**CERTIFICATE OF ANALYSIS**

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

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | LONGRIDE 30 TABLETS | | REF. NO: NDQD201504176 |
| **DATE RECEIVED:** 14.04.2015 | **LABEL CLAIM:** | Each - film coated tablet contains Dapoxetine hydrochloride equivalent to Dapoxetine 30 mg. | |
| **BATCH NO.:** BT1503128A | **PRESENTATION:** | Grey coloured, circular shaped, biconvex faced tablets, plain on both faces, packed in a blister strip of 10 tablets and 3 such strips in a unit box. | |
| **MGF. DATE:** Mar. 2015 | **MANUFACTURER:** | MSN Laboratories Private Limited. | |
| **EXP. DATE:** Feb. 2017 | **ADDRESS:** | Plot No 42, Anrich Industrial Estate, Bollaram, Medak District - 502 325, A.P., INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Simba Pharmaceuticals Limited P.O.Box 1541 - 00600, Nairobi | |
| - | **TEST(S) REQUESTED:** | Uniformity of Weight, Uniformity of Content, Dissolution, Assay | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | B.P. 2012 Vol. V App XII C | NMT 2 tablets deviate by more than 7.5% from mean weight | None Deviate | **COMPLIES** |
| **Uniformity of Content** | HPLC | Manufacturer's In - House Method | RT of the Component peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 3.3 Â± 10% min. present in both the assay and standard sample preparations | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In - House Method | No tablet less than 80.0% (n=6) | 96.1% (RSD = 0.4%; n = 6) | **COMPLIES** |
| **Assay** | HPLC | Manufacturer's In - House Method | 90.0 - 110.0% | 102.6% (RSD = 0.6%; n = 6) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | MR. M. SANGALE |  | DATE:30-09-2015 |
| REVIEWER: | DR. G. WANG'ANG'A |  | DATE:02-10-2015 |
| ANALYST: | SERAH MUTERU |  | DATE:10-12-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:10-15-2015 |