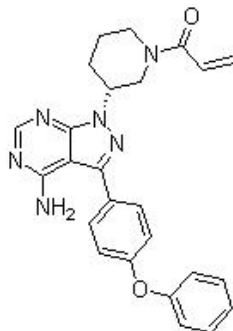


Certificate of Analysis

Ibrutinib



| Batch No: 20180312 | Quantity: 36kg | |
|---------------------------------------|---|---|
| Manufacture Date: Mar.12.2018 | CAS: 936563-96-1 | |
| Expiration date : Mar.11, 2020 | | |
| Items | Specifications | Results |
| Appearance | White to off-white crystalline powder | White crystalline powder |
| Identification | H-NMR, MS | Complies |
| Solubility | Soluble in DMSO and THF slightly soluble in MeOH, insoluble in H ₂ O | Soluble in DMSO and THF slightly soluble in MeOH, insoluble in H ₂ O |
| Melting point | 154~159°C | 155.9°C |
| Specific rotation | -122~-132° | -128.6° |
| Residual Solvents | MeOH≤0.3% | ND |
| | EtOH≤0.5% | ND |
| | Acetone≤0.5% | 0.10% |
| | ACN≤0.041% | ND |
| | EtOAc≤0.5% | 0.0003% |
| | THF≤0.072% | ND |
| | 2-Me THF≤0.072% | ND |
| | n-Heptane≤0.5% | 0.0002% |
| | Toluene≤0.089 | ND |

| | | |
|--------------------------|------------------------------|------------------|
| Residue on ignition | $\leq 0.5\%$ | 0.05% |
| Loss on Drying | $\leq 0.5\%$ | 0.25% |
| Heavy metal | $\leq 10\text{ppm}$ | $< 10\text{ppm}$ |
| Related substances | IBR-IM-D $\leq 0.1\%$ | ND |
| | IBR-IM-G $\leq 0.1\%$ | 0.02% |
| | IBR-IM-H $\leq 0.1\%$ | ND |
| | IBR-IM-I $\leq 0.1\%$ | 0.02% |
| | IBR-IM-O $\leq 0.1\%$ | 0.01% |
| Related Impurity by HPLC | Single impurity $\leq 0.1\%$ | 0.02% |
| | Total impurity $\leq 0.5\%$ | 0.07% |
| EE% | $\geq 99.0\%$ | 99.88% |
| Purity (HPLC) | $\geq 99.5\%$ | 99.93% |

Conclusion: the above substance has been tested according to In house Standards , and it meets requirements .
