**CERTIFICATE OF ANALYSIS**

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

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | LEVOGASTROL 25 mg TABLETS | | REF. NO: NDQD201503148 |
| **DATE RECEIVED:** 24.03.2015 | **LABEL CLAIM:** | Each tablet contains Levosulpiride 25 mg and Excipients q.s.p. | |
| **BATCH NO.:** G002 | **PRESENTATION:** | Off white, circular shaped, biconvex faced tablets, embossed '25' on one face and plain on the other, packed in a blister strip of 15 tablet and 2 such strips in a unit box. | |
| **MGF. DATE:** Feb. 2012 | **MANUFACTURER:** | LABORATORIOS SALVAT, S.A. | |
| **EXP. DATE:** Feb. 2016 | **ADDRESS:** | Gall, 30-36,Esplugues de Llobregeat, 08950 Barcelona, SPAIN. | |
| **CLIENT REF NO:** | **CLIENT:** | MACNAUGHTON LTD. p.o box 148-00502, Karen, Nairobi KENYA. | |
| - | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, 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** |
| **Identification** | 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 3.6 Â± 10% min. present in both the assay and standard sample preparations | **COMPLIES** |
| **Dissolution** | :UV | Manufacturer's In - House Method | No Tablet less than 85.0% (n=6) |  | **COMPLIES:** |
| **Dissolution** | :UV | Manufacturer's In - House Method | No Tablet less than 85.0% (n=6) | 94.5% (RSD=1.8%,n=9) | **COMPLIES:** |
| **Assay** | HPLC: | Manufacturer's In - House Method | 92.0 - 105.0% |  | **COMPLIES:** |
| **Assay** | HPLC: | Manufacturer's In - House Method | 92.0 - 105.0% | 94.5%, (RSD=1.8%,n=9) | **COMPLIES:** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | DR. K. BOTA |  | DATE:23-09-2015 |
| REVIEWER: | DR. R. MANANI |  | DATE:09-10-2015 |
| ANALYST: | SERAH MUTERU |  | DATE:10-12-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:10-14-2015 |