**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-17/117

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| **PRODUCT** | FLUSORT NASAL SPRAY | | **REF. NO: NDQD201601718** |
| **DATE RECEIVED:** 28.01.2016 | **LABEL CLAIM:** | Composition:Fluticasone Propionate BP 0.05% w/w. | |
| **BATCH NO.:** 12150302 | **PRESENTATION:** | A cloudy suspension for use as a nasal spray in a pressurized plastic bottle crimped with a nasal applicator fitted with a plastic cap in a unit box. | |
| **MFG. DATE:** 13.Jun.2015 | **MANUFACTURER:** | GLENMARK Pharmaceuticals Ltd. | |
| **EXP. DATE:**  12.Jun.2017 | **ADDRESS:** | Unit III, Village Kishanpura, Baddi-Nalagarh Road, Tehsil Nalagarh, Distt.Solan,(H.P.)-174 101, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Glenmark Pharmaceuticals (K) Ltd, P.O Box 6915-00200 Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Plate count | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Counts (TAMC) NMT 200 CFU/mL | < 10 CFU/mL | **COMPLIES** |
| **Microbial Load** |  |  | Total Combined Yeast/Moulds Counts( TYMC) NMT 20 CFU/mL | < 10 CFU/mL |  |
| **Identification** | HPLC | Manufacturer's In-House Method | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 3.8, 6.9 and 10.8 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | Manufacturer's In-House Method | 80.0 - 120.0 % | Fluticasone Propionate 105.2% (RSD = 0.2%; n = 9) | **COMPLIES** |
| **Assay** |  |  |  | Benzalkonium Chloride 93.8% (RSD = 0.3%; n = 9) | **COMPLIES** |
| **Acidity/Alkalinity** | pH | BP 2016 Vol. V App XII C | 5.0 - 7.0 | 6.4 | **COMPLIES** |

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

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| **ANALYST:** | MR. E. NGANMAU | .......................................................... | DATE: 09-03-2016 |
| **ANALYST:** | DR. S. MWANGI | .......................................................... | DATE: 27-05-2016 |
| **ANALYST:** | DR. E. MBAE | .......................................................... | DATE: 16-06-2016 |
| **DIRECTOR:** | DR.H. K. CHE | .......................................................... | DATE: 08-24-2016 |