**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | FAST 125mg SUPPOSITORIES | | REF. NO: NDQD201511540 |
| **DATE RECEIVED:** 10.11.2015 | **LABEL CLAIM:** | Each suppository contains Paracetamol BP 125 mg. | |
| **BATCH NO.:** S0014062 | **PRESENTATION:** | Off white coloured, bullet shaped suppositories for rectal use only packed in blister strips of 5 suppositories and 2 such trips in a unit box. | |
| **MGF. DATE:** Nov. 2014 | **MANUFACTURER:** | The ACME Laboratories Ltd. | |
| **EXP. DATE:**  Nov. 2016 | **ADDRESS:** | Dhaka, BANGLADESH. | |
| **CLIENT REF NO:** | **CLIENT:** | HEMANGI DANGI P.O BOX 32982-00600 NAIROBI | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Microbial Load, Identification, Disintegration, 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 suppositories deviate by more than 5% from mean weight | None Deviates | **COMPLIES** |
| **Microbial Load** | Microbial Load | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) 200 CFU/g :Total Combined Yeasts /Moulds Count (TYMC) 20 CFU/g | < 10 TAMC CFU/g | **COMPLIES:COMPLIES** |
| **Microbial Load** | Microbial Load | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) 200 CFU/g :Total Combined Yeasts /Moulds Count (TYMC) 20 CFU/g | < 10 TYMC CFU/g | **COMPLIES:COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 page 2008 | RT of the component peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 4.3 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Disintegration** | Disintegration | BP 2016 Vol. V App XII A | Not more than 30 minutes [n=6] | All suppositories disintegrate in 16 minutes | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 page 2008 | 90.0-110.0% | 97.4% (RSD=1.3%, n=9) | **COMPLIES** |

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

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| ANALYST: | MR. F. NAULA |  | DATE:30-11-2015 |
| ANALYST: | DR. E. MUTUA |  | DATE:01-02-2016 |
| ANALYST: | DR. E. TANUI |  | DATE:15-02-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:02-16-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:02-22-2016 |