**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:**  CAN/2016-17/XYZ

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| **PRODUCT** | BIOTRIM SUSPENSION | | REF. NO: NDQA201509377 |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Contents: Trimethoprim BP 40 mg, Sulphamethoxazole BP 200 mg, Colour, Flavour, Excipients & Vehicle to 5 mL. | |
| **BATCH NO.:** 0814067 | **PRESENTATION:** | Pink coloured suspension for oral administration, contained in a 500 mL white high density plastic bottle. | |
| **MGF. DATE:** Aug. 2014 | **MANUFACTURER:** | BIODEAL Laboratories Ltd | |
| **EXP. DATE:** Jul. 2017 | **ADDRESS:** | P.O BOX 32040-00600, Nairobi, KENYA. | |
| **CLIENT REF NO:** | **CLIENT:** | Pharmacy and Poisons Board P.O. Box 27663-00506 Nairobi, KENYA | |
| COT/01/12.3.15/00174 | **TEST(S) REQUESTED:** | Microbial Load, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Microbial Load** | Plate Count Method | BP 2016 Vol. V Appendix XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/mL Total Combined Yeasts/Moulds Count (TYMC) NMT 20 CFU/mL | < 200 TAMC CFU/mL < 20 TYMC CFU/mL | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 5397-5398 | RT of the component peaks in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peaks at RT 3.6 and 9.2 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5397-5398 | 90.0 - 110.0% | Sulphamethoxazole 94.4% (RSD = 0.9%; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5397-5398 | 90.0 - 110.0% | Trimethoprim 92.7% (RSD = 0.8%; n=9) | **COMPLIES:COMPLIES** |
| **Acidity/Alkalinity** | pH | USP 38 NF 33 Page 5397-5398 | 5.0 - 6.5 | 5.5 | **COMPLIES** |

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

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| ANALYST: | FRANCIS NAULA |  | DATE:22-01-2016 |
| ANALYST: | JOYFRIDA CHEPCHUMBA |  | DATE:22-01-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:22-01-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:01-26-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-26-2016 |