER:** | REGAL Pharmaceuticals Ltd, | |
| **EXP. DATE:** Sep.2017 | **ADDRESS:** | Plot No.7879/18, Off Baba Dogo Road, Ruaraka, P.O BOX 44421-00100, Nairobi, KENYA | |
| **CLIENT REF NO:** | **CLIENT:** | Centrale Humanitaire Medico Pharmaceutique P.O. Box 10397 - 00400, Nairobi, Kenya | |
|  | **TEST(S) REQUESTED:** | pH, Microbial Load, Identification, Assay | |

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **pH** | Acidity/Alkalinity | BP 2012, Vol V Appendix VL | - | 3.85 |  |
| **Microbial Load** | Plate count | In House Method | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL :Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/mL | < 200 TAMC CFU Per ML | **COMPLIES:COMPLIES** |
| **Microbial Load** | Plate count | In House Method | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL :Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/mL | < 20 TYMC CFU Per mL | **COMPLIES:COMPLIES** |
| **Identification** | HPLC | BP 2012, Vol III, pg 3268 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation |  | **COMPLIES** |
| **Identification** | HPLC | BP 2012, Vol III, pg 3268 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT Value 9.2 Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | ::HPLC: | BP 2012, Vol III, pg 3268 | 90.0 % - 105.0 % | 101.4% (RSD = 0.4% ; n = 9) | **COMPLIES** |

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

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| ANALYST: | MR. F. NAULA |  | DATE:08-12-2015 |
| ANALYST: | DR. S. MWANGI |  | DATE:08-25-2015 |
| ANALYST: | DR. E. TANUI |  | DATE:09-09-2015 |
| ANALYST: | SERAH MUTERU |  | DATE:10-07-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:10-09-2015 |