**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/840

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| **PRODUCT** | MARIPRIST TABLETS | | REF. NO: NDQD201512572 |
| **DATE RECEIVED:** 01.12.2015 | **LABEL CLAIM:** | Each blister pack contains a light yellow uncoated tablet containing Mifepristone 200 mg and a white uncoated tablet containing Misoprostol 200 mcg | |
| **BATCH NO.:** MAR150604 | **PRESENTATION:** | One light yellow coloured, flat-faced, circular shaped, bevel edged tablet, single scored on one face and plain on the other, co-packed with 4 white caplet shaped, biconvex faced tablets in a blister strip in a combipack box and 10 such boxes in a bigger box. | |
| **MGF. DATE:** Jun. 2015 | **MANUFACTURER:** | ACME Formulation Pvt. Ltd. | |
| **EXP. DATE:**  May 2017 | **ADDRESS:** | Ropar Road, Nalagarh, Dist. Solan, Himachal Pradesh 174 101, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | PHARM ACCESS AFRICA P.O Box 21507-00505, Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Uniformity of Content, 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 the mean Mifepristone tablet weight | None Deviates | **COMPLIES** |
| **Uniformity of Content** | HPLC | Manufacturer's In-House Method | Acceptance Value (AV) of 10 Misoprostol tablets is NMT 15% | AV = 8 [n=10] | **COMPLIES** |
| **Identification** | HPLC:UV | Manufacturer's In-House Method | Misoprostol RT of the component peak in the assay sample preparation corresponds to that in the assay standard preparation:Mifepristone UV absorption spectra of the assay sample preparation exhibits a maxima at wavelength 303.5 +/- 2 nm corresponding to that in the assay standard preparation. | Super-imposable peak at RT 5.3 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES:COMPLIES** |
| **Identification** | HPLC:UV | Manufacturer's In-House Method | Misoprostol RT of the component peak in the assay sample preparation corresponds to that in the assay standard preparation:Mifepristone UV absorption spectra of the assay sample preparation exhibits a maxima at wavelength 303.5 +/- 2 nm corresponding to that in the assay standard preparation. | UV absorption spectra of the assay sample preparation exhibited a maxima at wavelength 304.9 nm. | **COMPLIES:COMPLIES** |
| **Dissolution** | UV:HPLC | Manufacturer's In-House Method | Mifepristone No tablet less than 75% [n=6]:Misopristol No tablet less than 85% [n=6] | Average 95%; Range | **COMPLIES** |
| **Dissolution** | UV:HPLC | Manufacturer's In-House Method | Mifepristone No tablet less than 75% [n=6]:Misopristol No tablet less than 85% [n=6] | 94% - 98%; (RSD=1.6%; n=6) | **COMPLIES** |
| **Dissolution** | UV:HPLC | Manufacturer's In-House Method | Mifepristone No tablet less than 75% [n=6]:Misopristol No tablet less than 85% [n=6] | Average 98%; Range | **COMPLIES** |
| **Dissolution** | UV:HPLC | Manufacturer's In-House Method | Mifepristone No tablet less than 75% [n=6]:Misopristol No tablet less than 85% [n=6] | 86% - 108%; (RSD=8.0%; n=6) | **COMPLIES** |
| **Assay** | UV:By Uniformity of | Manufacturer's In-House Method | 90.0 -110.0% | Mifepristone 95.8% (RSD=0.8%, n=9) | **COMPLIES** |
| **Assay** | UV:By Uniformity of | Manufacturer's In-House Method | 90.0 -110.0% | Misopristol 104.5% (RSD=2.0%, n=10) | **COMPLIES** |

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

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| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:28-06-2016 |
| ANALYST: | DR. N. MWAURA |  | DATE:04-07-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:07-18-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:07-20-2016 |