**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/231

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| **PRODUCT** | MAXICORT® CREAM 1.0%w/w | | **REF. NO: NDQD201609102** |
| **DATE RECEIVED:** 08.09.2016 | **LABEL CLAIM:** | Each gram contains Hydrocortisone 10 mg B.P. | |
| **BATCH NO.:** K2340 | **PRESENTATION:** | Off white translucent smooth cream, packed in a 15 g green collapsible aluminium tube in a unit box. | |
| **MFG. DATE:** Mar.2016 | **MANUFACTURER:** | MAC'S Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Feb. 2019 | **ADDRESS:** | Off Shimo La Tewa Road, P. O. BOX 43912 - 00100, Nairobi KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | MAC'S Pharmaceutical Ltd. P. O. BOX 43912 - 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 | TAMC; NMT 200 CFU/g, TYMC; NMT 20 CFU/g) | TAMC; <10CFU/g, TYMC; <10CFU/g) | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 3780 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 9.0 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 Page 2223 | - | 4.2 | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 3780 | 90.0 - 110.0 % | 90.8% (RSD=0.4%; n=9) | **COMPLIES** |

**CONCLUSION:** The sample complies with the specifications for the tests performed. However, the content of the active ingredient is within the lower acceptable limit.

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| **ANALYST:** | MR. F. NAULA | .......................................................... | DATE: 10-11-2016 |
| **ANALYST:** | DR. S. MWANGI | .......................................................... | DATE: 10-11-2016 |
| **ANALYST:** | DR. S. MUTERU | .......................................................... | DATE: 10-11-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-10-2016 |