**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/615

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| **PRODUCT** | BIOPOLIO R VACCINE | | REF. NO: NDQD201512584 |
| **DATE RECEIVED:** 03.12.2015 | **LABEL CLAIM:** | 1 dose = 0.1 mL (2 drops) contains Poliovirus ( Sabin) PMKCC. Type 1 ? 10 6.0 CCID 50, Type 2 ? 10 5.0 CCID 50, Type 3 ? 10 5.8 CCID 50, Neomycin Sulphate USP 15 ug and Kanamycin Sulphate USP 15 ug. | |
| **BATCH NO.:** 63AS05015100 | **PRESENTATION:** | Light pink coloured solution for oral administration, contained in a clear glass vial fitted with a grey rubber closure, aluminum band and 25 such vials packed in a box. | |
| **MGF. DATE:** Jun. 2015 | **MANUFACTURER:** | BHARAT Biotech International Ltd. | |
| **EXP. DATE:**  May. 2017 | **ADDRESS:** | Genome Valley, Shameerpet Mandal, Ranga ReddyDistrict 500 078, Telangana INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Kenya Expanded Programme on Immunization | |
|  | **TEST(S) REQUESTED:** | Identification | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Identification** | HPLC | USP 38 NF 33 Page 3375 | RT of the Component Peaks in the assay sample preparation correspond to those in the assay standard preparation | No Super-imposable peak at RT 6.0 & 8.0 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |

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

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| ANALYST: | MR. M. SANGALE |  | DATE:04-01-2016 |
| ANALYST: | DR. M. KWENA |  | DATE:06-04-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:05-09-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-12-2016 |