**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/523

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| **PRODUCT** | PROCALIS-20 TABLETS | | REF. NO: NDQA201511560 |
| **DATE RECEIVED:** 17.11.2015 | **LABEL CLAIM:** | Each film coated tablet contains tadalafil 20 mg. | |
| **BATCH NO.:** T-7208 | **PRESENTATION:** | Light brown coloured, ovoid shaped, biconvex faced tablets, plain on both faces packed in a blister strip of 10 tablets in a transparent resealable plastic bag. | |
| **MGF. DATE:** Apr. 2015 | **MANUFACTURER:** | EUPHORIA Healthcare PVT. Ltd. | |
| **EXP. DATE:**  Mar. 2018 | **ADDRESS:** | UNIT NO 3, 3rd floor, Empress Nucleus Building, Near Metro Rail, Behind Visha Hall, Andheri-Kurla Road, Gondavali, Andheri East, Mumbai-400069. INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Uniformity of Content, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** |  |  |  |  | **COMPLIES** |
| **Uniformity of Content** | HPLC | USP 38 NF 33 Page 5434 | Acceptance Value (AV) of the 10 dosage units < 15% | AV = 8% | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 5434 | RT of the component peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 12.7 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 5434 | S2: After 10 Mins average of 12 tablets not less than 40% and no tablet less than 25% (n=12) : S2: After 30 Mins average of 12 tablets not less than 80% and no tablet less than 65% (n=12) | 58% (RSD=9.4%, n=12) | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 5434 | S2: After 10 Mins average of 12 tablets not less than 40% and no tablet less than 25% (n=12) : S2: After 30 Mins average of 12 tablets not less than 80% and no tablet less than 65% (n=12) | 80% (RSD=15.3%, n=12) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5434 | 90.0 - 110.0 % | 96.6% (RSD=0.5%, n=9) | **COMPLIES** |

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

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| ANALYST: | DR. S. MWANGI |  | DATE:04-03-2016 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:14-03-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:04-12-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-19-2016 |