**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | IBUMEX SUSPENSION | | REF. NO: NDQD201508064 |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each 5 ml of syrup contains Ibuprofen 100 mg BP. | |
| **BATCH NO.:** 150651 | **PRESENTATION:** | Orange coloured, viscous suspension for oral administration, contained in a 100 mL amber coloured glass bottle packed along with a 10 mL graduated plastic measuring cap in a unit box. | |
| **MGF. DATE:** Apr.2015 | **MANUFACTURER:** | REGAL Pharmaceuticals Ltd, | |
| **EXP. DATE:** Mar.2018 | **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 | USP 38 NF 33 Page 3828 | 3.6 - 4.6 | 4.0 | **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 | < 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 | B.P. 2012 Vol 3 Page 2924 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation |  | **COMPLIES** |
| **Identification** | HPLC | B.P. 2012 Vol 3 Page 2924 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peaks at RT 2.6 Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | B.P. 2012 Vol 3 Page 2924 | 95.0% - 105.0% | 99.2%, (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:16-09-2015 |
| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:06-10-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:10-14-2015 |