**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-7/112

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| **PRODUCT** | GLEMONT - IR 10 TABLETS | | **REF. NO: NDQD201602749** |
| **DATE RECEIVED:** 04.02.2016 | **LABEL CLAIM:** | Each film coated tablet contains: Montelukast Sodium equivalent to 10 mg Montelukast. | |
| **BATCH NO.:** 19151915 | **PRESENTATION:** | Light pink coloured, circular shaped, biconvex faced tablets, embossed "G" on one face and "392" on the other, packed in a white childproof multidose plastic container of 30 tablets in a unit box. | |
| **MFG. DATE:** Sep. 2015 | **MANUFACTURER:** | GLENMARK Pharmaceuticals Ltd | |
| **EXP. DATE:**  Aug. 2017 | **ADDRESS:** | B/2, Mahalaxmi Chambers,22, Bhulabhai Desai Road,Mumbai-400 026, Plot No. S-7, Colvale Industrial Easte, Colvale, bardez, Goa -403 573 INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Glenmark Pharmaceuticals (K) Ltd, P.O Box 6915-00200 Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Disintegration, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App XII C | NMT 2 tablets deviate by more than 7.5% 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 standard preparation | Super-imposable peak at RT 6.7 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Disintegration** | Disintegration | Adopted In-House Method | All Tablets disintegrate within 30 minutes [n=6] | All Tablets disintegrated within 4 minutes [n=6] | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | No tablet less than 85% (n=6) | Average = 102% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 100 - 105% (RSD=1.9, n=6) |  |
| **Assay** | HPLC | Adopted In-House Method | 95.0 - 105.0 % | 97.2% (SD=0.8%, n=9) | **COMPLIES** |

**CONCLUSION:** The sample complies with the specifications of the tests performed.

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| **ANALYST:** | DR. S. MWANGI | .......................................................... | DATE: 24/08/2016 |
| **ANALYST:** | DR. G. WANG'ANG'A | .......................................................... | DATE: 24/08/2016 |
| **ANALYST:** | DR. E. MBAE | .......................................................... | DATE: 24/08/2016 |
| **DIRECTOR:** | DR. H. K. CHEPKWONY | .......................................................... | DATE: 24/08/2016 |