**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/615

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| **PRODUCT** | ORGYL 500 mg TABLETS | | REF. NO: NDQD201509268 |
| **DATE RECEIVED:** 08.09.2015 | **LABEL CLAIM:** | Each film coated Tablet contains: Ornidazole 500 mg. | |
| **BATCH NO.:** OB4004 | **PRESENTATION:** | Orange coloured, circular shaped, biconvex faced tablets, plain on both faces, packed in amber coloured blister strip of 10 tablets each and 10 such strips in a unit box. | |
| **MGF. DATE:** May 2014 | **MANUFACTURER:** | KUSUM Healthcare Pvt. Ltd. | |
| **EXP. DATE:**  Apr. 2017 | **ADDRESS:** | SP 289 (A), RIICO, Indl. Area, Chopanki, Bhiwadi (Raj.), INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Highridge Pharmaceuticals Ltd. P. O. Box 32982 - 00600, 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 | NMT 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House Method | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 4.9 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In-House Method | Not less than 80% [n=6] | 101.7% (RSD=5.0%; n=6) | **COMPLIES** |
| **Assay** | HPLC | Adopted In-House Method | 90.0 - 110.0% | 107.8% (RSD=1.0%; n=9) | **COMPLIES** |

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

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| ANALYST: | DR. L. KARANJA |  | DATE:09-05-2016 |
| ANALYST: | DR. N. MWAURA |  | DATE:09-05-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-10-2016 |