**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**

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| **PRODUCT** | TELMI 80 H TABLETS | | **REF. NO: NDQA201508086** |
| **DATE RECEIVED:** 06.08.2015 | **LABEL CLAIM:** | Each uncoated tablet contains: Telmisartan 80 mg and Hydrochlorothiazide USP 12.5 mg | |
| **BATCH NO.:** KN745 | **PRESENTATION:** | Off white coloured, flat-faced, circular shaped, bevel edged tablets, single scored on one face but plain on the other, packed in aluminium foil blister strips contained in a box carrying 3 strips of 10 tablets each. | |
| **MGF. DATE:** Dec. 2014 | **MANUFACTURER:** | PRISM Life Sciences Ltd. | |
| **EXP. DATE:** Nov. 2017 | **ADDRESS:** | 122/1, Ravi. Ind. Estate, Bileshwarpura, Chatral, Dist. Gandhinagar (Gujarat), INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Friability, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Identification** | HPLC | USP 38 NF 33 Page 5474 | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 3.2 and 8.1 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 5474 | No tablet less than 85% | Telmisartan 90.5% (RSD = 2.0%; n=6) Hydrochlorthiazide 89.7% (RSD = 1.8%; n=6) | **COMPLIES** |
| **Friability** | Weight | BP 2016 Vol. V App. XVII G | NMT 1.0% | 0.3% | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5474 | Telmisartan 95 - 105% Hydrochlorthiazide 90 - 107.5% | Telmisartan 103.4% (RSD = 0.8%; n=9) Hydrochlorthiazide 102.0% (RSD = 1.3%; n=9) | **COMPLIES** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App. XII C | NMT 2 tablets deviate by more than 5% from mean weight | None Deviates | **COMPLIES** |

**CONCLUSION:** The sample complies with the specifications of the tests performed.

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| **ANALYST:** | LORNA WANGARI | .......................................................... | DATE: 10-27-2015 |
| **REVIEWER:** | SERAH MUTERU | .......................................................... | DATE: 12-15-2015 |
| **DIRECTOR:** | H. K. CHEPKWONY | .......................................................... | DATE: 12-23-2015 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 12-23-2015 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 01-15-2016 |