

CERTIFICATE OF ANALYSIS

Product: Montelukast Sodium[CAS:151767-02-1]

Batch No: 20150221

Manufacturing Date: Feb., 2015

Expiry Date: Feb., 2016

Quantity: 20 Kgs

Analysis Items	Acceptance criteria	Analysis results
Appearance	White or almost white, hygroscopic powder	Almost white powder
Solubility	Freely soluble in water and methylene chloride, freely soluble to very soluble in ethanol	Conforms
Identification	The IR spectrum is consistent with that obtained with the reference standard	Conforms
	Enantiomeric purity	Conforms
	It gives reaction of sodium :Positive	Positive
Water	NMT 4.0%	0.48%
Heavy metals	NMT 10ppm	Conforms
Enantiomeric purity	Impurity A NMT 0.2%	Not detected
Related substances	Impurity B NMT 0.3%	0.06%
	Impurity C NMT 0.2%	Below disregard limit
	Impurity F NMT 0.15%	Not detected
	Impurity G NMT 0.15%	Not detected
	Impurity D&E NMT 0.15%	Not detected
	Unspecified impurities NMT 0.10%	Below disregard limit
	Total impurities NMT 0.6%	0.12%
Residual solvents (GC)	Toluene NMT 890ppm	25ppm
	Methanol NMT 3000ppm	Not detected
	Heptane NMT 5000ppm	1635ppm
Assay	98.0~102.0% (anhydrous substance)	99.2%

Conclusion:It Complies with EP7.3.