**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/55

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| **PRODUCT** | ZEALARGY TABLETS 10 mg | | **REF. NO: NDQD201604886** |
| **DATE RECEIVED:** 2016-04-28 | **LABEL CLAIM:** | Each uncoated tablet contains: Rupatadine Fumarate equivalent to Rupatadine10 mg. | |
| **BATCH NO.:** 13/044/010 | **PRESENTATION:** | Light pink coloured, circular shaped, biconvex faced tablets, packed in a box carrying 3 blister packs of 10 tablets each. | |
| **MFG. DATE:** Apr 2015 | **MANUFACTURER:** | CADILA Pharmaceuticals Limited. | |
| **EXP. DATE:**  Mar 2017 | **ADDRESS:** | 1389, Dholka - 387 810, INDIA | |
| **CLIENT REF NO:** | **CLIENT:** | Cadila pharmaceuticals E.A. P.O. Box 79642-00200 Nairobi, KENYA | |
| - | **TEST(S) REQUESTED:** | Uniformity of Content, Identification, Dissolution, Assay | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Content** | HPLC | Adopted In - house Method | Acceptance Value (AV) of 10 dosage units is NMT 15% | AV=3 (n=10) | **COMPLIES** |
| **Identification** | HPLC | Adopted In - house Method | RT of the Major Peak in the sample preparation corresponds to that in the standard preparation | Super-imposable peak at RT 7.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Adopted In - house Method | No tablet less than 85% | Average = 94% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 90-98%, (RSD=3.3%, n=6) |  |
| **Assay** | HPLC | Adopted In - house Method | 95.0 - 105.0 % | 98.7% (RSD=0.7%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | LORNA WANGARI | .......................................................... | DATE: 06-03-2016 |
| **ANALYST:** | GEORGE WANG'ANG'A | .......................................................... | DATE: 07-11-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 07-21-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 08-15-2016 |