**CERTIFICATE OF ANALYSIS**

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

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | B-BACT OINTMENT | | REF. NO: NDQD201410907 |
| **DATE RECEIVED:** 08.10.2014 | **LABEL CLAIM:** | Composition Mupirocin U.S.P. 2% w/w in a water soluble base qs. | |
| **BATCH NO.:** Q47 | **PRESENTATION:** | Off white coloured ointment for topical application contained in a 5 g, white coloured collapsible aluminium tube in a unit box. | |
| **MGF. DATE:** Aug. 2014 | **MANUFACTURER:** | WALLACE Pharmaceuticals PVT Ltd. | |
| **EXP. DATE:** Feb. 2016 | **ADDRESS:** | Plot No. 2-9 Bethora Ind. Est, Bethora Ponda, Goa - 403 409, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | CCL Pharmaceuticals Ltd co Harleys Ltd P.o Box 42718-00100 Nairobi | |
|  | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Plate count | BP 2013 Vol. V App. XVIB | Total Aerobic Total Aerobic Microbial Count (TAMC) < 100 CFU/g :Total Combined Yeasts /Moulds Count (TYMC) < 10 CFU/g | < 200 TAMC CFU/g | **COMPLIES:COMPLIES** |
| **Microbial Load** | Plate count | BP 2013 Vol. V App. XVIB | Total Aerobic Total Aerobic Microbial Count (TAMC) < 100 CFU/g :Total Combined Yeasts /Moulds Count (TYMC) < 10 CFU/g | < 20 TAMC CFU/g | **COMPLIES:COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Vol.3 Page 4463 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 12.0 +/- 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Vol.3 Page 4463 | 90.0 - 110.0% | 99.7% (RSD=0.2%; n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | MR. D. MOENGA |  | DATE:13-11-2015 |
| ANALYST: | DR. N. MWAURA |  | DATE:18-11-2015 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:11-23-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:11-25-2015 |