**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/487

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | MYLOVASC(TM)-5 TABLETS | | REF. NO: NDQD201512634 |
| **DATE RECEIVED:** 15.12.2015 | **LABEL CLAIM:** | Each uncoated tablets contains S-Amlodipine besilate equivalent to S-Amlodipine 5 mg | |
| **BATCH NO.:** 14SAMT 101 | **PRESENTATION:** | Off white coloured, circular shaped, biconvex faced tablets, plain on both sides, packed in a blister strip of 10 tablets and 3 such strips packed in a unit box. | |
| **MGF. DATE:** Dec. 2014 | **MANUFACTURER:** | BAFNA Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Nov. 2017 | **ADDRESS:** | 147,MADHAVARAM REDHILLS HIGH RD, GRANTLYON VILLAGE,CHENNAI-600052 INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | PHARMA SPECIALITIES Ltd P.O. Box 49146- 00100 GPO, Nairobi | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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** |
| **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] | 103.8% (RSD=1.1%, n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 2209 | 90.0 - 110.0% | 99.6% (RSD=0.3%, n=9) | **COMPLIES** |

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

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