**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/113

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| **PRODUCT** | ETHIONAMIDE TABLETS USP 250 mg | | **REF. NO: NDQD201508242** |
| **DATE RECEIVED:** 27.08.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Ethionamide 250 mg. | |
| **BATCH NO.:** PB50890 | **PRESENTATION:** | Orange coloured, circular shaped, biconvex faced tablets, plain on both faces, packed in blister strip of 10 tablets and 10 such strips in a unit box. | |
| **MFG. DATE:** May 2015 | **MANUFACTURER:** | CIPLA LTD | |
| **EXP. DATE:**  Apr. 2017 | **ADDRESS:** | MIDC Patalganga, M.S. 410 220, INDIA | |
| **CLIENT REF NO:** | **CLIENT:** | PHARMA SPECIALITIES Ltd P.O. Box 49146- 00100 GPO, Nairobi | |
|  | **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** | UV | USP 38 NF 33 Page 3411 | UV absorption spectra of the assay sample preparation exhibits an absorption maximum at 290 +/- 2 nm | UV absorption spectra of the assay sample preparation exhibited an absorption maximum at 290 +/- 2 nm. | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Page 3411 | No tablet less than 80% (n=6) | Average = 100% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 99 - 102% (RSD=1.1%, n=6) |  |
| **Assay** | UV | USP 38 NF 33 Page 3411 | 95.0 - 110.0% | 97.2% (RSD=1.2%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | DR. K. BOTA | .......................................................... | DATE: 12-05-2016 |
| **REVIEWER:** | DR. G. WANG'ANG'A | .......................................................... | DATE: 09-06-2016 |
| **ANALYST:** | DR. E. MBAE | .......................................................... | DATE: 07-04-2016 |
| **DIRECTOR:** | DR.H. K. CHEPKWONY | .......................................................... | DATE: 08-24-2016 |