**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/820

|  |  |  |  |
| --- | --- | --- | --- |
| **PRODUCT** | METROMAG(R) SUSPENSION | | **REF. NO: NDQD201506263** |
| **DATE RECEIVED:** 4-06-2015 | **LABEL CLAIM:** | Contains BP 7.5% w/v Magnesium Hydroxide. | |
| **BATCH NO.:** 20A02 | **PRESENTATION:** | White suspension for oral administration, contained in a 100 mL amber coloured glass bottle with a metallic cap in a unit box. | |
| **MGF. DATE:** Jan.2015 | **MANUFACTURER:** | HIGHTECH Pharmaceuticals and Research Ltd. | |
| **EXP. DATE:**  Jan.2018 | **ADDRESS:** | P.O Box 1850-00200, Nairobi, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | HIGHTECH Pharmaceuticals and Research Ltd. P.O Box 323-20100, Nakuru. | |
|  | **TEST(S) REQUESTED:** | Microbial Load, Assay, Acidity/Alkalinity | |

**RESULTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Assay** | Titration | USP38 NF33 Vol.3 Page 4174 | 90.0 - 115.0% | 95.7% (RSD=0.9% n=3) | **COMPLIES** |
| **Acidity/Alkalinity** | pH | BP 2016 Vol. V App. V L | - | 10.0 |  |
| **Microbial Load** | Plate Count | BP 2016 Vol. V App. XVI B | TAMC NMT 200 CFU/mL TYMC NMT 20 CFU/mL | 2715 CFU/mL 675 CFU/mL | **DOES NOT COMPLY** |

**CONCLUSION:** The sample fails to comply with the specifications for the microbial load test performed.

|  |  |  |  |
| --- | --- | --- | --- |
| **ANALYST:** | MR. E. NGAMAU | .......................................................... | DATE: 30-05-2016 |
| **ANALYST:** | MR. F. NAULA | .......................................................... | DATE: 30-05-2016 |
| **ANALYST:** | DR. E. MUTUA | .......................................................... | DATE: 30-05-2016 |
| **ANALYST:** | DR. G. WANG'ANG'A | .......................................................... | DATE: 30-05-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 06-22-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 07-18-2016 |