**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | BIOTRIM TABLETS | | REF. NO: NDQA201509394 |
| **DATE RECEIVED:** 29.09.2015 | **LABEL CLAIM:** | Each tablet contains Trimethoprim 80 mg and Sulfamethoxazole 400 mg | |
| **BATCH NO.:** 0714069 | **PRESENTATION:** | White circular shaped, flat-faced, bevel-edged tablets, embossed "BIOTRIM" on one face and plain on the other, loOsely packed in a polythene dispensing envelope. | |
| **MGF. DATE:** Jul. 2014 | **MANUFACTURER:** | BIODEAL Laboratories Ltd. | |
| **EXP. DATE:** Jun. 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/2/18/02/2015/00373 | **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 weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 5399 | 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** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 5399 | :No tablet is less than 75% [n=6] | Sulphamethoxazole 95.9% (RSD = 4.7%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | USP 38 NF 33 Page 5399 | :No tablet is less than 75% [n=6] | Trimethoprim 100.7% (RSD = 4.3%; n=6) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5399 | 93.0 - 107.0% | Sulphamethoxazole 99.4% (RSD = 0.3%; n=9) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 5399 | 93.0 - 107.0% | Trimethoprim 101.1% (RSD = 0.7%; n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | LORNA WANGARI |  | DATE:22-01-2016 |
| REVIEWER: | NICHOLAS MWAURA |  | DATE:22-01-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:01-26-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-26-2016 |