**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/491

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| **PRODUCT** | NEXUM(R) 40 INJECTION | | REF. NO: NDQD201510424 |
| **DATE RECEIVED:** 08.10.2015 | **LABEL CLAIM:** | Each vial contains Esomeprazole 40 mg (as lyophilized powder of Esomeprazole Sodium INN) and each ampoule contains 0.9% Sodium Chloride injection BP 5 mL. | |
| **BATCH NO.:** 505001 | **PRESENTATION:** | Off white coloured, lyophilized powder for intravenous administration, contained in a clear glass vial fitted with a pink flip off cap, packed along with a clear colourless solution of sodium chloride in a 5 mL clear colourless glass ampoule on a blister rack in a unit box. | |
| **MGF. DATE:** May 2015 | **MANUFACTURER:** | SQUARE Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Apr.2017 | **ADDRESS:** | BANGLADESH. | |
| **CLIENT REF NO:** | **CLIENT:** | Ace Pharmaceuticals Ltd, P.O BOX 29787-00202, Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Sterility, Identification, Bacterial Endotoxin, Assay, Acidity/Alkalinity | |

**RESULTS**

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | BP 2016 Vol. V App. XII C | NMT 2 vial contents deviate by more than 10% from mean content weight | None Deviates | **COMPLIES** |
| **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 Major Peak in the sample preparation corresponds to that in the standard preparation | Super-imposable peak at RT; 8.2 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Bacterial Endotoxin** | pH | Manufacturer's In-House Method | 9.0 - 12.0 | 11.1 | **COMPLIES** |
| **Assay** | LAL | Method BP 2016 Vol. III Page 1119 Manufacturer's In-House | Sodium Chloride; NMT 0.25 EU/mL Esomeprazol; NMT 5 EU/mg | 2.6 x 10-4 EU/mL 2.8 x 10-3 EU/mg | **COMPLIES** |
| **Acidity/Alkalinity** | HPLC Titration | Manufacturer's In-House Method BP 2016 Vol. III Page 1119 | Esomeprazole; 90.0% - 110.0% Sodium Chloride; 95.0% - 105.0% | Esomeprazole 107.0% (RSD=0.3%; n=9) Sodium Chloride 98.5% (RSD=0.8%; n=3) | **COMPLIES** |

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

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| ANALYST: | MR. E. NGAMAU |  | DATE:29-03-2016 |
| ANALYST: | DR. E. MUTUA |  | DATE:29-03-2016 |
| ANALYST: | DR. G. WANG’ANG’A |  | DATE:29-03-2016 |
| ANALYST: | ERNEST MBAE |  | DATE:03-30-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:04-12-2016 |