**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**  CAN/2016-17/XYZ

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| **PRODUCT** | BE-STEDY 16 TABLETS | | REF. NO: NDQD201509263 |
| **DATE RECEIVED:** 08.09.2015 | **LABEL CLAIM:** | Each uncoated tablet contains; Betahistine dihydrochloride Ph.Eur. 16 mg. | |
| **BATCH NO.:** BB1615005-B | **PRESENTATION:** | White coloured, circular shaped, biconvex faced tablets, single scored and embossed 'X' on one side of the score on one face and'88' on the other, packed in an aluminium blister pack of 10 tablets and 10 such strips in a unit box. | |
| **MGF. DATE:** Jan.2015 | **MANUFACTURER:** | AUROBINDO Pharma Limited. | |
| **EXP. DATE:**  Dec.2017 | **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 - 00600, Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, 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 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Adopted In - House Method | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 4.2 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In - House Method | Not Less than 75.0% [n=6] | 98.5% (RSD=2.9%; n=6) | **COMPLIES** |
| **Assay** | HPLC | Adopted In - House Method | 90.0 - 110.0% | 100.7% (RSD=0.3%; n=9) | **COMPLIES** |

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

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| ANALYST: | DR. L. KARANJA |  | DATE:15-02-2016 |
| REVIEWER: | DR. E. TANUI |  | DATE:15-02-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:02-16-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:02-22-2016 |