**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-2016/270

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| **PRODUCT** | AXCEL CLINDAMYCIN 1% TOPICAL SOLUTION | | REF. NO: NDQD201509258 |
| **DATE RECEIVED:** 08.09.2015 | **LABEL CLAIM:** | Clindamycin Phosphate equivalent to Clindamycin 1% w/v, Methylparaben 0.08% w/v and Propylparaben 0.02% w/v as preservatives Isopropyl Alcohol 44% v/v as disinfectant. | |
| **BATCH NO.:** 1503029 | **PRESENTATION:** | Clear colourless solution for topical application, contained in a 30 mL translucent plastic bottle in a unit box. | |
| **MGF. DATE:** Mar.2015 | **MANUFACTURER:** | KOTRA Pharma (M)Sdn.Bhd. | |
| **EXP. DATE:**  Mar.2018 | **ADDRESS:** | 1, Jalan TTC 12,Cheng Industrial Estate,75250 Melaka, MALAYSIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kotra Pharma c/o Harleys Ltd P. O. Box 42718 - 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) < 200 CFU/mL Total Combined Yeasts/ Moulds Count (TYMC) < 20 CFU/mL | TAMC < 200 CFU/mL TYMC < 20 CFU/mL | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 2869 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 6.1 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2869 | 90.0 - 110.0% | 106.0% (RSD=0.9%; n=6) | **COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 Page 2869 | 4.0 - 7.0 | 4.3 | **COMPLIES** |

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

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| ANALYST: | MR. F.NAULA |  | DATE:22-02-2016 |
| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:22-02-2016 |
| REVIEWER: | DR. S. MWANGI |  | DATE:22-02-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:02-29-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-01-2016 |