**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2015-16/644

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| **PRODUCT** | D-ARTEPP R DISPERSIBLE TABLETS | | REF. NO: NDQD201507026 |
| **DATE RECEIVED:** 30.07.2015 | **LABEL CLAIM:** | Dihydroartemesinin 40 mg/Piperaquine Phosphate 320 mg Dispersible Tablets. | |
| **BATCH NO.:** SQ150304 | **PRESENTATION:** | Off white coloured, circular shaped, biconvex faced tablets, single scored on one face and embossed 'D' on the other, packed in a blister strip of 3 tablets and 2 such strips in a unit box. | |
| **MGF. DATE:** Mar. 2015 | **MANUFACTURER:** | GUILIN Pharmaceutical Co. Ltd. | |
| **EXP. DATE:**  Mar. 2017 | **ADDRESS:** | No.43 Qilidian Road, Guilin 541004, Guangxi, CHINA. | |
| **CLIENT REF NO:** | **CLIENT:** | PHARMA SPECIALITIES Ltd P.O. Box 49146- 00100 GPO, Nairobi | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Disintegration, 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 weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's In-House Method | RT of the Component Peaks in the sample preparation correspond to those in the standard preparation | Super-imposable peaks at RT 4.3, 5.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | No tablet less than 65% [n=6] No tablet less than 80% [n=6] | Dihydroartemisinin 96.1% (RSD=0.5%; n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC | Manufacturer's In-House Method | No tablet less than 65% [n=6] No tablet less than 80% [n=6] | Piperaquine Phosphate 88.1% (RSD=1.0%;n=6) | **COMPLIES:COMPLIES** |
| **Disintegration** | Disintegration | BP 2016 Vol. V App. XVI A | All Tablets disintegrate within 30 minutes [n=6] | All Tablets disintegrated within 5 minutes | **COMPLIES** |
| **Assay** | HPLC | Manufacturer's In-House Method | Dihydroartemisinin 90.0 - 110.0 % :Piperaquine Phosphate 93.0 - 107.0 % | 97.1% (RSD=1.9%;n=7) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC | Manufacturer's In-House Method | Dihydroartemisinin 90.0 - 110.0 % :Piperaquine Phosphate 93.0 - 107.0 % | 105.1% (RSD=0.9%;n=9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. S. MWANGI |  | DATE:18-05-2016 |
| ANALYST: | DR. G. WANG'ANG'A |  | DATE:18-05-2016 |
| ANALYST: | EMMANUEL TANUI |  | DATE:05-19-2016 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:05-24-2016 |