**CERTIFICATE OF ANALYSIS**

**CERTIFICATE No:** CAN/2016-2017/124

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| **PRODUCT** | HEPCINAT 400 TABLET | | **REF. NO: NDQD201602746** |
| **DATE RECEIVED:** 2016-02-04 | **LABEL CLAIM:** | Each film coated tablet contains: Sofosbuvir 400 mg | |
| **BATCH NO.:** 406273 | **PRESENTATION:** | Brown coloured, caplet shaped, biconvex faced tablets, embossed '400' on one face and plain on the other, 28 tablet packed in a white plastic multi - dose container in a unit box. | |
| **MFG. DATE:** Sep. 2015 | **MANUFACTURER:** | NATCO Pharma Limited | |
| **EXP. DATE:**  Aug. 2017 | **ADDRESS:** | Kothur - 509 228, Mahaboobnagar District Telangana, INDIA | |
| **CLIENT REF NO:** | **CLIENT:** | PHARMA SPECIALITIES Ltd, P.O. Box 49146 - 00100 GPO, Nairobi, KENYA. | |
|  | **TEST(S) REQUESTED:** | Uniformity of Weight, 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 weight | None deviates | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's In - house Method | RT of the Major Peak in the assay sample preparation corresponds to that in the assay standard preparation | Super-imposable peak at RT 5.4 -/+ 10% min. present in both the assay sample and standard preparations | **COMPLIES** |
| **Dissolution** | UV | Manufacturer's In - house Method | No tablet less than 85% [n=6] | Average = 99% Range | **COMPLIES** |
| **Dissolution** |  |  |  | 99 - 100% (RSD=1.1%, n=6) |  |
| **Assay** | HPLC | Manufacturer's In - house Method | 90.0 - 110.0% | 98.8% (RSD=0.4%, n=9) | **COMPLIES** |

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

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| **ANALYST:** | LORNA WANGARI | .......................................................... | DATE: 06-03-2016 |
| **ANALYST:** | MICHAEL SANGALE | .......................................................... | DATE: 06-15-2016 |
| **ANALYST:** | ERNEST MBAE | .......................................................... | DATE: 09-28-2016 |
| **DIRECTOR:** | HEZEKIAH CHEPKWONY | .......................................................... | DATE: 09-29-2016 |