**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | LUBTEAR EYE DROPS | | REF. NO: NDQD201507030 |
| **DATE RECEIVED:** 17.07.2015 | **LABEL CLAIM:** | Each mL contains: Dextran 70 USP 1 mg & Hypromellose USP 3 mg. Preservative: Benzalkonium Chloride BP 0.01%. | |
| **BATCH NO.:** 5044001 | **PRESENTATION:** | Clear colourless solution, contained in a 10 mL transparent plastic dropper bottle packed in a unit box. | |
| **MGF. DATE:** Apr. 2015 | **MANUFACTURER:** | SQUARE Pharmaceuticals Ltd. | |
| **EXP. DATE:** Mar. 2017 | **ADDRESS:** | Dhaka Unit, Kaliakoir, Gazipur, BANGLADESH. | |
| **CLIENT REF NO:** | **CLIENT:** | Ace Pharmaceuticals Ltd, P.O BOX 29787-00202, 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 | Manufacturer's In - House Method | RT of the Benzalkonium Component Peak in the assay sample preparation correspond to those in the assay standard preparation | Super-imposable peak at RT; 7.2 and 9.4 Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Assay** | Polarimetry/HPLC/ | Manufacturer's In - House Method | Dextran 70 and Hypromellose: 90.0 - 115.0% Benzalkonium Chloride: 90.0 - 110.0% | Dextran 70 | **COMPLIES** |
| **Assay** | Polarimetry/HPLC/ | Manufacturer's In - House Method | Dextran 70 and Hypromellose: 90.0 - 115.0% Benzalkonium Chloride: 90.0 - 110.0% | 101.3% (RSD = 0.00%; n=3) Hypromellose | **COMPLIES** |
| **Assay** | Polarimetry/HPLC/ | Manufacturer's In - House Method | Dextran 70 and Hypromellose: 90.0 - 115.0% Benzalkonium Chloride: 90.0 - 110.0% | 110.1% (RSD = 0.3%; n=9) Benzalkonium Chloride | **COMPLIES** |
| **Assay** | Polarimetry/HPLC/ | Manufacturer's In - House Method | Dextran 70 and Hypromellose: 90.0 - 115.0% Benzalkonium Chloride: 90.0 - 110.0% | 93.5% (RSD = 0.9%; n=9) | **COMPLIES** |
| **Acidity/Alkalinity** | pH | Manufacturer's In - House Method | 6.0 - 7.0 | 6.2 | **COMPLIES** |

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

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| ANALYST: | MR. F. NAULA |  | DATE:15-01-2016 |
| ANALYST: | DR. L. KARANJA |  | DATE:15-01-2016 |
| ANALYST: | DR. S. MUTERU |  | DATE:15-01-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:01-18-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-21-2016 |