

## Certificate of Analysis

Product Name: Montelukast Sodium			
Sr No.	TSET	Specification	Results
1	Description	White or almost white, hygroscopic powder	White, hygroscopic powder
2	Identification By IR	The Infrared absorption spectrum of substance being examined must be concordant with the IR spectrum obtained from Montelukast sodium reference standard (or) with the reference spectrum of Montelukast sodium	Complies
3	Test for sodium	Should be positive	Complies
4	Water content by KF	Not More than 3.0	1.80
5	Specific optical rotation (*) (1% solution in Methanol)	Should be between (+) 95.0 and (+) 106.0	101.7
6	Heavy Metals (ppm)	Not more than 20	Less than 20 ppm
7	Related Substance by HPLC(% w/w)		
	Sum of Sulfoxide isomers	Not more than 0.3	0.05
	Styrene impurity	Not more than 0.3	0.03
	Any other individual impurity	Not more than 0.3	0.09
	Total Impurities	Not more than 1.0	0.17
8	Assay By HPLC on anhydrous Basis (%w/w)	Not less than 98.0 and Not more than 102.0	99.5
9	Residual solvents By GC (ppm)		
	Methanol	Not more than 3000	649
	Acetonitrile	Not more than 410	Not Detected
	Ethyl acetate	Not more than 5000	Not Detected
	Toluene	Not more than 890	Not Detected
	Dimethyl sulfoxide	Not more than 5000	Not Detected
	Cyclohexane	Not more than 3880	Not Detected