**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/234

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| **PRODUCT** | CATAFLAM LIQUID CAPSULES 50 mg | | **REF. NO: NDQD201505223** |
| **DATE RECEIVED:** 05 May 2015 | **LABEL CLAIM:** | 1 soft capsule contains 50 mg diclofenac potassium. | |
| **BATCH NO.:** T0001A | **PRESENTATION:** | Pale yellow coloured, transparent, ovoid shaped, fused soft gelatin capsules containing a clear oily liquid and imprinted 'NVR' on one face and 'C50' on the other side of the fused capsule halves packed in a blister strip of 10 capsules in a unit box. | |
| **MFG. DATE:** Mar. 2014 | **MANUFACTURER:** | CATALENT Germany Eberbach GmbH for Novartis Pharma AG, Basle, SWITZERLAND. | |
| **EXP. DATE:**  Aug. 2016 | **ADDRESS:** | Gammelsbacherstrasse 269412 Eberbach, GERMANY. | |
| **CLIENT REF NO:** | **CLIENT:** | Norvatis Pharma services Inc P.O Box 46057-00100,Nairobi, Kenya | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | Not more than 2 capsule contents deviate by more than 7.5% from mean capsule content weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Adopted from USP 38 NF 33 Page 3086 | Retention time of major peak in assay sample preparation corresponds to that in the standard assay preparation | Super-imposable peak at RT 10.0 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted from USP 38 NF 33 Page 3086 | No capsule less than 80% | Average | **COMPLIES** |
| **Dissolution** |  |  |  | 97% Range |  |
| **Dissolution** |  |  |  | 94 - 101% (RSD=3.2%; n=6 ) |  |
| **Assay** | HPLC | Adopted from USP 38 NF 33 Page 3086 | 90.0% - 110.0% | 106.8% (RSD=0.5%; n=9) | **COMPLIES** |

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

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| **ANALYST:** | MICHAEL SANGALE | .......................................................... | DATE: 05-08-2015 |
| **ANALYST:** | LORNA WANGARI | .......................................................... | DATE: 05-08-2015 |
| **REVIEWER:** | NICHOLAS MWAURA | .......................................................... | DATE: 10-10-2016 |
| **ANALYST:** | EMMANUEL TANUI | .......................................................... | DATE: 11-14-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-15-2016 |