**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/122

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | SUMAFIX 50 mg TABLETS | | **REF. NO: NDQD201504211** |
| **DATE RECEIVED:** 2015-04-23 | **LABEL CLAIM:** | Each uncoated tablet contains: Sumatriptan Succinate Ph.Eur. equivalent to Sumatriptan 50 mg. | |
| **BATCH NO.:** SW0512010-D | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, embossed 'C' on one face and '33' on the other, packed in aluminium blister strip of 4 tablets in a box carrying 5 such packs. | |
| **MFG. DATE:** Nov. 2012 | **MANUFACTURER:** | Aurobindo Pharma LImited | |
| **EXP. DATE:**  Oct. 2016 | **ADDRESS:** | Unit III, 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**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 the mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 5415 | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peak at RT 2.8 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Page 5415 | No tablet less than 85% [n=6] | Sumatriptan Average = 94% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 93 - 95% (RSD=0.7%, n=6) |  |
| **Assay** | HPLC | USP 38 NF 33 Page 5415 | 90.0 -110.0% | 94.0% (RSD=0.6%, n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | DR LORNA WANGARI | .......................................................... | DATE: 08-09-2016 |
| **ANALYST:** | DR MATHAYO KWENA | .......................................................... | DATE: 08-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-27-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-29-2016 |