

CERTIFICATE OF ANALYSIS

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| Product Name | Montelukast sodium | Batch NO. | RY190107 |
| Production date | 2019.01.07 | Expired Date | 2021.01.06 |
| CAS NO. | 151767-02-1 | Standard | USP |
| Tests | Limits | | Test results |
| Appearance | White or almost white, hygroscopic powder | | White and hygroscopic powder |
| Solubility | Freely soluble in water, ethanol, methanol and methylene chloride, practically insoluble in acetonitrile | | Up to specification |
| Identification | IR: positive | | positive |
| | HPLC: positive | | positive |
| | Reaction of sodium: positive | | Conforms |
| | Enantiomeric purity: positive | | Conforms |
| Water | ≤4.0% | | 0.67% |
| Specific rotation | +100° ~ +110° | | +107° |
| Alkalinity | 8.7~10.2 | | 9.4 |
| Related substances | Methylstyrene impurity(impurity B) ≤0.3% | | 0.018% |
| | Sulfoxide impurity(impurity C) ≤0.2% | | 0.013% |
| | Michael adducts 1 and 2(impurity D/E) ≤0.15% | | N.D. |
| | Methylketone impurity F≤0.15% | | N.D. |
| | Cis-isomer(impurity G) ≤0.15% | | 0.018% |
| | The single impurity ≤0.10% | | N.D. |
| | Total impurities 0.60% | | 0.050% |
| Impurity J(MT-B3) | ≤0.1% | | 0.0025% |
| Enantiomeric purity | ≤0.2% | | N.D. |
| Residual solvents | Methanol ≤0.3% | | |
| Assay (HPLC, on anhydrous and solvents-free basis) | 98%~102.0% | | 100.0% |
| Conclusion: This batch meets USP standard. | | | |



Tested by: Esther

Checked by: Alice

Approved by: Mich