**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | PTS159 CEFACLOR 375 mg TABLETS (EDQM PT SAMPLES) | | REF. NO: NDQE201509293 |
| **DATE RECEIVED:** 25.09.2015 | **LABEL CLAIM:** | Cefaclor 375 mg tablets. | |
| **BATCH NO.:** PTS15900 | **PRESENTATION:** | Sky blue coloured, caplet shaped, biconvex faced tablets, plain on both faces, and 8 such tablets packed in an amber coloured vial fitted with a metallic cap. | |
| **MGF. DATE:** - | **MANUFACTURER:** | European Directorate for the Quality of Medicines and HealthCare Department of Biological Standardisation | |
| **EXP. DATE:** - | **ADDRESS:** | DBO, OMCL Network, CS 30026 - F67081 Srasbourg, FRANCE. | |
| **CLIENT REF NO:** | **CLIENT:** | European Directorate for the Quality of Medicines and Healthcare 7 allee Kastner, CS 30026, FR-67081 Strasbourg (Francce) | |
|  | **TEST(S) REQUESTED:** | Dissolution, Assay | |

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Dissolution** | UV | U.S.P. 37 N.F. 32 Vol. 2 Page 2180 | In 30 Mins; 5% - 30% In 60 Mins; 20% - 50% In 240 Mins; NLT 80% |  | **COMPLIES::COMPLIES:COMPLIES** |
| **Dissolution** | UV | U.S.P. 37 N.F. 32 Vol. 2 Page 2180 | In 30 Mins; 5% - 30% In 60 Mins; 20% - 50% In 240 Mins; NLT 80% | 13.7%, (n=6; RSD=3.5%) | **COMPLIES::COMPLIES:COMPLIES** |
| **Dissolution** | UV | U.S.P. 37 N.F. 32 Vol. 2 Page 2180 | In 30 Mins; 5% - 30% In 60 Mins; 20% - 50% In 240 Mins; NLT 80% | 30.5%, (n=6; RSD=2.4%) | **COMPLIES::COMPLIES:COMPLIES** |
| **Dissolution** | UV | U.S.P. 37 N.F. 32 Vol. 2 Page 2180 | In 30 Mins; 5% - 30% In 60 Mins; 20% - 50% In 240 Mins; NLT 80% | 95.3% (n=6; RSD=3.1%) | **COMPLIES::COMPLIES:COMPLIES** |
| **Assay** |  |  |  | - |  |

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

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| ANALYST: | DR. S. MWANGI |  | DATE:07-10-2015 |
| REVIEWER: | DR.E. MBAE |  | DATE:27-10-2015 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:11-04-2015 |