**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/769

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| **PRODUCT** | FORECOX TRAC TABLETS | | **REF. NO: NDQD2016061085** |
| **DATE RECEIVED:** 03.06.2016 | **LABEL CLAIM:** | Each film coated tablet contains Rifampicin BP 150 mg, Isoniazid BP 75 mg, Pyrazinamide BP 400 mg and Ethambutol Hydrochloride BP 275 mg. | |
| **BATCH NO.:** ERC6563A | **PRESENTATION:** | Beige coloured, caplet shaped, biconvex faced tablets, plain on both faces, packed in a blister strip of 28 tablets in a zip lock polythene bag. | |
| **MGF. DATE:** May 2015 | **MANUFACTURER:** | MACLEODS Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Apr. 2018 | **ADDRESS:** | Atlanta Arcade, Marol Church Road, Andheri (E), Mumbai - 400 059, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | National AIDS and STI Control Programme P. O. Box 19361, Nairobi, KENYA | |
| RHZE/01/07.03.2016/0135 | **TEST(S) REQUESTED:** | Uniformity of Weight, 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 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 5176 | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peak at RT 2.7,3.1, 3.7 and 6.4 -/+ 10% min. present in both the assay sample and standard preparationss | **COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 5176 | No tablet less than 80.0% [n=6] | Ethambutol hydrochloride 90.3% (RSD=0.8%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Isoniazid 88.5% (RSD=0.1%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Pyrazinamide 90.5% (RSD=0.1%, n=6) | **COMPLIES** |
| **Dissolution** |  |  |  | Rifampicin 89.4% (RSD=0.6%, n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5176 | 90.0% - 110.0% | Ethambutol hydrochloride 101.4% (RSD=1.2%, n=9) | **COMPLIES** |
| **Assay** |  |  |  | Isoniazid 104.3% (RSD=0.6%, n=6) | **COMPLIES** |
| **Assay** |  |  |  | Pyrazinamide 106.6% (RSD=1.8%, n=6) | **COMPLIES** |
| **Assay** |  |  |  | Rifampicin 97.4% (RSD=1.9%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | MR. M. SANGALE | .......................................................... | DATE: 14-06-2016 |
| **ANALYST:** | DR. E. TANUI | .......................................................... | DATE: 21-06-2016 |
| **ANALYST:** | NICHOLAS MWAURA | .......................................................... | DATE: 06-24-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 06-30-2016 |