**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/492

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | CETIRIZINE TABLETS I.P. | | REF. NO: NDQA201509404 |
| **DATE RECEIVED:** 30.09.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Cetirizine Hydrochloride I.P. 10 mg. | |
| **BATCH NO.:** LT41227 | **PRESENTATION:** | Off white coloured, caplet shaped, biconvex faced tablets, single scored on one face plain on the other, packed in a blister strip of 70 tablets and 10 such strips in a unit box. | |
| **MGF. DATE:** Mar.2015 | **MANUFACTURER:** | OMEGA Biotech Ltd. | |
| **EXP. DATE:**  Aug.2017 | **ADDRESS:** | 7th Mile Stone, Dehradun Road, Roorkee-247667, (Uttarakhand), INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 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 mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 2731 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 7.8 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 2731 | Average NLT 80% and no single tablet is less than 65% (n=12) |  | **DOES NOT COMPLY:DOES NOT COMPLY** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 2731 | Average NLT 80% and no single tablet is less than 65% (n=12) | 48.6% (RSD=21.2%; n=12) | **DOES NOT COMPLY:DOES NOT COMPLY** |
| **Assay** | HPLC | USP 38 NF 33 Page 2731 | 90.0 % - 110.0% | 94.6% (RSD=1.4%; n=9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  | DATE: |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-12-2016 |