**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-2016/271

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| **PRODUCT** | FANIGAN FAST GEL | | REF. NO: NDQD201509267 |
| **DATE RECEIVED:** 08.09.2015 | **LABEL CLAIM:** | Each gram of gel contains: Diclofenac diethylamine BP equivalent to Diclofenac sodium 10 mg (1% w/w); Menthol USP 50 mg (5% w/w); Methyl salicylate BP 100 mg (10% w/w); Linseed oil BP 30 mg (3% w/w). | |
| **BATCH NO.:** F15014 | **PRESENTATION:** | White coloured, smooth gel for topical application, contained in a 30 g collapsible alluminium tube, packed in a unit box. | |
| **MGF. DATE:** Mar. 2015 | **MANUFACTURER:** | KUSUM Healthcare Pvt. Ltd. | |
| **EXP. DATE:**  Feb. 2017 | **ADDRESS:** | SP 289 (A), RIICO, Indl. Area, Chopanki, Bhiwadi (Rajasthan), INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Highridge Pharmaceuticals Ltd. P. O. Box 32982 - 00600, 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 Count (TAMC) NMT 200 CFU/g Total Combined Yeasts/ Moulds Count (TYMC) NMT 20 CFU/g | TAMC < 200 CFU/mL TYMC < 20 CFU/mL | **COMPLIES** |
| **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 5.7,10.4 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | Manufacturer's In-House Method | Diclofenac Diethylamine 95.0 - 110.0% Methyl Salicylate 90.0 - 115.0% | 103.0% (RSD = 0.4%; n = 9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Manufacturer's In-House Method | Diclofenac Diethylamine 95.0 - 110.0% Methyl Salicylate 90.0 - 115.0% | 106.9% (RSD = 1.4%; n = 6) | **COMPLIES:COMPLIES** |
| **Acidity/Alkalinity** | pH | Manufacturer's In-House Method | 6.5 - 8.0 | 7.4 | **COMPLIES** |

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

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| ANALYST: | MR. F. NAULA |  | DATE:22-02-2016 |
| ANALYST: | DR. L. KARANJA |  | DATE:22-02-2016 |
| REVIEWER: | DR. S. MUTERU |  | DATE:22-02-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:02-29-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-01-2016 |