**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/818

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| **PRODUCT** | PROLERT(R) CAPSULES | | **REF. NO: NDQD201601651** |
| **DATE RECEIVED:** 01.01.2016 | **LABEL CLAIM:** | Each capsule contains Fluoxetine 20 mg as Fluoxetine Hydrochloride BP. | |
| **BATCH NO.:** 511001 | **PRESENTATION:** | Hard gelatin capsules with an ocean blue coloured cap imprinted 'Square' and sky blue coloured body imprinted 'Square' filled with an off white coloured powder, packed in a blister strip of 10 capsules and 5 such strips in a unit box. | |
| **MGF. DATE:** Nov. 2015 | **MANUFACTURER:** | SQUARE Formulations Ltd | |
| **EXP. DATE:**  Oct. 2017 | **ADDRESS:** | Tangail, BANGLADESH. | |
| **CLIENT REF NO:** | **CLIENT:** | Ace Pharmaceuticals Ltd, P.O BOX 19900-00202, 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 capsules deviate by more than 10% from mean capsule weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 3554 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 7.0 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 3554 | Average NLT 80% and no tablet less than 65% [n=6] | 89% (RSD=9.1%;n=12) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 3554 | 90.0 - 110.0% | 99.7% (RSD=0.7%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | MR. M. SANGALE | .......................................................... | DATE: 23-05-2016 |
| **ANALYST:** | DR. N. MWAURA | .......................................................... | DATE: 23-05-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 06-22-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 07-18-2016 |