**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/169

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | ISONIAZID TABLETS BP | | **REF. NO: NDQB201609118** |
| **DATE RECEIVED:** 27-09-2016 | **LABEL CLAIM:** | Each tablet contains: Isoniazid BP 300 mg. | |
| **BATCH NO.:** 60949 | **PRESENTATION:** | Off white coloured, circular shaped, flat faced, bevel edged tablets, single scored on one face and embossed 'COSMOS' on the other, packed in a blister strip of 10 tablets and 10 such strips in a printed box. | |
| **MFG. DATE:** Sep. 2016 | **MANUFACTURER:** | COSMOS Limited. | |
| **EXP. DATE:**  Aug. 2020 | **ADDRESS:** | Rangwe Rd; Off Lunga Lunga Rd., P. O. Box 41433-00100, Nairobi, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Medical Supplies Authority, P.O. Box 47715 - 00100, Nairobi, Kenya. | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 3955 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 1.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 page 3955 | No Tablet Less Than 85% | Average = 90% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 89 - 91% (RSD = 0.6%; n = 6) |  |
| **Assay** | HPLC | USP 38 NF 33 page 3955 | 90.0 - 110.0% | 92.4% (RSD = 0.6%; n = 9) | **COMPLIES** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | SARAH KARIUKI | .......................................................... | DATE: 09-28-2016 |
| **REVIEWER** | DR. GEORGE WANG'ANG'A | .......................................................... | DATE: 06-10-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 10-06-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 10-10-2016 |