**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/268

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| **PRODUCT** | AMEBAZOLE TABLETS | | **REF. NO: NDQD201609096** |
| **DATE RECEIVED:** 08-09-2016 | **LABEL CLAIM:** | Each sugar coated tablet contains: Metronidazole BP 200 mg. | |
| **BATCH NO.:** 00122MT | **PRESENTATION:** | White coloured, circular shaped, biconvex faced tablets, packed in a plastic multidose container of 1000 tablets. | |
| **MFG. DATE:** Jun. 2016 | **MANUFACTURER:** | SPHINIX Pharmaceuticals Ltd. | |
| **EXP. DATE:**  May 2019 | **ADDRESS:** | Old Airport North Road, Embakasi, P. O. Box 69512 - 00400, Nairobi, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | SPHINX Phamaceutical Ltd. P. O. BOX 69512 - 00400, 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 | One Deviates (+7%) | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 4385 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 6.8 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Page 4385 | No Tablet Less Than 90% | Average | **COMPLIES** |
| **Dissolution** |  |  |  | 97%, Range |  |
| **Dissolution** |  |  |  | 97 - 98% (RSD = 0.4%; n = 6) |  |
| **Assay** | HPLC | USP 38 NF 33 Page 4385 | 90.0 - 110.0% | 98.3% (RSD = 0.5%; n = 8) | **COMPLIES** |

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

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| **ANALYST:** | KENNEDY RUTTO | .......................................................... | DATE: 10-03-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 13-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-14-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-18-2016 |