**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/681

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| **PRODUCT** | DILUR R 4 mg TABLETS | | REF. NO: NDQD201605906 |
| **DATE RECEIVED:** 05.05.2016 | **LABEL CLAIM:** | Each tablet contains Doxazosina 4 mg. | |
| **BATCH NO.:** M132316 | **PRESENTATION:** | Off white coloured, rhomboid shaped, biconvex faced, sharp edged tablets, single scored on one face and embossed '4' on the other, packed in a blister strip of 10 tablets. | |
| **MGF. DATE:** Jul. 2013 | **MANUFACTURER:** | PROSPA Italia Srl. | |
| **EXP. DATE:**  Jul. 2016 | **ADDRESS:** | PROSPA Italia S.r.l c/o MEDA Pharma Ltd. P.O Box19226-00100- Nairobi, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | MEDA Pharma Ltd. P.O Box 19226-00100 Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Uniformity of Content, 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 7.5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Uniformity of Content** | Weight | USP 38 NF 33 Page 3210 | Not more than 1 unit is less than 85% or greater than 115% of the average tablet content. Acceptance Value of the 10 dosage units is < 15 | AV = 7 | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 3210 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 5.2 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Page 3210 | No tablet less than 75% [n = 6] | 82.4% (RSD=4.0%, n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 3210 | 90.0% - 110.0% | 100.4% (RSD=0.7%, n=6) | **COMPLIES** |

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

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| ANALYST: | DR. E. MUTUA |  | DATE:19-05-2016 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:20-05-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:05-31-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:06-08-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:06-08-2016 |