**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | DUO - ARTEPEP TABLTES | | REF. NO: NDQD201507016 |
| **DATE RECEIVED:** 2015-07-09 | **LABEL CLAIM:** | Each film coated tablet contains Dihydroartemisinin 40 mg and Piperaquine Phosphate 320 mg, Excipient q.s. | |
| **BATCH NO.:** DDZ1402 | **PRESENTATION:** | Blue coloured, circular shaped, biconvex faced tablets, plain on both faces, packed in a blister strip of 9 tablets in a unit box | |
| **MGF. DATE:** Dec.2014 | **MANUFACTURER:** | CORAL Laboratories Ltd. | |
| **EXP. DATE:** Nov.2017 | **ADDRESS:** | Plot No.57/1(18)Bhenslora, Dunetha Nani Daman - 396210, INDIA. | |
| **CLIENT REF NO:** | **CLIENT:** | Signature Healthcare Ltd P.O. Box 66172- 00800 NBI | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, Identification, Dissolution, Assay | |

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| **TEST** | **METHOD** | **COMPEDIA** | **SPECIFICATION** | **DETERMINED** | **REMARKS** |
| **Uniformity of Weight** | Weight | B.P. 2012. Vol. V APP XII C | < 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's In-House Method | RT of the Component peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 8.4, 9.7 Ãƒâ€šÃ‚Â± 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | ::HPLC:: | Manufacturer's In-House Method | No tablet less than 70.0% | Dihydroartemesinin 88.2% (RSD = 6.7% ; n = 6) | **COMPLIES:COMPLIES** |
| **Dissolution** | ::HPLC:: | Manufacturer's In-House Method | No tablet less than 70.0% | Piperaquine Phosp 92.9% (RSD = 0.2% ; n = 6) | **COMPLIES:COMPLIES** |
| **Assay** | ::HPLC:: | Manufacturer's In-House Method | 90 - 110% | Dihydroartemesinin 106.6% (RSD = 0.9% ; n = 9) | **COMPLIES:COMPLIES** |
| **Assay** | ::HPLC:: | Manufacturer's In-House Method | 90 - 110% | Piperaquine Phosp 99.0% (RSD = 1.1% ; n = 9) | **COMPLIES:COMPLIES** |

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

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| ANALYST: | MR. M. SANGALE |  | DATE:17-08-2015 |
| REVIEWER: | DR. E. MBAE |  | DATE:04-09-2015 |
| ANALYST: | SERAH MUTERU |  | DATE:09-07-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:09-11-2015 |