**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/261

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| **PRODUCT** | UNIBROM EYE DROPS | | **REF. NO: NDQD201507004** |
| **DATE RECEIVED:** 02.07.2015 | **LABEL CLAIM:** | Each mL contains: Bromfenac Sodium 1.035 mg equivalent to Bromfenac free acid 0.9 mg and Benzalkonium Chloride NF 0.005% w/v (As Preservative). | |
| **BATCH NO.:** CA0255A | **PRESENTATION:** | Yellow coloured solution for ophthalmic administration, contained in a white 5 mL plastic dropper bottle, packed in a unit box. | |
| **MFG. DATE:** Jan. 2015 | **MANUFACTURER:** | Ajanta Pharma Limited | |
| **EXP. DATE:**  Dec. 2016 | **ADDRESS:** | Ajanta House, Charkop, Kandivli (W), Mumbai 400 067, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Ajanta Pharma Ltd c/o Harleys Ltd, P.O Box 42718 - 00100 Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Sterility, Identification, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Sterility** | Membrane Filtration | BP 2016 Vol. V App. XVI A. | No microbial growth | No microbial growth | **COMPLIES** |
| **Identification** | HPLC | Adopted In-House Method | RT of the major peak in the assay sample preparations correspond to those in the assay standard preparation | Super-imposable peak at RT 6.1 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Identification** |  |  |  | Super-imposable peaks at RT 5.1 & 7.9 -/+ 10% min. present in both the assay sample and standard preparations |  |
| **Assay** | HPLC | Manufacturer's In-House Method | Bromfenac 95.0% - 115.0% | 119.7% (RSD = 2.1%; n=18) | **COMPLIES** |
| **Assay** |  |  | Benzalkonium Chloride 90.0 - 110.0% | 106.9% (RSD = 0.8%; n =9) | **COMPLIES** |
| **Acidity/Alkalinity** | pH | Manufacturer's In-House Method | 7.3 - 9.3 | 8.7 | **COMPLIES** |

**CONCLUSION:** The sample does not comply with the specifications for the assay of Bromfenac.

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| **ANALYST:** | DR. L. KARANJA | .......................................................... | DATE: 29-06-2016 |
| **ANALYST:** | DR. G. WANG'ANG'A | .......................................................... | DATE: 30-06-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 08-23-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 11-17-2016 |