**CERTIFICATE OF ANALYSIS**

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

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | 0 | | REF. NO: NDQD201505254 |
| **DATE RECEIVED:** 26.05.2015 | **LABEL CLAIM:** | Composition; Each film coated tablets contains; Telmisartan 40 mg,Hydrochlorothiazide BP 12.5mg. | |
| **BATCH NO.:** KS01 501 | **PRESENTATION:** | White coloured, circular shaped, flat faced tablets, plain on both faces and packed in a blister strips of 10 tablets and 3 such strips in a unit box. | |
| **MGF. DATE:** Jan. 2015 | **MANUFACTURER:** | ATOZ Pharmaceuticals Pvt. Ltd. | |
| **EXP. DATE:** Dec.2016 | **ADDRESS:** | Chennai, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | PHARMA SPECIALITIES Ltd P.O. Box 49146- 00100 GPO, Nairobi | |
|  | **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 Deviates | **COMPLIES** |
| **Identification** | HPLC | U.S.P. 38 N.F. 33 Vol. 3 Page 5474 | RT of the Component peaks in the assay sample preparation correspond to that in the assay standard preparation | Super-imposable peaks at RT 4.2, 10.6 Ãƒâ€šÃ‚Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | :HPLC | U.S.P. 38 N.F. 33 Vol. 3 Page 5474 | No Tablet Less Than 85% [n=6] | Telmisartan; 89.8% (RSD = 0.6% ; n = 6) | **COMPLIES:** |
| **Dissolution** | :HPLC | U.S.P. 38 N.F. 33 Vol. 3 Page 5474 | No Tablet Less Than 85% [n=6] | Hydrochlorothiazide; 87.5% (RSD = 0.7% ; n = 6) | **COMPLIES:** |
| **Assay** | :HPLC | U.S.P. 38 N.F. 33 Vol. 3 Page 5474 | 95-105% 90-107.5% | Telmisartan; 100.0% (RSD = 0.4% ; n = 9) | **COMPLIES:COMPLIES** |
| **Assay** | :HPLC | U.S.P. 38 N.F. 33 Vol. 3 Page 5474 | 95-105% 90-107.5% | Hydrochlorothiazide; 103.3% (RSD = 1.4% ; n = 9) | **COMPLIES:COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| ANALYST: | DR. E. MUTUA |  | DATE:05-08-2015 |
| REVIEWER: | DR. E. MBAE |  | DATE:11-09.2015 |
| ANALYST: | SERAH MUTERU |  | DATE:09-17-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:09-29-2015 |