**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | D-ARTEPP DISPERSIBLE TABLETS | | REF. NO: NDQD201507025 |
| **DATE RECEIVED:** 16.07.2015 | **LABEL CLAIM:** | Dihydroartemisinin/Piperaquine Phosphate 20 mg/160mg. | |
| **BATCH NO.:** SQ150307 | **PRESENTATION:** | White coloured, circular shaped, biconvex faced tablets, single scored on one face and embossed 'D' on the other, packed in a aluminium blister strip of 3 tablets and 2 such strips in a unit box. | |
| **MGF. DATE:** 16. Mar. 2015 | **MANUFACTURER:** | GUILIN Pharmaceutical Co. Ltd. | |
| **EXP. DATE:** 15. Mar. 2017 | **ADDRESS:** | No.43 Qilidian Road, Guilin 541004, Guangxi, Distr.:Guilin Pharmaceutical (Shanghai) Co., Ltd. ( GPSC). 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 2012 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 assay sample preparation correspond to those in standard preparation | Super-imposable peaks at RT 4.3 and 5.5 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | HPLC:UV | Manufacturer's In-House Method:Manufacturer's In-House Method | Dihydroartemisinin: No Tablet Less than 65% [n=6] Piperaquine Phosphate: No Tablet Less than 80% [n=6] | Dihydroartemisinin; | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:UV | Manufacturer's In-House Method:Manufacturer's In-House Method | Dihydroartemisinin: No Tablet Less than 65% [n=6] Piperaquine Phosphate: No Tablet Less than 80% [n=6] | 73.2% (RSD = 2.9%, n=6) | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:UV | Manufacturer's In-House Method:Manufacturer's In-House Method | Dihydroartemisinin: No Tablet Less than 65% [n=6] Piperaquine Phosphate: No Tablet Less than 80% [n=6] | Piperaquine Phosphate | **COMPLIES:COMPLIES** |
| **Dissolution** | HPLC:UV | Manufacturer's In-House Method:Manufacturer's In-House Method | Dihydroartemisinin: No Tablet Less than 65% [n=6] Piperaquine Phosphate: No Tablet Less than 80% [n=6] | 86.8% (RSD = 0.7%, n=6) | **COMPLIES:COMPLIES** |
| **Disintegration** | Disintegration | Manufacturer's In-House Method | All Tablets disintegrate within 3 minutes [n=6] | All Tablets disintegrated in 40 seconds | **COMPLIES** |
| **Assay** | HPLC:HPLC | Manufacturer's In-House Method:Manufacturer's In-House Method | 90.0 - 110.0 %:93.0 - 107.0% | Dihydroartemisinin; 106.2% (RSD=1.9%, n=8) | **COMPLIES:COMPLIES** |
| **Assay** | HPLC:HPLC | Manufacturer's In-House Method:Manufacturer's In-House Method | 90.0 - 110.0 %:93.0 - 107.0% | Piperaquine Phosphate; 106.0% (RSD = 1.9%, n=8) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | DR. S. MWANGI |  | DATE:08-12-2015 |
| ANALYST: | DR.G. WANG'ANG'A |  | DATE:08-12-2015 |
| ANALYST: | ERNEST MBAE |  | DATE:12-09-2015 |
| DIRECTOR: |  |  | DATE:01-12-2016 |