**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/483

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| **PRODUCT** | AMLOAS -10 TABLETS | | REF. NO: NDQD201512577 |
| **DATE RECEIVED:** 01.12.2015 | **LABEL CLAIM:** | Each uncoated tablet contains Amlodipine Besylate USP equivalent to Amlodipine 10 mg. | |
| **BATCH NO.:** R004 | **PRESENTATION:** | Off white coloured,round shaped, flat faced level-edged tablets, embossed '1' on one face and plain on the other, packed in a blister strip of 10 tablets and 10 such strips packed in a unit box. | |
| **MGF. DATE:** Mar. 2015 | **MANUFACTURER:** | ASTRA Lifecare (PVT) Ltd. | |
| **EXP. DATE:**  Feb. 2018 | **ADDRESS:** | Plot NO. 57/P, Sarkhej-Balva Highway, Post Rajoda-38220, Taluka: Balva Dist Ahmedabad. INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Opera Pharma K Ltd No 8 of CB and SB Patel Building ICD Road, Next to KPA-Inland Container Depot P.o Box 14406 - 00800 | |
|  | **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** | Weight | BP 2016 Vol. V App XII C | NMT 2 tablets deviate by more than 7.5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Uniformity of Content** | HPLC | USP 38 NF 33 Page 2209 | Not more than 1 unit is less than 85% or greater than 115% of the average tablet content. Acceptance Value of the 10 dosage units is < 15 | AV=8 | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 2209 | RT of the Component Peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 10.1 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Page 2209 | No Tablet Less than 80% [n=6] | 86.0% (RSD=5.1%, n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2209 | 90.0% - 110.0% | 94.7% (RSD=0.2%, n=9) | **COMPLIES** |

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

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| ANALYST: | DR. E. MUTUA |  | DATE:02-22-2016 |
| ANALYST: | DR. E. TANUI |  | DATE:03-09-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:04-04-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-11-2016 |