**CERTIFICATE OF ANALYSIS**

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

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | EBASTEL 20 mg TABLETS | | REF. NO: NDQD201508172 |
| **DATE RECEIVED:** 11.08.2015 | **LABEL CLAIM:** | Composition per tablet; Ebastine (INN) 20 mg,Excipients( cont. lactose), q.s. | |
| **BATCH NO.:** 508K | **PRESENTATION:** | White coloured, circular shaped, biconvex faced tablets, embossed 'E & 20' on one face and plain on the other, packed in a blister strip of 10 tablets and 2 such strips in a unit box. | |
| **MGF. DATE:** Apr. 2015 | **MANUFACTURER:** | Industrias Farmaceuticas Almirall, S.A. | |
| **EXP. DATE:** Apr.2018 | **ADDRESS:** | Barcelona, SPAIN. | |
| **CLIENT REF NO:** | **CLIENT:** | Harleys Limited | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2012 Vol. V App XII C | NMT 2 tablets deviate by more than 5% from mean weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's 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; 8.7 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | Manufacturer's In House Method | No tablet less than 90.0% | 94.8% (RSD = 2.4%, n=6) | **COMPLIES** |
| **Assay** | HPLC | Manufacturer's In House Method | 90.0 - 110.0% | 99.1% (RSD = 0.5%, n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | DR. L. KARANJA |  | DATE:18-12-2015 |
| ANALYST: | DR. S. MUTERU |  | DATE:18-12-2015 |
| ANALYST: | ERNEST MBAE |  | DATE:12-18-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-12-2016 |