



武汉福鑫化工有限公司

Wuhan Fortuna Chemical Co.,Ltd

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CERTIFICATE OF ANALYSIS

Product: Montelukast sodium

Lot No.: 210115

Mfg. date: Jan, 15, 2021

Quantity: 120kg

Exp. date: Jan, 14, 2024

Items	Specifications	Results
Appearance	White or almost white hygroscopic powder	White powder
Identification	The IR spectrum is consistent with that obtained with the reference standard.	Conforms
	Meets the requirements of the test for Enantiomeric purity.	Conforms
	It gives reaction of sodium: Positive.	Positive
Water	NMT 4.0%	0.43%
Enantiomeric purity	NMT 0.2%	Not detected
Related substances	Sulfoxide impurity: NMT 0.2%	0.05%
	Cis-isomer: NMT 0.15%	Not detected
	Michael adducts 1 and 2: NMT 0.15%	Not detected
	Methylketone impurity: NMT 0.15%	Not detected
	Methylstyrene impurity: NMT 0.3%	0.07%
	Any other individual impurity: NMT 0.10%	0.03%
	Total impurities: NMT 0.6%	0.18%
Residual solvents (GC)	Toluene: NMT 890ppm	136ppm
	Methanol: NMT 3000ppm	Not detected
	Heptane: NMT 5000ppm	1041ppm
Assay	98.0%~102.0% (anhydrous and solvent-free basis)	99.6%
Conclusion	The product conforms to the standard of USP42.	

QC: Luo Xiaofeng

Tester: AT02

Re-tester: AT03