**CERTIFICATE OF ANALYSIS**

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

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| **PRODUCT** | BIORAN RAPID DISPERSIBLE TABLETS | | REF. NO: NDQD201509284 |
| **DATE RECEIVED:** 17.09.2015 | **LABEL CLAIM:** | Each uncoated tablet contains Diclofenac free acid 46.5 mg equivalent to Diclofenac Sodium 50 mg Excipients q.s. | |
| **BATCH NO.:** 20061501 | **PRESENTATION:** | white coloured, circular tablets, single scored on one side and plain on the other. Packed in an aluminium blister strip of 10 tablets and 2 such strips in a unit box. | |
| **MGF. DATE:** May.2015 | **MANUFACTURER:** | RUSAN Pharma Ltd | |
| **EXP. DATE:** Apr.2018 | **ADDRESS:** | KHASRA No. 122 MI, Selaqui,Selaqui, Dehradun - 248 197, Uttarakhand. H.O.: 58-D, Govt.Ind. Estate, Charkop, Kandivli(West),Mumbai-400 067, INDIA. | |
| **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 | < 2 tablets deviate by more than 5% from mean tablet weight | None Deviates | **COMPLIES** |
| **Identification** | HPLC | Manufacturer's In-House Method | RT of the major peak in the sample assay preparation corresponds to that in the assay standard preparation. | Super-imposable peak at RT value 7.8 Â± 10%min. Present in both the assay sample and standard preparation. | **COMPLIES** |
| **Dissolution** | UV | Manufacturer's In-House Method | No tablet less than 85% (n=6) | 99.9% (RSD = 0.4%, n=6) | **COMPLIES** |
| **Disintegration** | Disintegration | Manufacturer's In-House Method | No tablet more than 3 min (n=6) | All tablets disintegrated within 7 seconds | **COMPLIES** |
| **Assay** | HPLC | Manufacturer's In-House Method | 90.0-110.0% | 102.0% (RSD = 1.5%, n=9) | **COMPLIES** |

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

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| ANALYST: | MR. D. MOENGA |  | DATE:5-11-2015 |
| REVIEWER: | DR. M. KWENA |  | DATE:11-11-2015 |
| ANALYST: | ERNEST MBAE |  | DATE:12-21-2015 |
| DIRECTOR: | HEZEKIAH CHEPKWONY |  | DATE:01-12-2016 |