**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/624

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| **PRODUCT** | GLEMONT(TM)-CT 4 (TM) CHEWABLE TABLETS | | REF. NO: NDQD201504204 |
| **DATE RECEIVED:** 23.04.2015 | **LABEL CLAIM:** | Each uncoated tablet contains: Montelukast Sodium equivalent to Montelukast 4 mg | |
| **BATCH NO.:** 05141973 | **PRESENTATION:** | Off white coloured, oval shaped tablets, embossed '390' on one side and 'G' on the other, packed in an aluminium blister strip of 10 tablets and 10 such strips in a unit box. | |
| **MGF. DATE:** Dec.2014 | **MANUFACTURER:** | GLENMARK Pharmaceuticals Ltd | |
| **EXP. DATE:**  Nov.2016 | **ADDRESS:** | B/2, Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai-400 026, At:Village:Kishanpura, Baddi Nalagarh Road, Dist.Solan,(H.P.)-174 101, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Glenmark Pharmaceuticals (K) Ltd, P.O BOX 6915-00200 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 | < 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House Method | RT of the component peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House Method | RT of the component peak in the assay sample preparation corresponds to that in the assay standard preparation | 10.8 Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 80.0% [n = 6] | 83.8% (RSD=3.9%; n=6) | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90-110% | 98.4% (RSD=0.8%; n=6) | **COMPLIES** |

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

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| ANALYST: | DR. L. KARANJA |  | DATE:05-11-2015 |
| ANALYST: | DR. M. KWENA |  | DATE:20-11-2015 |
| ANALYST: | ERNEST MBAE |  | DATE:12-21-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-10-2016 |