**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/229

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| **PRODUCT** | BETAFEN SYRUP | | **REF. NO: NDQD201609103** |
| **DATE RECEIVED:** 2016-09-08 | **LABEL CLAIM:** | Each 5 mL contains 100 mg Ibuprofen BP. | |
| **BATCH NO.:** 1604054 | **PRESENTATION:** | Orange coloured flavoured viscous syrup for oral administration contained in an amber coloured 60 mL glass bottle packed along with a clear 10 mL graduated plastic cap in a unit box. | |
| **MFG. DATE:** Apr. 2016 | **MANUFACTURER:** | BETA Healthcare International Ltd. | |
| **EXP. DATE:**  Apr. 2019 | **ADDRESS:** | Plot No. L.R 209/6554 Mogadishu Road, Industrial Area, P. O. Box 42569 - 00100, GPO Nairobi, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | Beta Healthcare International Ltd, P. O. Box 42569-00100, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Plate count | BP 2016 Vol. V App XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL | <10 CFU/mL | **COMPLIES** |
| **Microbial Load** |  |  | Total Combined Yeast/Moulds Count (TYMC) NMT 20 CFU/mL | <10 CFU/mL | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 3828 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 4.6 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 Page 3828 | 3.6 - 4.6 | 4.0 | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 3828 | 90.0 - 110.0% | 108.7% (RSD=1.2%; n=9) | **COMPLIES** |

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

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| **ANALYST:** | LORNA WANGARI | .......................................................... | DATE: 10-03-2016 |
| **ANALYST:** | FRANCIS NAULA | .......................................................... | DATE: 09-23-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 10-11-2016 |
| **ANALYST:** | EMMANUEL TANUI | .......................................................... | DATE: 11-10-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-10-2016 |