**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/604

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| **PRODUCT** | CEF-OD DS SUSPENSION 100mg/5ml | | REF. NO: NDQD201508244 |
| **DATE RECEIVED:** 27.08.2015 | **LABEL CLAIM:** | Each 5 mL of reconstituted suspension contains Cexifime Trihydrate U.S.P. Equivalent to Cefixime 200 mg. | |
| **BATCH NO.:** Powder JB60 Diluent 4126080 | **PRESENTATION:** | White coloured, free flowing, powder for reconstitution into oral suspension contained in a 30 mL amber coloured glass bottle and supplied along with a plastic dispensing 5 mL spoon and a 20 mL plastic ampoule diluent, packed in a unit box. | |
| **MGF. DATE:** May 2015 | **MANUFACTURER:** | CCL Pharmaceuticals pvt Ltd. | |
| **EXP. DATE:**  Apr. 2017 | **ADDRESS:** | 62-Industrial Estate,Kot Lakhpat,Lahore PAKISTAN. | |
| **CLIENT REF NO:** | **CLIENT:** | CCL Pharmaceuticals Ltd co Harleys Ltd P.o Box 42718-00100 Nairobi | |
|  | **TEST(S) REQUESTED:** | Sterility, Microbial Load, Identification, Bacterial Endotoxin, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V App. XVI A | No Microbial Growth | No Microbial Growth | **COMPLIES** |
| **Microbial Load** | Microbial Load | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL:Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/mL | NMT 10 CFU/mL | **COMPLIES:COMPLIES** |
| **Microbial Load** | Microbial Load | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL:Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/mL | NMT 10 CFU/mL | **COMPLIES:COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 2215 | RT of the component peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 9.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Bacterial Endotoxin** | LAL | USP 38 NF 33 Page 5806 | Less than 0.25 EU/mL | 3.6 \* 10-5 EU/mg | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2666 | 90.0 - 120.0% | Day 1 115.1% ( RSD=1.3%,n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2666 | 90.0 - 120.0% | Day 7 112.0% ( RSD=1.0%,n=9) | **COMPLIES:COMPLIES:COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 Page 2666 | 2.5 - 4.5 | 3.8 | **COMPLIES** |

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

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| ANALYST: | MR. E. NGAMAU |  | DATE:15-09-2015 |
| ANALYST: | MR. F. NAULA |  | DATE:28-09-2015 |
| ANALYST: | DR. K. BOTA |  | DATE:09-02-2016 |
| REVIEWER: | DR. M. KWENA |  | DATE:08-04-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:04-14-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-09-2016 |