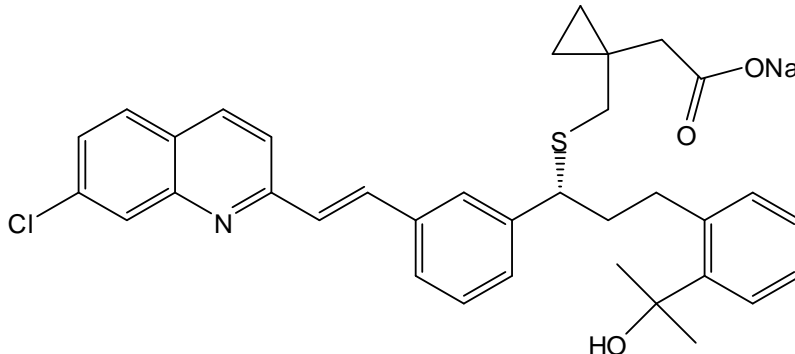


SPECIFICATIONS

Product Name		<div>Montelukast Sodium Crystal</div> <div></div>		
CAS No.		158966-92-8		
Molecular Formula		C ₃₅ H ₃₅ ClNNaO ₃ S	Molecular Weight	608.17
No.	Items	Specifications		
1	Description	Almost white or pale yellow powder		
2	Identification 1) IR 2) HPLC 3) Qualitative test	Similar intensities of absorption at the same wave number. The retention time of sample is concordant with that of STD. For sodium salt : a yellow flame should be appeared.		
3	Water	Not more than 2.0%		
4	Heavy metals	Not more than 20 ppm		
5	Related substances 1) Impurity A 2) Impurity B 3) Impurity C 4) Impurity D 5) Impurity E 6) Impurity F 7) Any single impurity 8) Total impurities	Not more than 0.10% (Sulfoxide impurity) Not more than 0.10% (Acid impurity) Not more than 0.10% (Ester impurity) Not more than 0.10% (Dehydrated impurity) Not more than 0.10% (Keto impurity) Not more than 0.10% (Chloro alcohol impurity) Not more than 0.10% Not more than 1.0%		
6	S-enantiomer	Not more than 0.2%		
7	Sodium acetate	Not more than 0.3%		
8	Assay	98.5 ~ 101.5% (as anhydrous, C ₃₅ H ₃₅ ClNNaO ₃ S)		
9	Residual solvents	ICH guide-line		