**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/427

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| **PRODUCT** | PRAZIQUANTEL - 600 TABLETS USP | | REF. NO: NDQD201509259 |
| **DATE RECEIVED:** 08.09.2015 | **LABEL CLAIM:** | Each film coated tablet contains: Praziquantel USP 600 mg. | |
| **BATCH NO.:** 140005 | **PRESENTATION:** | White coloured, caplet shaped, biconvex faced tablets, single scored and engraved 'SHELYS' on one face and triple scored and engraved 'P600' on the other, packed in blister strips of 10 tablets and 10 such strips in a unit box. | |
| **MGF. DATE:** Aug. 2014 | **MANUFACTURER:** | SHELYS Pharmaceuticals Ltd. | |
| **EXP. DATE:**  Jul. 2018 | **ADDRESS:** | Plot No. 696, New Bagamoyo Road, Mwenge, P.O. Box 3016, Dar es salaam, TANZANIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Beta Healthcare International Ltd P. O. Box 42569-00100, Nairobi, KENYA | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Microbial Load, 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 mean tablet weight | None Deviates | **COMPLIES** |
| **Microbial Load** | Plate count | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/g : Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/g | < 10 CFU/g | **COMPLIES:COMPLIES** |
| **Microbial Load** | Plate count | BP 2016 Vol. V App. XVI B | Total Aerobic Microbial Count (TAMC) NMT 200 CFU/g : Total Combined Yeasts /Moulds Count (TYMC) NMT 20 CFU/g | < 10 CFU/g | **COMPLIES:COMPLIES** |
| **Identification** | HPLC | USP 38 NF 33 Page 4969 | RT of the major peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 9.8 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | USP 38 NF 33 Page 4969 | No tablet less than 80% (n=6) | 93.8% (RSD=6.4%; n=6) | **COMPLIES** |
| **Assay** | HPLC | USP 38 NF 33 Page 4969 | 90.0 - 110.0% | 93.5% (RSD=1.5%; n=9) | **COMPLIES** |

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

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| ANALYST: | MR. F. NAULA |  | DATE:28-09-2015 |
| ANALYST: | DR. J. CHEPCHUMBA |  | DATE:22-02-2016 |
| ANALYST: | DR. S. MUTERU |  | DATE:24-02-2016 |
| ANALYST: | NICHOLAS MWAURA |  | DATE:03-07-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:03-09-2016 |