**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/401

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| **PRODUCT** | RESICALM 2 TABLETS | | REF. NO: NDQD201509262 |
| **DATE RECEIVED:** 08.09.2015 | **LABEL CLAIM:** | Each film-coated tablet contains: Risperidone Ph.Eur. 2 mg. | |
| **BATCH NO.:** RS0214007-C | **PRESENTATION:** | Pink coloured, caplet shaped tablets, single scored and alternately embossed '5' and '2' on either half of the score on one face and 'A' on the opposite, unscored face, packed in a blister strip of 10 tablets and 3 such strips in a unit box. | |
| **MGF. DATE:** Jul. 2014 | **MANUFACTURER:** | AUROBINDO Pharma Ltd. | |
| **EXP. DATE:**  Jun. 2016 | **ADDRESS:** | Unit 111, Survey No. 313, Bachupally Village, Quthubullapur Mandal, Ranga Reddy District (A.P.), INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Simba Pharmaceuticals Limited P. O. Box 1541 - 00606, 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 2012 Vol. V App XII C | NMT 2 tablets deviate by more than 7.5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 5195 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation. | Super-imposable peak at RT 9.2 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 5195 | No tablet less than 80% | 99.2% (RSD=5.2%, n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5195 | 90.0 - 110.0% | 101.0% (RSD=0.4%, n=6) | **COMPLIES** |

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

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| 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 |