**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | FAST 250mg SUPPOSITORIES | | REF. NO: NDQD201511541 |
| **DATE RECEIVED:** 10.11.2015 | **LABEL CLAIM:** | Each suppository contains Paracetamol BP 250 mg. | |
| **BATCH NO.:** S0024062 | **PRESENTATION:** | Off white coloured bullet shaped suppositories for rectal use only packed in a blister strip of 5 suppositories and 2 such strips in a unit box | |
| **MGF. DATE:** Nov. 2014 | **MANUFACTURER:** | The ACME Laboratories Ltd. | |
| **EXP. DATE:**  Nov. 2016 | **ADDRESS:** | Dhaka, BANGLADESH. | |
| **CLIENT REF NO:** | **CLIENT:** | Highridge Pharmaceuticals Ltd. P. O. Box 32982 - 00600, Nairobi, KENYA. | |
|  | **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** | Plate Count | USP 38 NF 33 Pg 2008 | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/g :Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/g | < 10 TAMC CFU/g | **COMPLIES:COMPLIES** |
| **Microbial Load** | Plate Count | USP 38 NF 33 Pg 2008 | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/g :Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/g | < 10 TYMC CFU/g | **COMPLIES:COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Pg 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 | B.P. 2016 Vol. V App XII A | Not more than 30 minutes [n=6] | 16 min. 40 sec. | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Pg 2008 | 90.0 - 110.0% | 92.6% (RSD=0.3%; 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 |
| REVIEWER: | DR. E. TANUI |  | DATE:15-02-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:02-16-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:02-22-2016 |